FOOD AND DRUG ADMINISTRATION

CITIZEN'S CHARTER
2024 [1st Edition]

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2024 [1st Edition]

I.Mandate:

To protect the general public by ensuring the safety, efficacy, and quality of health products.

II.Vision:

To be an internationally recognized center of excellence in health product regulation by 2026.

III.Mission:

To guarantee the safety, quality, purity, efficacy of health products in order to protect and promote the right to health of the general public.

IV.Service Pledge:

Ensure the safety, efficacy, quality, and purity of health products by fostering integrity, transparency, and excellence-based standards and policies, in a healthy and safe work environment.

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ADMINISTRATIVE AND FINANCE SERVICE
EXTERNAL SERVICES

1.COLLECTION OF FEES AND ISSUANCE OF OFFICIAL RECEIPT (OR) VIA OVER-THE-COUNTER

This process covers the collection of FDA application fees and other charges. It also involves the corresponding issuance of Official Receipts via the FDA Cashier over-the-counter.

Center/Office/Division	:	Administrative and Finance Service/General Services Division/Cashier Section
Classification	:	Simple
Type of Transaction	:	Government to Businesses (G2B); Government to Government (G2G)
Who May Avail	:	Internal and External Client
Fees to be paid	:	AO (Administrative Order) 50 s. 2001

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Two (2) copies of printed Doctrack Slip (DTN); or one (1) original copy plus one (1) photocopy of issued Assessment Slip; or two (2) copies of emailed Assessment slip (for Batch Notification applications) Emailed payment schedule confirmation (in print or in electronic form) Amount to Pay based on AO 50 s. 2001	FDA Doctrack System https://doctrack.fda.gov.ph/ Email from the FDAC/Centers.

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submits/presents the emailed schedule and the copies of the DTN or Assessment Slip to the FDA Cashier	1.1 Receives and verifies the details of the emailed schedule vis-à-vis the presented DTN/Assessment Slip in the FDA Doctrack System	None	3 minutes	Client and Special Collecting Officer (SCO)
	1.2 Encodes the details of application and payment in the ***OR system***.	None	5 minutes	SCO

Pays the corresponding fee in cash or manager's check or a combination of cash and manager's check	2.1 Receives the Payment from the client. Counts* the amount of cash and verifies the authenticity* of the bills received; and/or verifies the check payment details* including the Payee name, amount in figures and words and the date of the check vs. the amount stated in the DTN/Assessment Slip (*done twice)	AO 50 s. 2001	5 minutes	SCO
	2.2 Prints the pre-numbered Official Receipt (OR) and affixes the signature on the side of the name and e-signature of the Collecting Officer	None	3 minutes	SCO
	2.3 Posts payment details including the OR number in the DTN	None	5 minutes	SCO
	2.4 Stamps with "PAID" and affixes signature and date on the DTN/Assessment Slip	None	2 minutes	SCO
Receives and checks the details encoded in the Official Receipt	3. Releases the Original OR and the stamped and signed DTN/Assessment Slip to the client.	None	2 minutes	Client and SCO
TOTAL:		None	25 minutes	

2.HIRING PROCESS FOR PLANTILLA POSITION (PER VACANT POSITION)

This procedure covers the end-to-end process in filling-up each vacant plantilla position existing in this Office and aims to provide equal opportunities for employment to all applicants to be selected on the basis of merit and fitness in accordance with the existing internal and Civil Service Commission (CSC) rules and regulations to perform the duties and responsibilities the vacant position will be undertaking.

Center/Office/Division	:	Administrative and Finance Service – Human Resource Development Division
Classification	:	Highly technical
Type of Transaction	:	Government to Citizen
Who May Avail	:	All interested and qualified applicants

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Publication	
Notice of Vacancy/ Request for Publication of Vacant Positions (CS Form no. 9)	www.fda.gov.ph/about/careers and www.csc.gov.ph/career
Application Documentary Requirements	
Application Letter with specific Item Number and Position applied for	Provided by applicant
Four (4) set of Notarized Personal Data Sheet (CS Form 212 Rev. 2017) with attached Work Experience Sheet	Provided by applicant www.csc.gov.ph/
Any Proof of eligibility (Report of Rating/License/Certificate of Eligibility/Eligibility Card (photocopy, scanned copy, or site/screen capture of the eligibility using the Civil Service Eligibility Verification System [CSEVS], Professional Regulation Commission's [PRC]'s Licensure Examination and Registration Information System [LERIS], or Supreme Court of the Philippines [SC] Lawyer's List or other sites as may be applicable	Provided by applicant https://online.prc.gov.ph/verification https://csevs.csc.gov.ph/user/eligibility
Copy of Valid NBI Clearance	Provided by applicant
Photocopy of Diploma in any relevant Bachelor's Degree/Masters of Law/Bachelors Degree of Law and Transcript of Records (TOR)	Provided by applicant
Certificates of Trainings Attended	Provided by applicant

Latest Performance Rating (IPCR) available (applicable for government employees only) for those applying for promotion	Provided by applicant/AFS-HRDD
Latest appointment/Service Record/COE (applicable for government employees only)	Provided by applicant/AFS-HRDD
On-boarding Requirements	
.Employment requirements (please refer to the templated Congratulatory Letter for Original/Promotional appointees for complete list of requirements)	Provided by proposed appointee
.Oath of Office form (CS Form No. 32 revised 2018)	Provided by AFS-HRDD
.Appointment Paper (CS Form No. 33-B revised 2018)	Provided by AFS-HRDD
.Certificate of Assumption to Duty (CS Form No. 4 revised 2018)	Provided by AFS-HRDD
.Position Description Form (DBM-CSC Form No. 1 revised version No. 1, s. 2017)	Provided by AFS-HRDD

INTERNAL CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submits job application with complete documentary requirements	Receives incoming applications and check completeness of requirements submitted	None	10 minutes	AFS/HRDD/Administrative Assistant II/Administrative Officer II
	Reviews submitted documents of applicants and prepares applicant profiles detailing the qualification requirements of the position alongside a concise summary of each applicant's personal information and qualifications to serve as guide in the initial assessment process.	None	1 working day	AFS/HRDD/Administrative Assistant II/Administrative Officer II
	Requests for schedule of HRMSPB for the initial deliberations	None	15 working days (*Approval of requests depends on the availability of HRMPSB.	AFS/HRDD/Administrative Officer IV

			Quorum must be established for a meeting to commence)	
	Presents to Human Resource Merit Promotion and Selection Board (HRMPSB) applicants applied for vacancies	None	1 working day	AFS/HRDD/Administrative Officer II/IV
	Notifies applicants on the status of their application (Qualified applicants will proceed to take the qualifying examinations)	None	1 working day	AFS/HRDD/Administrative Assistant II/Administrative Officer II
2. Attends and take qualifying examinations	2.1. Facilitates conduct of qualifying examinations	None	1 working day	AFS/HRDD/Administrative Assistant II/Administrative Officer II
	Checking of General Aptitude Exam	None	1 working day	
	Endorses to center/office for checking of Technical Exams	None	15 working days	AFS/HRDD/Administrative Assistant II/Administrative Officer II
	Notifies applicants on the result of their examination	None	1 working day	AFS/HRDD/Administrative Assistant II/Administrative Officer II
	Requests for schedule of HRMSPB for the panel interview	None	15 working days (*Approval of requests depends on the availability of HRMPSB. Quorum must be established for a meeting to commence)	AFS/HRDD/Administrative Officer IV

3. Attends panel interview	3.1. Facilitates conduct of panel interview and assist HRMPSB	None	1 working day	AFS/HRDD/Administrative Assistant II/Administrative Officer II
	Conducts Character Investigation	None	7 working days	AFS/HRDD/Administrative Assistant II/Administrative Officer II
	Receives accomplished Character Investigation	None	1 working day	AFS/HRDD/Administrative Assistant II/Administrative Officer II
	Requests for schedule of HRMSPB for the final deliberations	None	15 working days (*Approval of requests depends on the availability of HRMPSB. Quorum must be established for a meeting to commence)	AFS/HRDD/Administrative Officer IV
	Prepares Comparative Assessment Result (CAR) and Board Resolution for presentation to the HRMPSB for final deliberation	None	1 working day	AFS/HRDD/Administrative Assistant II/Administrative Officer II and IV
	Submits CAR and HRMPSB Board Resolution to the Appointing Authority for appropriate action	None	30 working days	Chief Administrative Officer
	Sends result of application	None	1 working day	AFS/HRDD/Administrative Officer IV
4. Submission of employment requirements of proposed appointee	4.1. Checks the correctness and completeness of employment requirements submitted	None	1 working day	AFS/HRDD/Administrative Officer IV

	by proposed appointee			
	4.2. Prepares appointment papers and other supporting documents	None	1 working day	AFS/HRDD/Administrative Officer IV
	4.3. Submits the Appointment Papers and other supporting documents to the Appointing Authority	None	30 working days	AFS/HRDD/Administrative Officer IV
5. Assumption of appointee	5. Endorses appointee to respective Centers/Office	None	1 working day	AFS/HRDD/Administrative Officer IV
TOTAL:		None	140 working days and 10 minutes (*Processing of vacant plantilla position are valid up to 9 months reckoned from the date of posting/publication)	

Notes/References:

1. Omnibus Rules on Appointment and Other Human Resources Actions (ORAOHRA) 2017 and CSC MC No. 14, s. 2018 entitled 2017 Omnibus Rules on Appointments and Other Human Resource Actions, Revised July 2018
2. FDA Order 2018-015 Revised Recruitment, Selection and Promotion Guidelines Governing First and Second Level Positions at the Food and Drug Administration (FDA)
3. FDA Order 2018-137 Merit Selection Plan (MSP) for the First and Second Level Positions of the Food and Drug Administration

3.ISSUANCE OF CERTIFICATIONS (For Separated Employees)

This process covers the issuance of various certifications: Certificate of Employment, Service Record, Certificate of Last Salary, Certification of Availment/Non-Availment or entitlement for Benefit/incentive, Certificate of Transfer and Certificate of Leave Credits to separated employees of the agency. These certifications are requested to facilitate their personal transactions with other government entities.

Center/Office/Division	:	Administrative and Finance Service - Human Resource Development Division (HRDD)
Classification	:	Simple to Complex
Type of Transaction	:	Government-to-Citizen
Who May Avail	:	All FDA resigned/retired/transferred COS/plantilla employees

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Submission of Online Request through MS Forms or QR code (for service record and COE) For other certifications: Call or email the HRDD to request the needed certification	https://forms.office.com/r/NVXw9wnbpN or scan the QR code posted at the HRDD window
Clearance Form (cleared)	Provided by the HRDD

INTERNAL CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Accomplishes the online request form or sends request to HRDD	Receives request from online form or email/call	None	2 minutes	AFS/HRDD/Admin. Aide VI
Waits for the processing of the requested certificate/s	2.1. Retrieves employee's available data	None	2019-present – 2 minutes 2008-2018 – 1 day	AFS/HRDD/Admin. Aide VI

			1990-2007 – 3 days 1980-1990 – 5 days *Time for data retrieval varies depending on year of employee's available data	
	2.2. Prepares the requested certificate/s	None	5 minutes	AFS/HRDD/ Admin. Aide VI
	2.3. Reviews the certificate/s	None	2 minutes	AFS/HRDD/ Admin. Aide VI
	2.4. Submits the certificate/s to the authorized signatory	None	1 minutes	AFS/HRDD/ Admin. Aide VI
	2.5. Signs the certificate/s	None	2 minutes	AFS/HRDD/Chief Administrative Officer
	2.6. Informs respective employee for the availability of requested certificate/s	None	2 minutes	AFS/HRDD/ Admin. Aide VI
Claims the requested certificate/s	3.1 Releases the certificate/s (Through email (electronic copy) or hard copy)	None	1 minutes	AFS/HRDD/ Admin. Aide VI
	TOTAL:	None	5 working days and 15 minutes	

4.ISSUANCE OF OFFICIAL RECEIPT FOR ONLINE COLLECTION CHANNELS

This process refers to the issuance of Official Receipts from FDA's Online Collection Channels, requested by FDA clients through email.

Center/Office/Division	:	Administrative and Finance Service/General Services Division/Cashier Section
Classification	:	Complex
Type of Transaction	:	Government to Businesses (G2B); Government to Government (G2G)
Who May Avail	:	External Client
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Emailed schedule of pick-up of OR from cashier@fda.gov.ph (either in electronic form or printed copy)	Refer to FDA Advisory 2021-1686

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Requests for schedule of OR release via email.	Verifies the availability of the OR requested in the FDA Cashier's collection reports.	None	10 minutes	Client and Cashier Staff
	Emails the client on the date and time of schedule of OR pick up. (If OR is still unavailable, emails client on the details on the non-availability of the OR requested.)	None	10 minutes	Cashier Staff
	Encodes in the OR Releasing database the scheduled date time and the list of OR requested for pick-up in reference to the Monthly Collection Report*	None	15 minutes	Cashier Staff
	Prepares the original copy of the OR and encoding in the OR receiving copy/file of the FDA Cashier.	None	6 working days	Cashier Staff

Presents proof of authorization or identification to the Cashier Staff.	Checks the proof of authorization/ID of the client	None	5 minutes	Client and Cashier Staff
Verifies the accuracy of information stated in the Official Receipt received and signs the FDA Cashier's OR receiving copy/file.	Releases the OR to the client	None	2 minutes	Client and Cashier Staff
	*Bulk Transactions			
	TOTAL:	None	6 Working Days and 42 minutes	

5. POSTING OF PAYMENT FOR ONLINE COLLECTION CHANNELS

This involves the process of posting of application payments received through the different FDA Collection Channels other than Over-the-Counter collections.

Center/Office/Division	:	Administrative and Finance Service/General Services Division/Cashier Section
Classification	:	Simple
Type of Transaction	:	Government to Businesses (G2B); Government to Government (G2G)
Who May Avail	:	External Client
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Collection Report from the different Online Collection Channels	LBP (Land Bank of the Philippines) Oncoll via LBP Oncoll weAccess website. LBP LinkBiz via LBP Link.Biz Merchant Porrtal website. DBP BancNet via DBP BancNet Merchant Facility website.

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Pays prescribed fees and decks application to the “Payment” task	1.1. Receives and downloads the daily collection report (online) Note: Receipt of Collection Report is coming from different banks, the following day after payment	None	1 working day and 3 minutes	Cashier Staff
	Converts and verifies the downloaded collection report. (via Report Conversion tool, except for LBP Link.Biz Portal)	None	30 minutes	Cashier Staff
Waits for payment to be posted	Acts** on the details of collected payments in the collection report LBP Oncoll Payments	None	5 working days	Cashier Staff

	LBP Link.Biz Portal Bills Payment DBP BancNet Bills **Bulk Transactions (Acts by posting qualified payment in the corresponding FDA Portals and endorsement of unqualified payments to corresponding offices)			
TOTAL:		None	6 working days and 33 minutes	

ADMINISTRATIVE AND FINANCE SERVICE
INTERNAL SERVICES

1.ISSUANCE OF CERTIFICATIONS (For Active Employees)

This process covers the issuance of various certifications: Certificate of Employment, Certificate of Compensation and Benefits, Certificate of Duties and Responsibilities, Certificate of Good Moral, Certificate of No Scholarship, updated Service Record and other certificates not mentioned as may be required. These certifications are requested for various specific purposes such as employment, loan application, scholarship application and other legal purposes.

Center/Office/Division	:	Administrative and Finance Service - Human Resource Development Division (HRDD)
Classification	:	Simple
Type of Transaction	:	Government-to-Citizen
Who May Avail	:	All Active FDA Officials/ Employees

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Submission of Online Request through MS Forms/QR code	https://forms.office.com/r/NVXw9wnbpN or scan the QR code posted at the HRDD window
For Service Record (SR): Existing Service Record Data (For SR updating) One (1) copy of Assumption paper – For new entrant employee One (1) Certified True Copy (CTC) of Service Record issued by previous employer – For transfer employee One (1) photocopy of approved Resignation/Retirement Letter – For closing of Service Record Birth Certificate – for corrections in name, birthdate in COE or SR	2.1 Provided by the HRDD 2.2 Provided by the Recruitment Selection and Placement section of HRDD 2.3 Provided by the employee 2.4 Provided by the employee 2.5 Provided by the employee

Republic Act No. 11466 (Modified Salary Schedule for Civilian Personnel in National Government)	Official Gazette of the Republic of the Philippines
Copy of General Payroll (For Certificate of Compensation and Benefits)	Provided by the Payroll and Benefits section of HRDD
One (1) copy of Position Description Form (For Certificate of Duties and Responsibilities) or Statement of Current Duties and Responsibilities (SOCDAR)	Provided by the Recruitment Selection and Placement section of HRDD Provided by employees
Application for Scholarship (Certificate of No Scholarship)	Provided by the employees

INTERNAL CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Accomplishes the online request form	1.1 Receives request from online form	None	2 minutes	AFS/HRDD/Admin. Aide VI
	1.2 Retrieves employee's available data	None	5 minutes	AFS/HRDD/Admin. Aide VI
Waits for the processing of the requested certificate/s	2.1 Prepares requested certificate/s	None	5 minutes	AFS/HRDD/ Admin. Aide VI
	2.2 Review certificate/s	None	2 minutes	AFS/HRDD/Admin. Aide VI
	2.3 Submits the certificate/s to the authorized signatory	None	1 minutes	AFS/HRDD/ Admin. Aide VI
	2.4 Signs the certificate/s	None	2 minutes	AFS/HRDD/Chief Administrative Officer
	2.5 Informs respective employee of the availability of requested certificate/s	None	2 minutes	AFS/HRDD/ Admin. Aide VI
Claims the requested certificate/s	Releases certificate/s (Through email (electronic copy) or hard copy)	None	1 minute	AFS/HRDD/ Admin. Aide VI
	TOTAL:	None	20 minutes	

LICENSE TO OPERATE

1.LICENSE TO OPERATE OF ESTABLISHMENT

This process details the issuance of License to Operate (LTO) to establishments in the country. Establishments engaged in the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product are required to secure a LTO from the FDA.

1.1.LICENSE TO OPERATE – INITIAL APPLICATION FOR DRUG MANUFACTURERS

Center/Office/Division	**:**	Center for Drug Regulation and Research (CDRR)
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	All Manufacturers of Drug Products
Fees to be Paid	**:**	**Drug Manufacturer:** 20 Million and below - Php 10,000 +1 % LRF per year Over 20 Million but below 50 Million - Php 15,000 +1 % LRF per year 50 Million and above - Php 20,000 +1 % LRF per year **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	FDA website (www.fda.gov.ph)

Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) coordinates to be filled in the eApplication Form ● Name of the Qualified Person depending on the type of health product establishment ● Self-Declaration in the e-Application Form	FDA e-Portal System
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF) When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g., Mayor's Permit).	
3) Proof of income (Latest Audited Financial Statement with Balance Sheet) or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Site Master File (shall be presented to the FDA inspectors during inspection)	
6) Risk Management Plan (shall be presented to the FDA inspectors during inspection)	
7) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF format) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal System and email notification. Pays the assessed fee as per the system-generated Order of Payment through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd**	See above table		FDA Cashier Administrative and Finance Service
	1.2 Conducts pre-licensing inspection *Refer to Regional Field Office (RFO) Citizen's Charter for the issuance of Certificate of Compliance /Recommendation for Disapproval/ Recommendation Letter.*	None		Regional Field Officer/ Inspector
	1.3 Evaluates completeness and veracity of the documents submitted.	None	13 working days	FDA Evaluator (Center/Licensing and Registration)
	1.4 Checks evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of Center

	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the LTO application If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working days	Center Director
2. Receives notification and link of LTO for printing				Qualified Person
TOTAL:			**20 working days**	

1.2.LICENSE TO OPERATE – RENEWAL APPLICATION FOR DRUG MANUFACTURERS

Center/Office/Division	:	Center for Drug Regulation and Research (CDRR)
Classification	:	Complex
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Manufacturers of Drug Products
Fees to be Paid	:	**Drug Manufacturer:** 20 Million and below - Php 30,000 +1 % LRF over 20 Million but below 50 Million - Php 45,000 +1 % LRF 50 Million and above - Php 60,000 +1 % LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-004** *Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes* **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE

1) Basic Requirements based on the Administrative Order No. 2020-0017:	FDA website (www.fda.gov.ph)
● Accomplished e-Application Form as prescribed by FDA regulations. ● Declaration and Undertaking	FDA e-Portal (www.fda.gov.ph)
2) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
3) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal System (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification Pays the assessed fee as per the system-generated Order of Payment through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center/Office **LBP OnColl Payment : 5 wd** **Other Payment Channels : 2 wd**	See above table		FDA Cashier Administrative and Finance Service
	1.2 Conducts inspection (if necessary)	None		Regional Field Officer/ Inspector

	Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/ Recommendation for Disapproval/ Recommendation Letter			
	1.3 Evaluates completeness and veracity of the documents submitted	None	3 working days	FDA Evaluator (Center/Licensing and Registration
	1.4 Checks evaluation and veracity of documents submitted.	None	1 working day	Technical Officer of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the Approval of LTO If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director
2. Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			**7 Working Days**	

1.3.LICENSE TO OPERATE – MAJOR VARIATION APPLICATION FOR DRUG ESTABLISHMENT (MANUFACTURERS)

Center/Office/Division	**:**	Center for Drug Regulation and Research (CDRR)
Classification	**:**	Complex
Type of Transaction	**:**	G2B – Government to Business
Who May Avail	**:**	All Drug Manufacturers
Fees to be Paid	**:**	Major Variation: Php 500 + 1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS (based on Administrative Order No. 2020-0017)	WHERE TO SECURE
Major Variation	FDA ePortal System (www.fda.gov.ph)
Transfer of Location of Manufacturing Plant - Accomplished e-Application Form - Business permit reflecting the new address - Updated Site Master File to be presented upon inspection - Payment of fees	
Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity - Accomplished e-Application Form - Updated Site Master File to be presented upon inspection	

- Payment of fees	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF format) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal System and email notification. Pays the assessed fee as per the system-generated Order of Payment through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO. **LBP OnColl Payment: 5 wd** **Other Payment Channels:** **2 wd**	See above table		FDA Cashier Administrative and Finance Service
	1.2 Conducts inspection *Refer to Regional Field Office (RFO) Citizen's Charter for the issuance of Certificate of Compliance /Recommendation for Disapproval/ Recommendation Letter.*	None		Regional Field Officer/ Inspector
	1.3 Evaluates completeness and	None	13 working days	FDA Evaluator (Center/Licensing and Registration)

	veracity of the documents submitted.			
	1.4 Checks evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the LTO application If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working days	Center Director
2. Receives notification and link of LTO for printing				Qualified Person
TOTAL:			**20 working days**	

1.4.LICENSE TO OPERATE – INITIAL APPLICATION FOR DRUG TRADERS, DRUG DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER), DRUGSTORES, RETAIL OUTLETS FOR NON-PRESCRIPTION DRUGS (RONPD), CLINICAL RESEARCH ORGANIZATIONS AND SPONSORS

Center/Office/Division	:	Center for Drug Regulation and Research (CDRR)
Classification	:	Complex
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Drug Traders, Drug Distributors (Importer, Exporter, Wholesaler), Drugstores/Retail Outlets for Non-Prescription Drugs, Clinical Research Organizations and Sponsors
Fees to be Paid	:	**Drug Traders:** 20 Million and below – Php 3,000 + 1% LRF per year over 20 Million but below 50 Million – Php 5,000 + 1% LRF per year 50 Million and above – Php 7,000 + 1% LRF per year **Drug Distributors:** Importer, Exporter, Wholesaler- Php 5,000 + 1% LRF per year **Drug Outlets:** Drugstore and Retail Outlet for Non-Prescription Drugs - Php 1,000 + 1% LRF per year **Clinical Research Organizations and Sponsors :** 20 Million and below – Php 3,000 + 1% LRF per year over 20 Million but below 50 Million – Php 5,000 + 1% LRF per year 50 Million and above – Php 7,000 + 1% LRF per year

		Administrative Order 50 s. 2001 *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017:	FDA website (www.fda.gov.ph)
Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) coordinates to be filled in the e-Application Form ● Name of the Qualified Person depending on the type of health product establishment Self-Declaration in the e-Application Form	FDA eServices (www.fda.gov.ph)
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF)	

When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g., Mayor's Permit).	
3) Proof of income (for Trader) - Latest Audited Financial Statement with Balance Sheet or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through http://eservices.fda.gov.ph and click **"Applications"** found on the upper right corner of the system. Selects the product category (Drug) and the type of business establishment (Drug Trader, Drug Distributor, Drugstores, RONPD, CRO, Sponsor) before clicking "**Initial"** Application Fills-out all necessary information. All fields mark with asterisk (*) are required to be filled-out. Uploads the required documents as indicated on the Checklist of Requirements in pdf format. Reviews the duly filled out form in the **Self-Assessment Review**. Once reviewed, click on **"Confirm"** to submit the application.	1. Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness and correctness. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number via email. If not, the FDA shall notify the client the reason/s for non-acceptance and prompt the	None		FDA Evaluator (Center/Licensing and Registration)

	applicant to apply again through the eServices Portal.			
2. Prints the Order of Payment with Reference Number sent through the declared e-mail address Pays the application fee through existing payment channels	2. Posts payment in eServices Portal System for confirmed payments. This will prompt automatic decking of application to respective Center. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd** **Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.	See above table		FDA Cashier Administrative and Finance Service (AFS)
3. Receives Acknowledgement Receipt through email	3.1 Checks and quality assurance of the documents provided	None	4 working days	Technical Officer of Center
	3.2 Finalizes decision on the LTO application If application is approved, the FDA shall send the LTO to the	None	3 working days	Center Director

	registered email address of the applicant. If application is disapproved, the FDA shall inform the applicant through its registered email address of the reason for such action on the application.			
4. Receives notification and prints LTO if application is approved				Qualified Person
TOTAL:			**7 working days**	

1.5.LICENSE TO OPERATE – RENEWAL APPLICATION FOR DRUG TRADERS, DRUG DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER), DRUGSTORES, RETAIL OUTLETS FOR NON-PRESCRIPTION DRUGS (RONPD), CLINICAL RESEARCH ORGANIZATIONS AND SPONSORS

Center/Office/Division	:	Center for Drug Regulation and Research (CDRR)
Classification	:	Complex
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Drug Traders, Drug Distributors (Importer, Exporter, Wholesaler), Drugstores/Retail Outlets for Non-Prescription Drugs, Clinical Research Organizations and Sponsors
Fees to be Paid	:	**Drug Traders:** 20 Million and below – Php 9,000 + 1% LRF over 20 Million but below 50 Million – Php 15,000 + 1% LRF 50 Million and above – Php 21,000 + 1% LRF **Drug Distributors:** Importer, Exporter, Wholesaler- Php 15,000 + 1% LRF **Drug Outlets:** Drugstore and Retail Outlet for Non-Prescription Drugs - Php 3,000 + 1% LRF **Clinical Research Organizations and Sponsors :** 20 Million and below – Php 9,000 + 1% LRF over 20 Million but below 50 Million – Php 15,000 + 1% LRF 50 Million and above – Php 21,000 + 1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of*

		Food and Drugs **FDA Circular No. 2011-004** *Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes* **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	FDA Website (www.fda.gov.ph)
• Accomplished e-Application Form as prescribed by FDA regulations. • Declaration and Undertaking	FDA eServices (www.fda.gov.ph
2) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
3) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through https://eservices.fda.gov.ph and click **"Applications"** found on the upper right corner of the system.	1. Posts confirmed payments. This will prompt automatic routing of application to Center **LBP OnColl Payment: 5 wd**	None		FDA Cashier Administrative and Finance Service

Selects the product category (Drug) and the type of business establishment (Drug Trader, Drug Distributor, Drugstore, RONPD, CRO, Sponsor) before clicking **"Renewal"** application Reads the **"Declaration and Undertaking"** before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".** Fills-out all necessary information. All fields mark with asterisk (8*) are required to be filled-out. Updates contact numbers if necessary. Click **"Next"** to proceed to Self – Assessment Review Reviews all details in the **"Self-Assessment Review"**. Once reviewed, click on **"Confirm"** to submit application. Prints the Order of Payment with Reference Number sent through the declared email address Pays the application fee through existing payment channels	**LBP Linkbiz: auto posting** **Other Payment Channels: 2 wd** **Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.			
2. Receives Acknowledgement Receipt through email	2. Finalizes decision on the LTO application	None	3 working days	Center Director

	If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial			
3. Receives notification and link of LTO for Printing		None		
TOTAL:			**3 working days**	

1.6.LICENSE TO OPERATE – MINOR VARIATION APPLICATION FOR DRUG TRADERS, DRUG DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER), DRUGSTORES, RETAIL OUTLETS FOR NON-PRESCRIPTION DRUGS (RONPD), CLINICAL RESEARCH ORGANIZATIONS AND SPONSORS

Center/Office/Division	:	Center for Drug Regulation and Research (CDRR)
Classification	:	Complex
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Drug Traders, Drug Distributors (Importer, Exporter, Wholesaler), Drugstores/Retail Outlets for Non-Prescription Drugs, Clinical Research Organizations and Sponsors
Fees to be Paid	:	Minor Variation: Php 500 + 1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS (based on Administrative Order No. 2020-0017)	WHERE TO SECURE
Minor Variation	FDA website (www.fda.gov.ph)
Transfer of Location of Offices - Accomplished e-Application Form - Business permit reflecting new location of office - Payment of fees	

Transfer of Location of Drug Retailers - Accomplished e-Application Form - Business permit reflecting new address - Payment of fees	
Change of Distributor Activity - Accomplished e-Application Form - Contract Agreements showing change in activity - Payment of fees	
Transfer/Addition of Warehouse - Accomplished e-Application Form - Business Permit reflecting new warehouse location - Payment of fees	
Additional Drugstore Activities - Accomplished e-Application Form - Additional credentials of pharmacist (as applicable) - Other documents related or specific to the additional activity, such as but not limited to: • Adult Vaccination – Standard Operating Procedure • Dispense Vaccines and Biologicals – Standard Operating Procedure • Mobile Pharmacy – Standard Operating Procedure • Online Ordering and Delivery – Standard Operating Procedure and Website Screenshot • Sterile Compounding and Non-Sterile Complex Compounding – Standard Operating Procedure • Other additional activities that may require appropriate regulation - Payment of fees	
Expansion of Office Establishments and Drug Retailers - Accomplished e-Application Form - Expansion floor plan - Payment of fees	

Change of Ownership - Accomplished e-Application Form - Business name registration reflecting new ownership - Any proof on the transfer of ownership such as any of the following • Deed of Sale or assignment or transfer of rights/ownership • Memorandum of Agreement • Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer - Payment of fees	
Change of Business Name - Accomplished e-Application Form - Business permit reflecting the new name - Payment of fees	
Zonal Change in Address - Accomplished e-application Form - Certificate of Zonal Change - Payment of fees	
Change of Qualified Person - Accomplished e-Application Form - Name of new qualified person - Applicable requirements as specified in ANNEX B of AO 2020-0017 - Payment of fees	
Change of Authorized Person - Accomplished e-Application Form - Name of new authorized person - Updated contact details - Payment of fees	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through http://eservices.fda.gov.ph and click **"Applications** "found on the upper right corner of the system. Selects the product category (Drug) and the type of business establishment (Drug Trader, Drug Distributor, Drugstores, RONPD, CRO, Sponsor) before clicking "**Variations"** Reads the **"Declaration and Undertaking "**before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".** Fills-out all necessary information. All fields mark with asterisk (*) are required to be filled-out. Uploads the required documents as indicated on the Checklist of Requirements in pdf format. Reviews the duly filled out form in the **Self-Assessment Review**. Once reviewed, click on **"Confirm"** to submit the application.	1. Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness and correctness. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number via email. If not, the FDA shall notify the client the reason/s for non-acceptance and prompt the applicant to apply again through the eServices Portal.	None		CDRR Personnel

2. Prints the Order of Payment form with Reference Number sent through the declared e-mail address Pays the application fee through existing payment channels	2. Posts payment in eServices Portal System for confirmed payments. This will prompt automatic decking of application to respective Center. **LBP OnColl Payment:** **5 wd** **Other Payment Channels:** **2 wd** **Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.	See above table		FDA Cashier Administrative and Finance Service (AFS)
3. Receives Acknowledgement Receipt through email	3.1 Checks and quality assurance of the documents provided	None	4 working days	Technical Officer of Center
	3.2 Finalizes decision on the LTO application If application is approved, the FDA shall send the LTO to the registered email address of the applicant.	None	3 working days	Center Director

	If application is disapproved, the FDA shall inform the applicant through its registered email address of the reason for such action on the application.			
4. Receives notification and prints LTO if application is approved				Qualified Person
TOTAL:			**7 working days**	

1.7.LICENSE TO OPERATE – INITIAL APPLICATION FOR FOOD MANUFACTURERS

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	All Manufacturers of Drug Products
Fees to be Paid	**:**	**Food Manufacturer:** **250K and below- Php 1,000 + 1% LRF** **Over 250K but not more than 500K- Php 1,500 + 1% LRF** **Over 500K but not more than 1 Million- Php 2,000 + 1% LRF** Over 1 Million but below 5 Million – **Php 4,000 + 1% LRF** 5 Million but below 10 Million - **Php 6,000 + 1% LRF** 10 Million but below 20 Million – **Php 10,000 + 1% LRF** 20 Million but below 50 Million – **Php 20,000 + 1% LRF** 50 Million and above - **Php 30,000 + 1% LRF** **Iodized Salt Manufacturer:** **Large Manufacturer (exceeding 2,000 m.t/year)- Php 2,000 + 1% LRF** **Medium Manufacturer (>300 m.t to 2000 m.t/year)- Php 1000 + 1% LRF** **Small Manufacturer (>200 m.t to 300 m.t/year- Php 400 + 1% LRF** **Bottled Water Processor: Php 3,000 + 1% LRF** **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	
Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) coordinates to be filled in the eApplication Form ● Name of the Qualified Person depending on the type of health product establishment ● Self-Declaration in the e-Application Form	FDA e-Portal System
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF) When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g., Mayor's Permit).	
3) Proof of income (Latest Audited Financial Statement with Balance Sheet) or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Site Master File (shall be presented to the FDA inspectors during inspection)	
6) Risk Management Plan (shall be presented to the FDA inspectors during inspection)	

7) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF format) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal System and email notification. Pays the assessed fee as per the system-generated Order of Payment through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO. **LBP OnColl Payment : 5 wd** **Other Payment Channels: 2 wd**	See above table		FDA Cashier Administrative and Finance Service
	1.2 Conducts pre-licensing inspection *Refer to Regional Field Office (RFO) Citizen's Charter for the issuance of Certificate of Compliance /Recommendation for Disapproval/ Recommendation Letter.*	None		Regional Field Officer/ Inspector

	1.3 Evaluates completeness and veracity of the documents submitted.	None	13 working days	FDA Evaluator (Center/Licensing and Registration)
	1.4 Checks evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the LTO application If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working days	Center Director
2. Receives notification and link of LTO for sprinting				Qualified Person
TOTAL:			**20 working days**	

1.8.LICENSE TO OPERATE – RENEWAL APPLICATION FOR FOOD MANUFACTURERS

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Complex
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Manufacturers of Food Products
Fees to be Paid	:	**Food Manufacturer:** **250K and below- Php 1,000 + 1% LRF** **Over 250K but not more than 500K- Php 1,500 + 1% LRF** **Over 500K but not more than 1 Million- Php 2,000 + 1% LRF** Over 1 Million but below 5 Million – **Php 4,000 + 1% LRF** 5 Million but below 10 Million - **Php 6,000 + 1% LRF** 10 Million but below 20 Million – **Php 10,000 + 1% LRF** 20 Million but below 50 Million – **Php 20,000 + 1% LRF** 50 Million and above - **Php 30,000 + 1% LRF** **Iodized Salt Manufacturer:** **Large Manufacturer (exceeding 2,000 m.t/year)- Php 2,000 + 1% LRF** **Medium Manufacturer (>300 m.t to 2000 m.t/year)- Php 1000 + 1% LRF** **Small Manufacturer (>200 m.t to 300 m.t/year- Php 400 + 1% LRF** **Bottled Water Processor: Php 3,000 + 1% LRF** **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-004** *Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing*

		Rules and Regulations, and Other Purposes **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	
• Accomplished e-Application Form as prescribed by FDA regulations. • Declaration and Undertaking	FDA e-Portal (www.fda.gov.ph)
2) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
3) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal System (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification Pays the assessed fee as per the system- generated Order of Payment through the existing payment channels	1. Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center/Office **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd**	See above table		FDA Cashier Administrative and Finance Service

	1.2 Conducts inspection (if necessary) *Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/ Recommendation for Disapproval/ Recommendation Letter*	None		Regional Field Officer/ Inspector
	1.3 Evaluates completeness and veracity of the documents submitted	None	3 working days	FDA Evaluator (Center/Licensing and Registration
	1.4 Checks evaluation and veracity of documents submitted.	None	1 working day	Technical Officer of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the Approval of LTO If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director

2. Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			**7 working days**	

1.9.LICENSE TO OPERATE – MAJOR VARIATION APPLICATION FOR FOOD ESTABLISHMENT (MANUFACTURERS)

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Complex
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Food Manufacturers
Fees to be Paid	:	**Major Variation: Php 500 + 1% LRF** **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS (based on Administrative Order No. 2020-0017)	WHERE TO SECURE
Major Variation	FDA ePortal System (www.fda.gov.ph)
Transfer of Location of Manufacturing Plant - Accomplished e-Application Form - Business permit reflecting the new address - Updated Site Master File to be presented upon inspection - Payment of fees	
Expansion of Manufacturer and/or Additional Product Line ; or Change of Manufacturing Activity - Accomplished e-Application Form - Updated Site Master File to be presented upon inspection	

- Payment of fees	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF format) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal System and email notification. Pays the assessed fee as per the system-generated Order of Payment through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO. **LBP OnColl Payment : 5 wd** **Other Payment Channels : 2 wd**	See above table		FDA Cashier Administrative and Finance Service
	1.2 Conducts inspection *Refer to Regional Field Office (RFO) Citizen's Charter for the issuance of Certificate of Compliance /Recommendation for Disapproval/ Recommendation Letter.*	None		Regional Field Officer/ Inspector
	1.3 Evaluates completeness and veracity of the documents submitted.	None	13 working days	FDA Evaluator (Center/Licensing and Registration)

	1.4 Checks evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the LTO application If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working days	Center Director
2. Receives notification and link of LTO for printing				Qualified Person
TOTAL:			**20 working days**	

1.10.LICENSE TO OPERATE – INITIAL APPLICATION FOR FOOD TRADERS AND DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER)

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Complex
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Food Traders and Food Distributors (Importer, Exporter, Wholesaler)
Fees to be Paid	:	**Food Traders:** **250K and below- Php 1,000 + 1% LRF** **Over 250K but not more than 500K- Php 1,500 + 1% LRF** **Over 500K but not more than 1 Million- Php 2,000 + 1% LRF** Over 1 Million but below 5 Million – **Php 4,000 + 1% LRF** 5 Million but below 10 Million - **Php 6,000 + 1% LRF** 10 Million but below 20 Million – **Php 10,000 + 1% LRF** 20 Million but below 50 Million – **Php 20,000 + 1% LRF** 50 Million and above - **Php 30,000 + 1% LRF** **Food Distributors:** Importer, Exporter, Wholesaler – Php 8,000 + 1% LRF Iodized Salt Importer – Php 1,000 + 1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017:	
Accomplished e-Application Form as prescribed by FDA regulations. . ● Location plan and Global Positioning System (GPS) coordinates to be filled in the e-Application Form ● Name of the Qualified Person depending on the type of health product establishment Self-Declaration in the e-Application Form	FDA eServices (www.fda.gov.ph)
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF) When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g. Mayor's Permit).	
3) Proof of income (for Trader) - Latest Audited Financial Statement with Balance Sheet or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through http://eservices.fda.gov.ph and click **"Applications** "found on the upper right corner of the system. Selects the product category (Food) and the type of business establishment (Food Trader, Food Distributor) before clicking "**Initial"** Application Reads the **"Declaration and Undertaking "**before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".** Fills-out all necessary information. All fields mark with asterisk (*) are required to be filled-out. Uploads the required documents as indicated on the Checklist of Requirements in pdf format. Reviews the duly filled out form in the **Self-Assessment Review**. Once reviewed, click on **"Confirm"** to submit the application.	1. Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness and correctness. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number via email. If not, the FDA shall notify the client the reason/s for non-acceptance and prompt the applicant to apply again through the eServices Portal.	None		FDA Evaluator (Center/Licensing and Registration)
2. Prints the Order of Payment form with Reference Number sent through the declared e-mail address Pays the application fee through existing payment channels	2. Posts payment in eServices Portal System for confirmed payments. This will prompt automatic decking of application to respective Center.	See above table		FDA Cashier Administrative and Finance Service (AFS)

	LBP OnColl Payment: 5 wd **Other Payment Channels: 2 wd** **Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.			
1. Receives Acknowledgement Receipt through email	3.1 Checks and quality assurance of the documents provided	None	11 working days	Technical Officer of Center
	3.2 Finalizes decision on the LTO application If application is approved, the FDA shall send the LTO to the registered email address of the applicant. If application is disapproved, the FDA shall inform the applicant through its registered email address of the reason for such action on the application.	None	3 working days	Center Director
2. Receives notification and prints LTO if application is approved				Qualified Person
TOTAL:			**14 working days**	

1.11.LICENSE TO OPERATE – RENEWAL APPLICATION FOR FOOD TRADERS AND FOOD DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER)

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Complex
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Food Traders and Food Distributors (Importer, Exporter, Wholesaler)
Fees to be Paid	:	**Food Traders:** **250K and below- Php 1,000 + 1% LRF** **Over 250K but not more than 500K- Php 1,500 + 1% LRF** **Over 500K but not more than 1 Million- Php 2,000 + 1% LRF** Over 1 Million but below 5 Million – **Php 4,000 + 1% LRF** 5 Million but below 10 Million - **Php 6,000 + 1% LRF** 10 Million but below 20 Million – **Php 10,000 + 1% LRF** 20 Million but below 50 Million – **Php 20,000 + 1% LRF** 50 Million and above - **Php 30,000 + 1% LRF** **Food Distributors:** Importer, Exporter, Wholesaler – Php 8,000 + 1% LRF Iodized Salt Importer – Php 1,000 + 1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-004**

		Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	FDA Website (www.fda.gov.ph)
• Accomplished e-Application Form as prescribed by FDA regulations. • Declaration and Undertaking	
2) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
3) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through https://eservices.fda.gov.ph and click **"Applications"** found on the upper right corner of the system. Selects the product category (Drug) and the type of business establishment (Drug Trader, Drug Distributor, Drugstore, RONPD, CRO, Sponsor) before clicking **"Renewal"** application	1. Posts confirmed payments. This will prompt automatic routing of application to Center **LBP OnColl Payment: 5 wd** **LBP Linkbiz: auto posting** **Other Payment Channels: 2 wd**	None		FDA Cashier Administrative and Finance Service

Reads the **"Declaration and Undertaking"** before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".** Fills-out all necessary information. All fields mark with asterisk (8*) are required to be filled-out. Updates contact numbers if necessary. Click **"Next"** to proceed to Self – Assessment Review Reviews all details in the **"Self-Assessment Review"**. Once reviewed, click on **"Confirm"** to submit application. Prints the Order of Payment with Reference Number sent through the declared email address Pays the application fee through existing payment channels	**Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.			
2. Receives Acknowledgement Receipt through email				
3. Receives notification and link of LTO for Printing		None		
TOTAL:	**The LTO shall be automatically generated by the system once the payment has been posted by the FDA Cashier**			

1.12.LICENSE TO OPERATE – MINOR VARIATION APPLICATION FOR FOOD TRADERS AND FOOD DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER)

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Complex
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Food Traders and Food Distributors (Importer, Exporter, Wholesaler)
Fees to be Paid	:	**Minor Variation: Php 500 + 1% LRF** **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS (based on Administrative Order No. 2020-0017)	WHERE TO SECURE
Minor Variation	FDA eServices (www.fda.gov.ph)
Transfer of Location of Offices - Accomplished e-Application Form - Business permit reflecting new location of office - Payment of fees	
Change of Distributor Activity - Accomplished e-Application Form	

- Contract Agreements showing change in activity - Payment of fees	
Transfer/Addition of Warehouse - Accomplished e-Application Form - Business Permit reflecting new warehouse location - Payment of fees	
Expansion of Office Establishments and Drug Retailers - Accomplished e-Application Form - Expansion floor plan - Payment of fees	
Change of Ownership - Accomplished e-Application Form - Business name registration reflecting new ownership - Any proof on the transfer of ownership such as any of the following • Deed of Sale or assignment or transfer of rights/ownership • Memorandum of Agreement • Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer - Payment of fees	
Change of Business Name - Accomplished e-Application Form - Business permit reflecting the new name - Payment of fees	
Zonal Change in Address - Accomplished e-application Form - Certificate of Zonal Change - Payment of fees	

Change of Qualified Person - Accomplished e-Application Form - Name of new qualified person - Applicable requirements as specified in ANNEX B of AO 2020-0017 - Payment of fees	
Change of Authorized Person - Accomplished e-Application Form - Name of new authorized person - Updated contact details - Payment of fees	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through http://eservices.fda.gov.ph and click **"Applications** "found on the upper right corner of the system. Selects the product category (Food) and the type of business establishment (Food Trader, Food Distributor) before clicking "**Variations"** Reads the **"Declaration and Undertaking "**before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".** Fills-out all necessary information. All fields mark with asterisk (*) are required to be filled-out.	1. Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness and correctness. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number via email. If not, the FDA shall notify the client the reason/s for non-acceptance and	None		FDA Evaluator (Center/Licensing and Registration)

Uploads the required documents as indicated on the Checklist of Requirements in pdf format. Reviews the duly filled out form in the **Self-Assessment Review**. Once reviewed, click on **"Confirm"** to submit the application.	prompt the applicant to apply again through the eServices Portal.			
2. Prints the Order of Payment form with Reference Number sent through the declared e-mail address Pays the application fee through existing payment channels	2. Posts payment in eServices Portal System for confirmed payments. This will prompt automatic decking of application to respective Center. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd** **Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.	See above table		FDA Cashier Administrative and Finance Service (AFS)
3. Receives Acknowledgement Receipt through email	3.1 Checks and quality assurance of the documents provided	None	4 working days	Technical Officer of Center

	3.2 Finalizes decision on the LTO application If application is approved, the FDA shall send the LTO to the registered email address of the applicant. If application is disapproved, the FDA shall inform the applicant through its registered email address of the reason for such action on the application.	None	3 working days	Center Director
4. Receives notification and prints LTO if application is approved				Qualified Person
TOTAL:			**7 working days**	

1.13.LICENSE TO OPERATE – INITIAL APPLICATION FOR MEDICAL DEVICE MANUFACTURERS

Center/Office/Division	**:**	Center for Device Regulation, Radiation and Health Research (CDRRHR)
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	All Manufacturers of Medical Device Products
Fees to be Paid	**:**	**Medical Device Manufacturer:** 20 Million and below – Php 5,000 +1% LRF over 20 Million but below 50 Million – Php 7,000 +1% LRF 50 Million and above – Php 10,000 +1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	
Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) coordinates to be filled in the eApplication Form ● Name of the Qualified Person depending on the type of health product establishment ● Self-Declaration in the e-Application Form	FDA e-Portal System

2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF) When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g., Mayor's Permit).	
3) Proof of income (Latest Audited Financial Statement with Balance Sheet) or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Site Master File (shall be presented to the FDA inspectors during inspection)	
6) Risk Management Plan (shall be presented to the FDA inspectors during inspection)	
7) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and	1.1 Posts payment in ePortal for confirmed payments. This will	See above table		FDA Cashier

uploads the required documentary requirements (in PDF format) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal System and email notification. Pays the assessed fee as per the system-generated Order of Payment through the existing payment channels	prompt automatic decking of application to respective RFO. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd**			Administrative and Finance Service
	1.2 Conducts pre-licensing inspection *Refer to Regional Field Office (RFO) Citizen's Charter for the issuance of Certificate of Compliance /Recommendation for Disapproval/ Recommendation Letter.*	None		Regional Field Officer/ Inspector
	1.3 Evaluates completeness and veracity of the documents submitted.	None	13 working days	FDA Evaluator (Center/Licensing and Registration)
	1.4 Checks evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center

	1.6 Finalizes decision on the LTO application If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working days	Center Director
2. Receives notification and link of LTO for printing				Qualified Person
TOTAL:			**20 working days**	

1.14.LICENSE TO OPERATE – RENEWAL APPLICATION FOR MEDICAL DEVICE MANUFACTURERS

Center/Office/Division	:	Center for Device Regulation, Radiation and Health Research (CDRRHR)
Classification	:	Complex
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Manufacturers of Medical Device Products
Fees to be Paid	:	**Medical Device Manufacturer:** 20 Million and below – Php 5,000 +1% LRF over 20 Million but below 50 Million – Php 7,000 +1% LRF 50 Million and above – Php 10,000 +1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-004** *Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes* **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	
● Accomplished e-Application Form as prescribed by FDA regulations. ● Declaration and Undertaking	FDA e-Portal (www.fda.gov.ph)

2) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
3) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal System (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification Pays the assessed fee as per the system- generated Order of Payment through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center/Office **LBP OnColl Payment: 5 wd** **Other Payment Channels:** 1. **2 wd**	See above table		FDA Cashier Administrative and Finance Service
	1.2 Conducts inspection (if necessary) *Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/*	None		Regional Field Officer/ Inspector

	Recommendation for Disapproval/ Recommendation Letter			
	1.3 Evaluates completeness and veracity of the documents submitted	None	3 working days	FDA Evaluator (Center/Licensing and Registration
	1.4 Checks evaluation and veracity of documents submitted.	None	1 working day	Technical Officer of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the Approval of LTO If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director
2. Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			**7 working days**	

1.15..LICENSE TO OPERATE – MAJOR VARIATION APPLICATION FOR MEDICAL DEVICE ESTABLISHMENT (MANUFACTURERS)

Center/Office/Division	:	Center for Device Regulation, Radiation, and Health Research (CDRRHR)
Classification	:	Complex
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Medical Device Manufacturers
Fees to be Paid	:	**Major Variation: Php 500 + 1% LRF** **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS (based on Administrative Order No. 2020-0017)	WHERE TO SECURE
Major Variation	FDA ePortal System (www.fda.gov.ph)
Transfer of Location of Manufacturing Plant - Accomplished e-Application Form - Business permit reflecting the new address - Updated Site Master File to be presented upon inspection - Payment of fees	
Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity - Accomplished e-Application Form - Updated Site Master File to be presented upon inspection	

- Payment of fees	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF format) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal System and email notification. Pays the assessed fee as per the system-generated Order of Payment through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd**	See above table		Qualified Person FDA Cashier Administrative and Finance Service
	1.2 Conducts inspection *Refer to Regional Field Office (RFO) Citizen's Charter for the issuance of Certificate of Compliance /Recommendation for Disapproval/ Recommendation Letter.*	None		Regional Field Officer/ Inspector

	1.3 Evaluates completeness and veracity of the document submitted.	None	13 working days	FDA Evaluator (Center/Licensing and Registration)
	Checks evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of Center
	1.4 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.5 Finalizes decision on the LTO application 1.6 If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working days	Center Director
2. Receives notification and link of LTO for printing				Qualified Person
TOTAL:			**20 working days**	

1.16.LICENSE TO OPERATE – INITIAL APPLICATION FOR MEDICAL DEVICE TRADERS AND DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER)

Center/Office/Division	:	Center for Device Regulation, Radiation and Health Research (CDRRHR)
Classification	:	Complex
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Medical Device Traders and Distributors (Importer, Exporter, Wholesaler)

Fees to be Paid	:	**Medical Device Trader:** 20 million and below – Php 3,000 + 1% LRF Over 20 million but below 50 million – Php 5,000 + 1% LRF 50 million and above – Php 7,000 + 1% LRF **Medical Device Distributors (Importer, Exporter, Wholesaler) :** Php 4,000 + 1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017:	FDA website (www.fda.gov.ph)

Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) coordinates to be filled in the e-Application Form ● Name of the Qualified Person depending on the type of health product establishment Self-Declaration in the e-Application Form	FDA eServices (www.fda.gov.ph)
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF) When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g., Mayor's Permit).	
3) Proof of income (for Trader) - Latest Audited Financial Statement with Balance Sheet or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through http://eservices.fda.gov.ph and click **"Applications"** found on the upper right corner of the system. Selects the product category (Medical Device) and the type of business establishment (Medical Device Trader, Medical Device Distributor) before clicking "**Initial"** Application Reads the **"Declaration and Undertaking "**before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".** Fills-out all necessary information. All fields mark with asterisk (*) are required to be filled-out. Uploads the required documents as indicated on the Checklist of Requirements in pdf format. Reviews the duly filled out form in the **Self-Assessment Review**. Once reviewed, click on **"Confirm"** to submit the application. Prints the Order of Payment form with Reference Number sent through the declared e-mail address	1.1 Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness and correctness. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number via email. If not, the FDA shall notify the client the reason/s for non-acceptance and prompt the applicant to apply again through the eServices Portal.	None		FDA Evaluator (Center/Licensing and Registration)

2. Pays the application fee through existing payment channels Receives Acknowledgement Receipt through email	2.1 Posts payment in eServices Portal System for confirmed payments. This will prompt automatic decking of application to respective Center. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd** **Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.	See above table	0	Qualified Person FDA Cashier Administrative and Finance Service (AFS)
	2.2 Checks and quality assurance of the documents provided	None	11 working days	Technical Officer of Center
	2.3 Finalizes decision on the LTO application If application is approved, the FDA shall send the LTO to the registered email address of the applicant. If application is disapproved, the FDA shall inform the	None	3 working days	Center Director

	applicant through its registered email address of the reason for such action on the application.			
3. Receives notification and prints LTO if application is approved				Qualified Person
TOTAL:			**14 working days**	

1.17.LICENSE TO OPERATE – RENEWAL APPLICATION FOR MEDICAL DEVICE TRADERS AND MEDICAL DEVICE DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER)

Center/Office/Division	:	Center for Device Regulation, Radiation and Health Research (CDRRHR)
Classification	:	Complex
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Medical Device Traders and Medical Device Distributors (Importer, Exporter, Wholesaler)
Fees to be Paid	:	**Medical Device Trader :** 20 million and below – Php 3,000 + 1% LRF Over 20 million but below 50 million – Php 5,000 + 1% LRF 50 million and above – Php 7,000 + 1% LRF **Medical Device Distributors (Importer, Exporter, Wholesaler) :** Php 4,000 + 1% LRF **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-004** *Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes* **FDA Circular No. 2011-003** *Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	FDA Website (www.fda.gov.ph)
• Accomplished e-Application Form as prescribed by FDA regulations. • Declaration and Undertaking	
2) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
3) Refer to FROO Inspection Agenda of this Citizen's Charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through https://eservices.fda.gov.ph and click **"Applications"** found on the upper right corner of the system. Selects the product category (Drug) and the type of business establishment (Drug Trader, Drug Distributor, Drugstore, RONPD, CRO, Sponsor) before clicking **"Renewal"** application Reads the **"Declaration and Undertaking"** before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".** Fills-out all necessary information. All fields mark with asterisk (8*) are required to be filled-out.	1. System sends the Order of Payment after receipt of the application	None	0	Qualified Person

Updates contact numbers if necessary. Click **"Next"** to proceed to Self – Assessment Review Reviews all details in the **"Self-Assessment Review"**. Once reviewed, click on **"Confirm"** to submit application. Prints the Order of Payment with Reference Number sent through the declared email address				
2. Pays the application fee through existing payment channels Receives Acknowledgement Receipt through email	2. Posts confirmed payments. This will prompt automatic routing of application to Center **LBP OnColl Payment: 5 wd** **LBP Linkbiz: auto posting** **Other Payment Channels: 2 wd** **Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.	None		FDA Cashier Administrative and Finance Service

1.6.1.1 Receives notification and link of LTO for Printing		None		
TOTAL:	**The LTO shall be automatically generated by the system once the payment has been posted by the FDA Cashier**			

1.18.LICENSE TO OPERATE – MINOR VARIATION APPLICATION FOR MEDICAL DEVICE TRADERS AND MEDICAL DEVICE DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER)

Center/Office/Division	:	Center for Device Regulation, Radiation, and Health Research (CDRRHR)
Classification	:	Complex
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Medical Device Traders and Medical Device Distributors (Importer, Exporter, Wholesaler)
Fees to be Paid	:	**Minor Variation: Php 500 + 1% LRF** **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS (based on Administrative Order No. 2020-0017)	WHERE TO SECURE
Minor Variation	FDA eServices (www.fda.gov.ph)
Transfer of Location of Offices - Accomplished e-Application Form - Business permit reflecting new location of office - Payment of fees	
Change of Distributor Activity	

- Accomplished e-Application Form - Contract Agreements showing change in activity - Payment of fees	
Transfer/Addition of Warehouse - Accomplished e-Application Form - Business Permit reflecting new warehouse location - Payment of fees	
Expansion of Office Establishments and Drug Retailers - Accomplished e-Application Form - Expansion floor plan - Payment of fees	
Change of Ownership - Accomplished e-Application Form - Business name registration reflecting new ownership - Any proof on the transfer of ownership such as any of the following • Deed of Sale or assignment or transfer of rights/ownership • Memorandum of Agreement • Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer - Payment of fees	
Change of Business Name - Accomplished e-Application Form - Business permit reflecting the new name - Payment of fees	
Zonal Change in Address - Accomplished e-application Form - Certificate of Zonal Change	

- Payment of fees	
Change of Qualified Person - Accomplished e-Application Form - Name of new qualified person - Applicable requirements as specified in ANNEX B of AO 2020-0017 - Payment of fees	
Change of Authorized Person - Accomplished e-Application Form - Name of new authorized person - Updated contact details - Payment of fees	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through http://eservices.fda.gov.ph and click **"Applications"** found on the upper right corner of the system. Selects the product category (Food) and the type of business establishment (Food Trader, Food Distributor) before clicking "**Variations"** Reads the **"Declaration and Undertaking"** before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".**	1. Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness and correctness. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number via email.	None		FDA Evaluator (Center/Licensing and Registration)

Fills-out all necessary information. All fields mark with asterisk (*) are required to be filled-out. Uploads the required documents as indicated on the Checklist of Requirements in pdf format. Reviews the duly filled out form in the **Self-Assessment Review**. Once reviewed, click on **"Confirm"** to submit the application. Prints the Order of Payment form with Reference Number sent through the declared e-mail address	If not, the FDA shall notify the client the reason/s for non-acceptance and prompt the applicant to apply again through the eServices Portal.			
2. Pays the application fee through existing payment channels Receives Acknowledgement Receipt through email	2.1 Posts payment in eServices Portal System for confirmed payments. This will prompt automatic decking of application to respective Center. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd** **Note**: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will	See above table	0	FDA Cashier Administrative and Finance Service (AFS)

	signify the start of processing time of the application.			
	2.2 Checks and quality assurance of the documents provided	None	4 working days	Technical Officer of Center
	2.3 Finalizes decision on the LTO application If application is approved, the FDA shall send the LTO to the registered email address of the applicant. If application is disapproved, the FDA shall inform the applicant through its registered email address of the reason for such action on the application.	None	3 working days	Center Director
3. Receives notification and prints LTO if application is approved				Qualified Person
TOTAL:			**7 working days**	

1.19. LICENSE TO OPERATE – INITIAL APPLICATION FOR MANUFACTURERS OF COSMETICS, TOYS AND CHILD CARE ARTICLES (TCCAS) AND HOUSEHOLD URBAN PESTICIDES (HUPS)

Center/Office/Division	:	Center for Cosmetic and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	Manufacturers of Cosmetics, Toys and Child Care Articles and Household Urban Pesticides
Fees to be Paid	:	**Cosmetics Manufacturer:** 20 Million and below - Php 5,000 +1 % LRF over 20 Million but below 50 Million - Php 10,000 + 1 % LRF 50 Million and above - Php 15,000 + 1 % LRF **Household Hazardous Substance Manufacturer:** 1 Million and below - Php 1,000 + 1 % LRF over 1 Million but below 5 Million - Php 2,000 + 1 % LRF 5 Million but below 10 Million - Php 3,000 + 1 % LRF 10 Million but below 20 Million - Php 5,000 + 1 % LRF` 20 Million but below 50 Million - Php 10,000 + 1 % LRF 50 Million and above - Php 15,000 + 1 % LRF **Administrative Order 50 s. 2001*** Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs **FDA Circular No. 2011-003**

		Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017:	
Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) coordinates to be filled in the eApplication Form ● Name of the Qualified Person depending on the type of health product establishment ● Self-Declaration in the e-Application Form	FDA e-Portal System (www.fda.gov.ph)
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF) When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g. Mayor's Permit).	
3) Proof of income (Latest Audited Financial Statement with Balance Sheet) or Duly notarized Statement/Certification of Initial Capitalization.	

4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Site Master File (shall be presented to the FDA inspectors during inspection)	
6) Risk Management Plan (shall be presented to the FDA inspectors during inspection)	
7) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION1	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF format) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification. Pays the assessed fee as per the system-generated Order of Payment Form through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 3 wd**	See above table	0	Qualified Person FDA Cashier Administrative and Finance Service
	1.2 Conducts pre-licensing inspection. *Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/Recommendation for*	None	0	Regional Field Officer/Inspector

	Disapproval/ Recommendation Letter.			
	1.3 Evaluates completeness and veracity of the documents submitted.	None	13 working days	FDA Evaluator (Center/Licensing and Registration)
	1.4 Checks evaluation and veracity of the documents submitted.	None	3 working days	Technical Office of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the application. If application is disapproved, the applicant will be notified through email ad will receive the Letter of Denial	None	3 working days	Center Director
2. Receives notification and link of LTO for printing				Qualified Person
TOTAL:			**20 working days**	

1.20.LICENSE TO OPERATE – RENEWAL APPLICATION FOR MANUFACTURERS OF COSMETICS, TOYS AND CHILD CARE ARTICLES (TCCAS) AND HOUSEHOLD URBAN PESTICIDES (HUPS)

Center/Office/Division	:	Center for Cosmetic and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)
Classification	:	Complex
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	Manufacturers of Cosmetics, Toys and Childcare Articles and Household Urban Pesticides
Fees to be Paid	:	**Cosmetics Manufacturer:** 20 Million and below - Php 10,000 + 1 % LRF over 20 Million but below 50 Million - Php 20,000 + 1 % LRF 50 Million and above - Php 15,000 + 1 % LRF **Household Hazardous Substance Manufacturer:** 1 Million and below - Php 2,000 + 10 % LRF over 1 Million but below 5 Million - Php 4,000 + 1 % LRF 5 Million but below 10 Million - Php 6,000 + 1 % LRF 10 Million but below 20 Million - Php 10,000 + 1 % LRF 20 Million but below 50 Million - Php 20,000 + 1% LRF 50 Million and above - Php 30,000 + 1% LRF **Administrative Order 50 s. 2001*** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-004** *Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing*

		Rules and Regulations, and Other Purposes **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017:	
• Accomplished e-Application Form as prescribed by FDA regulations. • Declaration and Undertaking	FDA e-Portal (www.fda.gov.ph) Applicant /Qualified Person
2) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
3) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	Applicant/Qualified person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF) for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification Pay the assessed fee as per the system generated Order of Payment Form through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center/Office.	See above table	0	FDA Cashier Administrative and Finance Service

	1.2 Conducts inspection *Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/Recommendation for Disapproval/ Recommendation Letter*	None		Regional Field Officer/ Inspector
	1.3 Evaluates completeness and veracity of the documents submitted	None	3 working days	FDA Evaluator (Center/Licensing and Registration)
	1.4 Checks evaluation and veracity of documents submitted.	None	2 working day	Technical Officer of Center
	1.5 Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	1.6 Finalizes decision on the Approval of LTO If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	1 working day	Center Director
2. Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			**7 working days**	

1.21.LICENSE TO OPERATE – MAJOR VARIATION APPLICATION

Center/Office/Division	**:**	Center for Cosmetic and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	Manufacturers of Cosmetics, Toys and Childcare Articles, and Household Urban Pesticides
Fees to be Paid	**:**	**Major Variation – Php 500 +1% LRF** **Administrative Order 50 s. 2001** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS **(Based on Administrative Order No. 2020-0017)**	**WHERE TO SECURE**
Major Variation	
A. Transfer of Location of Manufacturing Plant 1. Accomplished e-Application Form 2. Business permit reflecting the new address 3. Updated Site Master File to be presented upon inspection 4. Payment of fees	Qualified Person

B. Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity 1. Accomplished e-Application Form 2. Updated Site Master File to be presented upon inspection 3. Payment of fees	
1) Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
2) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	Applicant/Qualified person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification Pays the assessed fee as per the system-generated Order of Payment Form through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO. **LBP OnColl Payment: 5wd** **Other Payment Channels: 2 wd**	See above table	0	FDA Cashier Administrative and Finance Service

	1.2 Conducts inspection Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/Recommendation for Disapproval/ Recommendation Letter	None	0	Regional Field Officer/ Inspector
	1.3 Evaluates completeness and veracity of the documents submitted.	None	12 working days	FDA Evaluator (Center/Licensing and Registration)
	1.4 Checks evaluation and veracity of documents submitted.	None	4 working days	Technical Officer of Center
	1.4 Quality assurance of the evaluation.	None	2 working day	Technical Officer of Center
	1.5 Finalizes decision on the LTO application If the application is disapproved, the applicant will be notified through email and will receive the letter of Denial	None	2 working days	Center Director
2. Receives notification and link of LTO for printing				Qualified Person
TOTAL:			**20 working days**	

1.22.LICENSE TO OPERATE – INITIAL APPLICATION FOR TRADERS, DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER) OF COSMETICS, TOYS AND CHILD CARE ARTICLES (TCCAS) AND HOUSEHOLD URBAN PESTICIDES (HUPS)

Center/Division	:	Center for Cosmetic and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Traders, Distributors (Importer, Exporter, Wholesaler) Cosmetics, Toys and Child Care Articles (TCCAs) and Household Urban Pesticides (HUPs)
Fees to be Paid	:	**Cosmetics Trader:** 20 Million and below -Php 3,000+ 1 % LRF over 20 Million but below 50 Million- Php 5,000+ 1% LRF 50 Million and above - Php 7,000+ 1 % LRF **Cosmetics Distributors:** Importer, Exporter, Wholesaler - Php 3,000+ 1 % LRF **Household Hazardous Substances:** Importer, Exporter, Wholesaler- Php 3,000+ 1 % LRF **Administrative Order 50 s. 2001*** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017: ● Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) to be filled in the eApplication Form ● Name of the Qualified Person Self-Declaration in the e-Application Form	FDA e-Portal (www.fda.gov.ph)
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration: ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter include Mayor's Permit or Barangay Clearance provision (1 Scanned copy PDF) A copy of Business permit (i.e., Mayor's Permit or Barangay Clearance provision) will be submitted for business or establishment address with different business name registration address.	
3) Proof of income (Latest Audited Financial Statement with Balance Sheet) or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification. Pays the assessed fee as per the system-generated Order of Payment Form through the existing payment channels	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center. **LBP OnColl Payment : 5wd** **Other Payment Channels : 3 wd**	See above table	0	FDA Cashier Administrative and Finance Service (AFS)
	1.2 Evaluates completeness and correctness of the documents submitted.	None	5 working days	FDA Evaluator (Center/Licensing and Registration Division)
	1.3 Checks the veracity of documents provided	None	4 working days	Technical Officer of Center
	1.4 Quality assurance of the documents provided and compliance	None	3 working days	Technical Officer of Center
	1.6 Finalizes decision on the LTO application	None	2 working days	Center Director

	If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial			
3. Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			**14 working days**	

1.23.LICENSE TO OPERATE – RENEWAL APPLICATION LICENSE TO OPERATE FOR TRADERS, DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER) OF COSMETICS, TOYS AND CHILD CARE ARTICLES (TCCAS) AND HOUSEHOLD URBAN PESTICIDES (HUPS)

Center/Office/Division	:	Center for Cosmetic and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Traders, Distributors (Importer, Exporter, Wholesaler) Cosmetics, Toys and Child Care Articles (TCCAs) and Household Urban Pesticides (HUPs)
Fees to be Paid	:	**Cosmetics Trader:** 20 Million and below - Php 6,000 + 1 % LRF over 20 Million but below 50 Million - Php 10,000 + 1 % LRF 50 Million and above - Php14,000 + 1 % LRF **Cosmetics Distributors:** Importer, Exporter, Wholesaler Php 6,000 + 1 % LRF **Household Hazardous Substances:** Importer, Exporter, Wholesaler - Php 6,000 + 1 % LRF **Administrative Order 50 s. 2001*** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856* **FDA Circular No. 2011-004**

		Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017: ● Accomplished e-Application Form as prescribed by FDA regulations. ● Declaration and Undertaking	 FDA e-Portal (www.fda.gov.ph) Applicant / Qualified Person
2) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
3) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	Applicant/Qualified person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification	1.1 Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center/Office.	See above table		FDA Cashier Administrative and Finance Service (AFS)

Pays the assessed fee as per the system-generated Order of Payment Form through				
	1.2 Evaluates completeness and correctness of documents submitted.	None	5 working days	FDA Evaluator (Center/Licensing and Registration Division)
	1.3 Checks and quality assurance of the documents provided and compliance	None	4 working days	Technical Officer of Center
	1.4 Quality assurance of the evaluation	None	3 working days	Technical Officer of Center
	1.5 Finalizes decision on LTO application If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director
2. Receives notification and link of LTO for printing				Qualified person
TOTAL:			**14 working days**	

1.24.LICENSE TO OPERATE – MINOR VARIATION APPLICATION FOR COSMETICS, TOYS AND CHILD CARE ARTICLES (TCCAS) AND HOUSEHOLD URBAN PESTICIDES (HUPS)

Center/Office/Division	:	Center for Cosmetic and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Traders, Distributors (Importer, Exporter, Wholesaler of Cosmetics, Toys and Child Care Articles (TCCAs) and Household Urban Pesticides (HUPs)
Fees to be Paid	:	**Minor Variation: Php 500 +1% LRF** **Administrative Order 50 s. 2001*** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS (based on Administrative Order No. 2020-0017)	**WHERE TO SECURE**
Minor Variation	**FDA website (www.fda.gov.ph)**
A. Transfer of Location Offices - Accomplished e-Application Form - Business permit reflecting new location of office - Payment of fees B. Change of Distributor Activity - Accomplished e-Application Form - Contract Agreements showing change in activity	Qualified Person

- Payment of fees C. Transfer or Addition of Warehouse - Accomplished e-Application Form - Business Permit reflecting new warehouse location - Payment of fees D. Expansion of Office Establishment - Accomplished e-Application Form - Current floor plan and Expansion floor plan - Payment of fees E. Change of Ownership - Accomplished e-Application Form - Business name registration reflecting new ownership - Any proof on the transfer of ownership ● Deed of sale or assignment or transfer of rights/ownership; ● Memorandum of Agreement; or ● Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer - Payment of fees F. Change of Business Name - Accomplished e-Application Form - Business permit reflecting the new name - Payment of fees G. Zonal Change in Address	

- Accomplished e-Application Form - Certificate of Zonal Address - Payment of Fees H. Change of Qualified Person - Accomplished e-Application Form - Name of new qualified person, with credentials when applicable - Applicable requirements as specified in ANNEX B of AO 2020-0017 - Payment of fees I. Change of Authorized Person - Accomplished e-Application Form - Name of new authorized person - Updated contact details - Payment of fees	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Logs in to the e-portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements for e-LTO application Downloads and prints the generated Order of Payment through the ePortal and Email notification.	1.1 Posts payment in ePortal for confirmed payments. This will automatic decking of application to respective Center.	See above table		FDA Cashier Administrative and Finance Service (AFS)

Pays the assessed fee as per the system generated Order of Payment Form through the existing payment channels				
	1.2 Evaluates completeness and correctness of submitted documentary requirements.	None	5 working days	FDA Evaluator (Center/Licensing and Registration Division)
	1.3 Checks evaluation and veracity of documents submitted.	None	4 working days	Technical Officer of Center
	1.4 ality assurance of the evaluation.	None	3 working days	Technical Officer of Center
	1.5 Finalizes decision on the LTO application If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director
2. Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			**14 working days**	

1.25.LICENSE TO OPERATE – INITIAL APPLICATION FOR MANUFACTURERS OF HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) BASED ON ADMINISTRATIVE ORDER NO. 2019-0019 AND FDA CIRCULAR 2020-025

Issuance of Electronic Portal (E-Portal) Ver.2.0 User Account

Center/Office/Division	:	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	Manufacturers of Household/Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1.Proof of Ownership of Establishment (refer to Annex B and B.1 of FDA Circular No. 2020-025)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1.1 Requests User Account credentials by accomplishing the Online User's Registration Form through the link: bit.ly/ePortal2 (refer to Annex B.1)	1. Checks for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff
2. Receives username and password	2. Issues user account (username and password) to the client	None	Next Working Day	CCHUHSRR Admin. Staff
	TOTAL:	**None**	**1 Working Day and 15 minutes**	

Center/Office/Division	:	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Manufacturers of Household/Urban Hazardous Substances (under Categories III and IV) based on Administrative Order No. 2019-0019 and FDA Circular No. 2020-025
Fees to be Paid	:	**Household Hazardous Substance Manufacturer:** 1 Million and below - Php 1,000 + 1 % LRF over 1 Million but below 5 Million - Php 2,000 + 1 % LRF 5 Million but below 10 Million - Php 3,000 + 1 % LRF 10 Million but below 20 Million - Php 5,000 + 1 % LRF` 20 Million but below 50 Million - Php 10,000 + 1 % LRF 50 Million and above - Php 15,000 + 1 % LRF Administrative Order 50 s. 2001* Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs FDA Circular No. 2011-003 Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017 and FDA Circular No. 2020-025:	FDA website (www.fda.gov.ph
Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) coordinates to be filled in the e-Application Form	FDA e-Portalv2 (https://eportal2.fda.gov.ph)

• Personnel information of the Authorized Person and Qualified Person of the establishment • Self-Declaration in the e-Application Form	
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): • For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) • For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) • For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) • For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF) When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g. Mayor's Permit).	
3) Proof of income (Latest Audited Financial Statement with Balance Sheet) or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Site Master File (shall be presented to the FDA inspectors during inspection).	
6) Risk Management Plan (shall be presented to the FDA inspectors during inspection)	
7) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE

1. Access the FDA e-Portal V2 at (https://eportal2.fda.gov.ph). Log in by entering the issued username and password In the Home tab, select New Application in the navigation pane and click e-License to Operate (Initial Application) to proceed to the LTO application form. Accomplish the application form as provided in parts by the application wizard. Fill-in the fields as completely as possible. Fields marked with a red asterisk (*) are required to be filled-in. Mark required fields with N/A, if not applicable. Upload Documents in PDF format. ● Proof of Business Name Registration, Proof of Income.Tick the box to certify all information is true and correct, then "Next". Applicants may upload documents simultaneously.	1. Pre-assessment on the completeness of application and documentary requirements submitted	None		FDA Evaluator
2. Pay the assessed fee as per the system generated Order of Payment Form, through existing payment channels	2.1 Post payment in ePortalv2 for confirmed payments. This will prompt automatic decking of application to respective RFO	See above table		Qualified Person FDA Cashier

	Posting of bank payment: LBP OnColl Payment – 5 wd Bancnet – 2 wd			Administrative and Finance Service
	2.2 Pre-license Inspection by Regional Field Offices (RFO) Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/ Recommendation for Disapproval/ Recommendation Letter	None		Regional Field Officer/ Inspector **Not currently required since HUHS manufacturer shall also undergo PLI (based on FDA Advisory 2020-2035)*
	2.3 Evaluation on the completeness and veracity of the documents submitted.	None	15 working days	FDA Evaluator (Center/Licensing and Registration)
	2.4 Checking of the evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of specific Center of jurisdiction
	2.5 Final Decision on the Approval of LTO If application is disapproved, the applicant will be notified through	None	2 working days	Center Director

	email and will receive the Letter of Denial.			
3 Receive notification and copy of e-LTO for printing				Qualified person
TOTAL:			**20 working days**	

1.26.LICENSE TO OPERATE – RENEWAL APPLICATION FOR MANUFACTURERS OF HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) BASED ON ADMINISTRATIVE ORDER NO. 2019-0019 AND FDA CIRCULAR 2020-025

Issuance of Electronic Portal (E-Portal) Ver.2.0 User Account

Center/Office/Division	:	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	All Manufacturers of Household/Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1.Proof of Ownership of Establishment (refer to Annex B and B.1 of FDA Circular No. 2020-025)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Request User Account credentials by accomplishing the Online User's Registration Form through the link: bit.ly/ePortal2 (refer to Annex B.1)	1. Check for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff
2. Receive username and password	2. Issue user account (username and password) to the client	None	Next Working Day	CCHUHSRR Admin. Staff
	TOTAL:	**None**	**1 Working Day and 15 minutes**	

Center/Office/Division	**:**	Center for Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	**:**	Complex
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	All Manufacturers Household Urban Hazardous Substances f Household/Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be Paid	**:**	**Household Hazardous Substance Manufacturer:** 1 Million and below - Php 2,000 + 10 % LRF over 1 Million but below 5 Million - Php 4,000 + 1 % LRF 5 Million but below 10 Million - Php 6,000 + 1 % LRF 10 Million but below 20 Million - Php 10,000 + 1 % LRF 20 Million but below 50 Million - Php 20,000 + 1% LRF 50 Million and above - Php 30,000 + 1% LRF **Administrative Order 50 s. 2001*** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856* **FDA Circular No. 2011-004** *Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017 and FDA Circular No. 2020-025:	

• Accomplished e-Application Form as prescribed by FDA regulations. • Declaration and Undertaking	FDA e-Portal V.2 (www.fda.gov.ph) Applicant / Qualified Person
2) Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
3) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	Applicant/Qualified person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the FDA e-Portal V2 at (https://eportal2.fda.gov.ph). Log in by entering the issued username and password. Accomplish the LTO renewal application form Download and print the generated Order of Payment through the ePortal and Email notification.	1. Pre-assessment on the completeness of application and documentary requirements submitted	None		CCHUHSRR Personnel
2. Pay the assessed fee as per the system generated Order of Payment Form through existing payment channels.	2. Post payment in ePortalv2 for confirmed payments. This will prompt automatic decking of application to respective Center.	See above table		Qualified Person and FDA Cashier Administrative and Finance Service
	2.1 Pre-Inspection by the Regional Field Office (RFO)	None		Regional Field

	Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/ Recommendation for Disapproval/ Recommendation Letter			Officer/ Inspector
	2.2 Evaluation on the completeness and veracity of the documents submitted.	None	3 working days	FDA Evaluator (Center/Licensing and Registration)
	2.3 Checking of the evaluation and veracity of documents submitted.	None	2 working day	Technical Officer of specific Center of jurisdiction
	2.4 Final Decision on the Approval of LTO If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director of jurisdiction
3. Receive notification and copy of e-LTO for printing		None		Qualified person
TOTAL:			**7 working days**	

1.27.LICENSE TO OPERATE – MAJOR VARIATION FOR MANUFACTURERS OF HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) BASED ON ADMINISTRATIVE ORDER NO. 2019-0019 AND FDA CIRCULAR 2020-025

Issuance of Electronic Portal (E-Portal) Ver.2.0 User Account

Center/Office/Division	:	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	Manufacturers of Household/Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1.Proof of Ownership of Establishment (refer to Annex B and B.1 of FDA Circular No. 2020-025)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1.1 Request User Account credentials by accomplishing the Online User's Registration Form through the link: bit.ly/ePortal2 (refer to Annex B.1)	1. Check for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff
1.2 Receive username and password	2. Issue user account (username and password) to the client	None	Next Working Day	CCHUHSRR Admin. Staff
	TOTAL:	**None**	**1 Working Day and 15 minutes**	

Center/Office/Division	**:**	Center for Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	All Manufacturers of Household/Urban Hazardous Substances (HUHS)
Fees to be Paid	**:**	Amendment of LTO or Re-issuance (if lost) – Php 500 +1% LRF Administrative Order 50 s. 2001* Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs FDA Circular No. 2011-003 Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) List of Requirements for Specific Variation based on Administrative Order No. 2020-0017: A. Transfer of Location of Manufacturing Plant Documentary Requirement: 1. Business permit reflecting the new address 2. Updated Site Master File to be presented upon inspection B. Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity Documentary Requirement: 1.Updated Site Master File to be presented upon inspection	Qualified Person

2 Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
3 Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	Applicant/Qualified person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the FDA e-Portal V2 at (https://eportal2.fda.gov.ph). Log in by entering the issued username and password. In the Home tab, select New Application in the navigation pane and click e-License to Operate (Variation Application) to proceed to the LTO application form. Accomplish the application form as provided in parts by the application wizard. Fill-in the fields as completely as possible. Fields marked with a red asterisk (*) are required to be filled-in. Mark required fields with N/A, if not applicable. Upload Documents in PDF format. ● Proof of Business Name Registration, Proof of Income. Tick the box to certify all information is true and correct, then "Next".	1. Pre-assessment on the completeness of application and documentary requirements submitted	None	0	Qualified Person

Applicants may upload documents simultaneously. Order of payment- A computer generated document will appear reflecting the appropriate fees and charges. Applicant should save and print a copy of document as reference for payment				
2. Pay the assessed fee as per the system generated Order of Payment Form through existing payment channels.	2.1 Post payment in ePortal V.2 for confirmed payments. This will prompt automatic decking of application to respective Center	See above table	0	Qualified Person/ FDA Cashier Administrative and Finance Service (AFS)
	2.2 Pre-Inspection by Regional Field Office (RFO) Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/ Recommendation for Disapproval/ Recommendation Letter	None		Regional Field Officer/ Inspector
	2.3 Evaluation of the correctness of submitted documentary requirements.	None	15 working days	FDA Evaluator (Center/Licensing and Registration Division)

	2.4 Checking of the evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of specific Center of jurisdiction
	2.5 Approval of LTO If the application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director of jurisdiction
3. Receives notification and copy of e-LTO for printing		None		Qualified Person
TOTAL:			**20 working days**	

1.28.LICENSE TO OPERATE – INITIAL APPLICATION FOR TRADERS, DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER) OF HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) BASED ON ADMINISTRATIVE ORDER NO. 2019-0019 AND FDA CIRCULAR 2020-025

Issuance of Electronic Portal (E-Portal) Ver.2.0 User Account

Center/Office/Division	:	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	All Traders, Distributors (Importer, Exporter, Wholesaler) of Household/Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1.Proof of Ownership of Establishment (refer to Annex B and B.1 of FDA Circular No. 2020-025)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Requests User Account credentials by accomplishing the Online User's Registration Form through the link: bit.ly/ePortal2 (refer to Annex B.1)	1. Check for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff
2. Receives username and password	2. Issue user account (username and password) to the client	None	Next Working Day	CCHUHSRR Admin. Staff

TOTAL:	**None**	**1 Working Day and 15 minutes**

Center/Division	:	Center for Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Traders, Distributors (Importer, Exporter, Wholesaler) of Household Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be Paid	:	**Household Hazardous Substances:** Importer, Exporter, Wholesaler- Php 3,000+ 1 % LRF Note: The fees charged for the manufacturers and traders of products regulated by BFAD are based **Administrative Order 50 s. 2001*** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856* **FDA Circular No. 2011-004** *Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017 and FDA Circular No. 2020-025: ● Location plan and Global Positioning System (GPS) coordinates to be filled in the e-Application Form	FDA e-Portalv2 (https://eportal2.fda.gov.ph) Authorized Person Qualified Person

• Personnel information of the Authorized Person and Qualified Person of the establishment • Self-Declaration in the e-Application Form	
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration: • For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) • For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) • For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) • For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter include Mayor's Permit or Barangay Clearance provision (1 Scanned copy PDF) A copy of Business permit (i.e., Mayor's Permit or Barangay Clearance provision) will be submitted for business or establishment address with different business name registration address.	Applicant/Qualified Person
3) Proof of income (Latest Audited Financial Statement with Balance Sheet) or Duly notarized Statement/Certification of Initial Capitalization.	Applicant/Qualified person
4) Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
5) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	Applicant/Qualified person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE

1. Access the FDA e-Portal V2 at (https://eportal2.fda.gov.ph). Log in by entering the issued username and password In the Home tab, select New Application in the navigation pane and click e-License to Operate (Initial Application) to proceed to the LTO application form. Accomplish the application form as provided in parts by the application wizard. Fill-in the fields as completely as possible. Fields marked with a red asterisk (*) are required to be filled-in. Mark required fields with N/A, if not applicable. Upload Documents in PDF format. ● Proof of Business Name Registration, Proof of Income. Tick the box to certify all information is true and correct, then "Next". Applicants may upload documents simultaneously.	Pre-assessment on the completeness of application and documentary requirements submitted	None		FDA Evaluator
2. Pay the assessed fee as per the system generated Order of Payment Form, through existing payment channels	2.1 Post payment in ePortalv2 for confirmed payments. This will prompt automatic decking of application to respective Center.	See above table		Qualified Person FDA Cashier

	Posting of Bank payment: LBP OnColl Payment – 5 wd Bancnet – 2 wd			Administrative and Finance Service
	2.2 Evaluation on the completeness and veracity of the documents submitted.	None	8 working days	FDA Evaluator (Center/Licensing and Registration)
	2.3 Checking of the evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of specific Center of jurisdiction
	2.4 Final Decision on the Approval of LTO If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial.	None	3 working days	Center Director of jurisdiction
3. Receive notification and copy of e-LTO for printing				Qualified person
TOTAL:			**14 working days**	

1.29.LICENSE TO OPERATE- RENEWAL APPLICATION FOR TRADERS, DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER) HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) BASED ON ADMINISTRATIVE ORDER NO. 2019-0019 AND FDA CIRCULAR 2020-025

Issuance of Electronic Portal (E-Portal) Ver.2.0 User Account

Center/Office/Division	:	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	All Traders, Distributors (Importer, Exporter, Wholesaler) of Household/Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1.Proof of Ownership of Establishment (refer to Annex B and B.1 of FDA Circular No. 2020-025)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
.1 Request User Account credentials by accomplishing the Online User's Registration Form through the link: bit.ly/ePortal2 (refer to Annex B.1)	1. Check for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff
.2 Receive username and password	2. Issue user account (username and password) to the client	None	Next Working Day	CCHUHSRR Admin. Staff
	TOTAL:	**None**	**1 Working Day and 15 minutes**	

Center/Division	:	Center for Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Traders, Distributors (Importer, Exporter, Wholesaler) Household Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be Paid	:	**Household Hazardous Substances:** Importer, Exporter, Wholesaler - Php 6,000 + 1 % LRF **Administrative Order 50 s. 2001*** Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs **FDA Circular No. 2011-003** Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856 **FDA Circular No. 2011-004** Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017 and FDA Circular No. 2020-025:	
● Accomplished e-Application Form as prescribed by FDA regulations. ● Declaration and Undertaking	FDA e-Portal V.2 (www.fda.gov.ph) Applicant / Qualified Person

2) Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
3) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	Applicant/Qualified person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the FDA e-Portal V2 at (https://eportal2.fda.gov.ph). Log in by entering the issued username and password. Accomplish the LTO renewal application form Download and print the generated Order of Payment through the ePortal and Email notification.	1. Pre-assessment on the completeness of application and documentary requirements submitted	None	0	FDA Evaluator
2. Pay the assessed fee as per the system-generated Order of Payment Form through existing payment channels.	2.1 Post payment in ePortalv2 for confirmed payments. This will prompt automatic decking of application to respective Center.	See above table	0	Qualified Person and FDA Cashier Administrative and Finance Service
	2.2 Pre-Inspection by the Regional Field Office (RFO) Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/	None		Regional Field Officer/ Inspector

	Recommendation for Disapproval/ Recommendation Letter			
	2.3 Evaluation on the completeness and veracity of the documents submitted.	None	3 working days	FDA Evaluator (Center/Licensing and Registration)
	2.4 Checking of the evaluation and veracity of documents submitted.	None	2 working day	Technical Officer of specific Center of jurisdiction
	2.5 Final Decision on the Approval of LTO If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director of jurisdiction
3. Receive notification and copy of e-LTO for printing		None		Qualified person
TOTAL:			**7 working days**	

1.30.LICENSE TO OPERATE – MINOR VARIATION APPLICATION FOR HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) BASED ON ADMINISTRATIVE ORDER NO. 2019-0019 AND FDA CIRCULAR 2020-025

Issuance of Electronic Portal (E-Portal) Ver.2.0 User Account

Center/Office/Division	:	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	All Manufacturers, Traders, Distributors (Importer, Exporter, Wholesaler) of Household/Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1.Proof of Ownership of Establishment (refer to Annex B and B.1 of FDA Circular No. 2020-025)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
2.5.1.1 Request User Account credentials by accomplishing the Online User's Registration Form through the link: bit.ly/ePortal2 (refer to Annex B.1)	1. Check for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff
2.5.1.2 Receive username and password	2. Issue user account (username and password) to the client	None	Next Working Day	CCHUHSRR Admin. Staff
	TOTAL:	**None**	**1 Working Day and 15 minutes**	

Center/Office/Division	:	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Complex
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Manufacturers, Traders, Distributors (Importer, Exporter, Wholesaler) of Household Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be Paid	:	Amendment of LTO or Re-issuance (if lost) – Php 500 +1% LRF **Administrative Order 50 s. 2001*** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)List of Requirements for Specific Variation based on Administrative Order No. 2020-0017: A. Transfer of Location Offices - Physical transfer of the office of the establishment Documentary Requirement: 1. Business permit reflecting new location of office - Physical transfer of the office of the establishment ● For Single Proprietorship: Business Permit/ Mayor's Permit or Barangay Business Permit/ Clearance reflecting the new office location; ● For SEC-registered establishments: a) Amended Articles of Incorporation (if transferred from one city/ municipality/province); or	Qualified Person

b) Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality/province) ● If the establishment address is different from the address indicated in the SEC Registration, provide LGU/Mayor's Permit or Barangay Business Permit/Clearance reflecting new office location B. Change of Distributor Activity -additional/deletion or change in activity that the distributor is currently engaged Documentary Requirement: 1. Contract Agreements showing change in activity C. Transfer or Addition of Warehouse -Physical transfer and addition of warehouse of the establishment Documentary Requirement: 1. Mayor's Permit or Barangay Business Permit/Clearance reflecting new warehouse location D. Expansion of Office Establishment - expansion made which is adjacent to the existing location of the establishment Documentary Requirement: a) Current floor plan b) Expansion floor plan E. Change of Ownership	

-Change in ownership of the licensed establishment Documentary Requirement: 1. Business name registration reflecting new ownership 2. Any proof on the transfer of ownership ● Deed of sale or assignment or transfer of rights/ownership; ● Memorandum of Agreement; or ● Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer F. Change of Business Name -Change only in the business name of the establishment Documentary Requirement: 1. Business name registration reflecting new business name. G. Zonal Change in Address -Change of the name/number of the street/building without physical transfer of the establishment Documentary Requirement: 1. Certificate of Zonal Address 2. Certification from Local Government Unit (City/Municipality) stating no physical transfer of the establishment H. Change of Qualified Person -Change in the identified qualified person initially registered with the FDA Documentary Requirement:	

1. Name of new qualified person, with credentials when applicable 2. Valid Professional Regulation Commission (PRC) ID 3. Signed Letter of Resignation duly noted by the former employer, if previously connected with another pharmacy/establishment I. Change of Authorized Person -Change in the authorized person initially registered with the FDA Documentary Requirement: 1. Name of new qualified person 2. Valid Government ID	
2) Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the FDA e-Portal V2 at (https://eportal2.fda.gov.ph). Log in by entering the issued username and password. In the Home tab, select New Application in the navigation pane and click e-License to Operate (Variation Application) to proceed to the LTO application form. Accomplish the application form as provided in parts by the application wizard. Fill-in the fields as completely as possible. Fields marked with a red	1. Pre-assessment on the completeness of application and documentary requirements submitted	None		Qualified Person

asterisk (*) are required to be filled-in. Mark required fields with N/A, if not applicable. Upload Documents in PDF format. ● Proof of Business Name Registration, Proof of Income. Tick the box to certify all information is true and correct, then "Next". Applicants may upload documents simultaneously Order of payment- A computer generated document will appear reflecting the appropriate fees and charges. Applicant should save and print a copy of document as reference for payment				
2. Pay the assessed fee as per the system generated Order of Payment Form through existing payment channels	2.1 Post payment in ePortal V.2 for confirmed payments. This will prompt automatic decking of application to respective Center	See above table		Qualified Person and FDA Cashier Administrative and Finance Service (AFS)
	2.2 Evaluation of correctness of submitted documentary requirements.	None	3 working days	FDA Evaluator (Center/Licensing and Registration Division)
	2.3 Checking of the evaluation and veracity of documents submitted.	None	2 working days	Technical Officer of specific Center of jurisdiction
	2.4 Approval of LTO	None	2 working days	Center Director of jurisdiction

	If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial			
3. Receive notification and copy of e-LTO for printing		None		Qualified Person
TOTAL:			**7 working days**	

Note:

1. The fees charged for manufacturers and traders of products regulated by FDA are based on the capital invested.
2. Renewal of HUHS LTO shall be valid for a maximum period of five (5) years.
3. Application for renewal shall be done within three (3) months prior to validity date of the LTO. Applications filed after the validity date of the LTO shall be subject to surcharge as prescribed in RA 9711 and its IRR.

1.31.LICENSE TO OPERATE – INITIAL APPLICATION FOR HOUSEHOLD/URBAN PEST CONTROL OPERATORS (PCO)

Center/Office/Division	:	Cosmetic and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	Pest Control Operators engaged in commercial, in-house, and government service application of Household/Urban Pesticide Products
Fees to be Paid	:	**Administrative Order No. 2019 – 0010, Annex E** Initial application – 6,000.00 php Renewal application – 3,000.00 php Variation application – 1,000.00 php The above fees are subject to a legal research fund (LRF) equivalent to Php 10.00 or 1% of the application fee, whichever is higher, as imposed by RA 3870, as amended by PD 200 and further amended by PD1856, and surcharges and penalties for renewal applications filed beyond the validity date in accordance with RA 9711

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2019-0010 Annex B:	
Accomplished e-Application Form as prescribed by FDA regulations. • Declaration and undertaking of the responsibilities of the applicant as a condition for the processing and approval of the LTO; • The location plan and global position system (GPS) coordinates of the establishment; • The name and credentials of the FDA-certified supervising pesticide handler	FDA eServices (www.fda.gov.ph) Applicant/Qualified person Applicant/Qualified person Applicant/Qualified person
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF)	Applicant/Qualified person

• For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) • For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) In cases of inconsistencies with the business name and/or address, the following supporting documents must be submitted: - If the Business Name is different from the Corporate Name, the SEC Certificate must reflect: "Doing business under the name and style of (Name of Establishment)" - Valid Mayor's Business Permit or Barangay Business Permit, if the business name and address is different from the registered name and address in the DTI or SEC	
3) Notarized Agreement with a DOH-accredited health facility that will conduct annual medical check-up for its supervising pesticide handlers, pesticide handlers and other personnel	Applicant/Qualified person
4) Risk Management Plan (contingency plan) and procedures for handling accidents and emergencies, and referrals to hospitals in case of accidents or casualties	Applicant/Qualified person
5) Safety training plan for supervising pesticide handlers, pesticide handlers and other personnel	Applicant/Qualified person
6.) Names and ID of the FDA-certified supervising pesticide handlers, pesticide handlers and other personnel (per branch or office) [1]	Applicant/Qualified person

[1] In the absence of availability of FDA-accredited trainings for SPH and PH, the PCO establishment shall submit copies of any proof of attendance to training/s of their SPH and PH related to household/urban pest management issued by: (1) the Fertilizer and Pesticide Authority (FPA) following FDA Circular No. 2016-008; or (2) any reputable organizations within the last five (5) years, in lieu of the required copy of ID of FDA-certified SPH and PH.

7.) If the owner/manager is not the FDA-certified supervising pesticide handler, submit written authorization from the appointed FDA-certified supervising pesticide handler and Certificate of Employment	Applicant/Qualified person
8.) Payment of prescribed fee	FDA Cashier/Other FDA Authorized Payment Portals or Banks
9.) In cases when less than the required number of certified supervising pesticide handler is employed by the pest control operator, the Standard Operating Procedure on the conduct of in-person and remote supervision of pest control activities in multiple branches.	Applicant/Qualified person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through (http://eservices.fda.gov.ph) and click "Applications " found at the upper right corner of the system. Proceeds to the Initial Application Reads the **"Declaration and Undertaking"** before proceeding with the application process. Check the box *"I agree to the Declaration and Undertaking"* and click on **"Start Application".** Uploads the required documents as indicated on the Checklist of Requirements (ex. Proof of Business Name Registration with DTI/SEC) in pdf format. File size should not be more than 2MB (per document requirement)	1. Conducts pre-assessment on the submitted application based on the completeness of the documents submitted in accordance with the requirements If complete, an Order of Payment will be generated and will be given to the client thru the eServices and Email notification. If incomplete, the application will not be received and will be returned to the client. A Pre-assessment Letter of Disapproval	None		FDA Pre-Assessor (Center/ Licensing and Registration)

Reviews the duly filled out form in the **Self-Assessment Review**. By agreeing to the Terms and Conditions, the applicant confirm the completeness, correctness, and accuracy of the information given. Click on **"Confirm"** to submit the application. Prints the Order of Payment with Reference Number sent through the declared e-mail address	will be given to the client thru eServices and Email notification.			
2. Pays the application fee through existing payment channels. Receives Acknowledgment Receipt through email	2.1 Posts payment in eServices Portal System for confirmed payments. This will prompt automatic decking of application to respective Center. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd** **Note:** Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.	See above table		FDA Cashier Administrative and Finance Service (AFS)
	2.2 Evaluates the correctness of the documents	None	12 working days	Food-Drug Regulation Officer

	2.3 Checks the evaluation and veracity of the documents submitted.		5 working days	Food-Drug Regulation Officer
3. Receives an application status through e-mail confirming that the application has been evaluated and queued for final decision.	3. Approval of LTO If the application is disapproved, the applicant will be notified through email and will receive the Letter of Disapproval	None	3 working days	Center Director
4. Receives an email notification containing the system-generated LTO through the declared e-mail address for printing.				Qualified Person
TOTAL:			**20 working days**	

CENTER FOR COSMETICS AND HOUSEHOLD URBAN HAZARDOUS/SUBSTANCES REGULATION AND RESEARCH EXTERNAL SERVICES

1.ISSUANCE OF CERTIFICATE OF EXEMPTION (COE) FOR TOYS

Issued to unlicensed establishments or individuals that will import toy products that are not notified but are solely intended for display or exhibit purposes and/or those that are not intended to be marketed in the Philippines, personal use, adult collector's use, or donation/charity/missionary work.

Center/Office/Division	**:**	Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research
Classification	**:**	Complex
Type of Transaction	**:**	G2B – Government to Business Entity
Who May Avail	**:**	Unlicensed establishments or individuals
Fees to be Paid	**:**	Php 500.00 + 1% LRF not less than Php 10.00

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
1. Letter of intent stating the purpose of importation	Applicant
2. Notarized affidavit of undertaking stating that the toy products are solely intended for: - display or exhibit purposes and/or those that are not intended to be marketed in the Philippines - personal use - adult collector's use, or - donation/charity/missionary work and that it will not be marketed or distributed in the Philippines	Applicant
3. Airway Bill or Bill of Lading	Designated courier
4. Packing List	Applicant
5. Proforma Invoice	Applicant
6. Pictures showing packaging and labeling requirements as per the IRR of RA 10620	Applicant
7. For Donation 7.1. Letter of endorsement from DOH-BIHC 7.2. Deed of donation	 DOH-BIHC Applicant
8. Copy of official receipt	FDA cashier

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant submits the requirements to Letters Section in FDAC	1. Checks completeness of documents	None		FDAC
2. Applicant pays the fee	2. Verifies payment	Php 510.00	Refer to FDA Cashier's Citizen's Charter	FDA Cashier personnel
3. Applicant submits requirements (hard copy)	3.1. Receives complete requirements	None		FDAC officer of the day
	3.2. Application is forwarded to CCHUHSRR	None		FDAC personnel
	3.3. Data Controller receives the application and update the database	None	30 Minutes	Administrative Assistant VI CCHUHSRR
	3.4. Evaluator checks the correctness of documents	None	6.5 working days	Food Drug Regulation Officer CCHUHSRR
	3.5. Checks if the recommendation is appropriate	None	2 Hours	
	3.6. CCHUHSRR Director signs the final certificate	None	30 Minutes	Director IV CCHUHSRR
	3.7. Data controller updates the database and forwards the authorization to records section	None	1 Hour	Administrative Assistant VI CCHUHSRR
	3.8. Releasing			AFS-Releasing personnel
TOTAL:		**Php 510.00**	**working days**[2]	

[2] CCHUHSRR reserves the right to avail of the extension of the prescribed timeline by the same number of working days provided in Republic Act (RA) No. 11032 on the condition that the Center adheres to the provisions given in the IRR of RA No. 11032.

2.ISSUANCE OF CERTIFICATE OF FREE SALE CFS (CFS)

Issued to licensed establishments that will export their products to other countries for distribution.

Center/Office/Division	**:**	Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research
Classification	**:**	Complex
Type of Transaction	**:**	G2B – Government to Business Entity
Who May Avail	**:**	Licensed Cosmetic, HUHS, HUP, TCCA Establishments with activity as exporter of finished products (Distributor, Trader, Manufacturer)
Fees to be Paid	**:**	Php 500.00 per product per country (except for U.S.A. or U.A.E. which is computed per state or emirate) + 1% LRF not less than Php 10.00

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
1. Integrated application form	FDA website (https://www.fda.gov.ph/downloadables/)
2. Letter of intent stating the country where the product will be exported	Applicant
3. Valid LTO with activity as exporter	FDA- CCHUHSRR
4. Copy of valid product registration/notification	FDA- CCHUHSRR
5. Copy of official receipt	FDA cashier

CLIENT STEPS	**AGENCY ACTION**	**FEES TO BE PAID**	**PROCESSING TIME**	**PERSON RESPONSIBLE**
1. Applicant requests for a schedule of submission of requirements	1. Checks the completeness of documents	None		FDAC personnel
2. Applicant pays the fee	2. Verifies the payment	Php 510.00 per product per country (except for U.S.A. or U.A.E. which is computed per state or emirate)	refer to the FDA Cashier's Citizen's Charter	FDA Cashier personnel

3. Applicant submits requirements (electronic copy)	3.1. Receives complete requirements	None		FDAC officer of the day
	3.2. Application is forwarded to CCHUHSRR	None		FDAC personnel
	3.3. Data Controller receives the application and update the database and forwards to evaluator	None	30 Minutes	Administrative Assistant VI, CCHUHSRR
	3.4. Evaluator checks the correctness of documents	None	6.5 working days	Food Drug Regulation Officer CCHUHSRR
	3.5. Checks if the recommendation is appropriate	None	2 Hours	Food Drug Regulation Officer CCHUHSRR
	3.6. CCHUHSRR Director signs the final authorization	None	30 Minutes	Director IV CCHUHSRR
	3.7. Data Controller updates the database and forwards the final authorization to records section	None	1 Hour	Administrative Assistant VI CCHUHSRR
	3.8. Releasing			AFS-Releasing personnel
TOTAL:		**Php 510.00**	**7 working days**[3]	

[3] CCHUHSRR reserves the right to avail of the extension of the prescribed timeline by the same number of working days provided in Republic Act (RA) No. 11032 on the condition that the Center adheres to the provisions given in the IRR of RA No. 11032.

3.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR HOUSEHOLD URBAN PESTICIDES (HUP)

Market Authorization issued to licensed establishments that are engaged in the manufacture, importation, exportation, sale, and offer for sale, distribution, donation, transfer, testing, promotion, advertising, or sponsorship of household pesticide products and/or their active ingredient/s. This will not cover genetically-modified/engineered household pesticide products.

Center/Office/Division	**:**	Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B – Government to Business Entity
Who May Avail	**:**	Licensed HUP Establishments (Distributor, Trader, Manufacturer)
Fees to be Paid	**:**	Based on years of validity applied for + 1% LRF 2 year validity – Php 1,000 + 1% LRF 3 year validity – Php 1,500 + 1% LRF 4 year validity – Php 2,000 + 1% LRF 5 year validity – Php 2,500 + 1% LRF For Variation Application Php 500.00 + 1% LRF not less than Php 10.00

3.1.INITIAL REGISTRATION OF ACTIVE INGREDIENT

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Integrated Application Form with Declaration	FDA website (https://www.fda.gov.ph/downloadables/)
2. Valid LTO	FDA-CCHUHSRR
3. Copy of Official Receipt	FDA Cashier
Refer to AO 2019-0008 Annex A for the specific data on the following requirements:	
4. Chemical Identity	Manufacturer or any 3rd Party Laboratory
5. Physical Properties of the Active Ingredient	
6. Product Specifications	
7. Certificate of Analysis	
8. Safety Data Sheet	
9. Any of the following proof of manufacturer's compliance to Good Manufacturing Practices (GMP) 9.1. Certificate of Free Sale (CFS) issued by the National Regulatory Authority of country of origin 9.2. Certificate of Good Manufacturing Practice (GMP) based on international manufacturing standards 9.3. Manufacturing License 9.4. ISO Certificate related to manufacturing *Note: Must be duly authenticated and notarized by the Philippine Embassy or apostillized for documents executed in Apostille-contracting countries except Austria, Finland, Germany and Greece (FDA Memorandum Circular No. 2019-008).*	Manufacturer
10. Submission of Actual Sample and Reference Standard	Applicant or Supplier/Manufacturer
11. Toxicity Data	Toxicity Testing Laboratory or Supplier/Manufacturer

11.1. Acute Toxicity 11.2. Corrosion / Irritation 11.3. Allergy / Sensitization 11.4. Sub-chronic Toxicity 11.5. Reproduction Effects 11.6. Teratogenicity 11.7. Neurotoxicity 11.8. Mutagenicity 11.9. Carcinogenicity and Chronic (Long Term) Toxicity Studies in Rats	
12. Human Exposure and Safety 12.1. Medical Data / Poisoning Symptoms / Antidote 12.2. Personal Protective Equipment 12.3. Other precautions	Manufacturer or Supplier
13. Environmental Data	
14. Labeling / Packaging	

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant sends a request for schedule of submission of application requirements to FDAC (fdac@fda.gov.ph). Requests for schedule may be submitted from **Monday to Friday.**	1. Schedules the submission of application requirements for pre-assessment on **Thursdays**, except for Holidays, from **8AM to 12NN.**		FDAC Personnel
2. Applicant submits the application requirements for pre-assessment to FDAC	2. Forwards the received application requirements for pre-assessment to CCHUHSRR from **1PM to 2PM.**		FDAC Personnel

(fdac.pacd@fda.gov.ph) on the day of the schedule, from **8AM to 12NN**.			
	2.1. Pre-assesses the submitted application for completeness of requirements. Only applications with complete requirements shall proceed to payment.		Food-Drug Regulation Officer CCHUHSRR
3. Applicant pays the fee.	3. Verifies the payment		FDA Cashier Personnel
4. Applicant submits the paid application (electronic copies of the complete requirements) to FDAC (fdac.pacd@fda.gov.ph).	4. Receives the lodged application.		FDAC Personnel
	4.1. Forwards the application to CCHUHSRR.		FDAC Personnel
	4.2. Receives the application and updates the database.	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
	4.3. Evaluates the correctness of documents.	10 Working Days	Food-Drug Regulation Officer / Consultant CCHUHSRR
	4.4. Reviews the bio- efficacy study and/or toxicity study.	7 Working Days	
	4.5. Reviews the recommendation of the consultant and prepares the overall recommendation.	2 Working Days	
	4.6. Checks if the recommendation is appropriate	6 Hours	Food-Drug Regulation Officer CCHUHSRR

	4.7. Renders the final decision on the recommendation.	1 Hour	Director IV CCHUHSRR
	4.8. Updates the database and forwards the final issued document/s to records section.	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
5. Applicant receives the final issued document.	5. Releasing		Releasing Personnel Records Section
TOTAL:		**20 Working Days**[4]	

3.2.INITIAL REGISTRATION OF FORMULATED PRODUCT

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
1. Integrated Application Form with Declaration	FDA website (https://www.fda.gov.ph/downloadables/)
2. Valid LTO	FDA- CCHUHSRR
3. Copy of Official Receipt	FDA Cashier
Refer to AO 2019-0008 Annex B for the specific data on the following requirements:	
4. Product Identity	Manufacturer
5. Quantitative and Qualitative Composition of Product	
6. Technical Specifications of the Formulated Product	
7. Product Specifications – Tolerance for the Active Ingredient/s	
8. Certificate of Analysis	Manufacturer or any 3rd Party Laboratory
9. Test Procedures/Methods Conducted on the Formulated Product	

[4] CCHUHSRR reserves the right to avail of the extension of the prescribed timeline by the same number of working days provided in Republic Act (RA) No. 11032 on the condition that the Center adheres to the provisions given in the IRR of RA No. 11032.

10. Safety Data Sheet of the Formulated Product	Manufacturer
11. Any of the following proof of manufacturer's compliance to Good Manufacturing Practices (GMP) 11.1. Certificate of Free Sale (CFS) issued by the National Regulatory Authority of country of origin 11.2. Certificate of Good Manufacturing Practice (GMP) based on international manufacturing standards 11.3. Manufacturing License 11.4. ISO Certificate related to manufacturing *Note: Must be duly authenticated and notarized by the Philippine Embassy or apostillized for documents executed in Apostille-contracting countries except Austria, Finland, Germany and Greece (FDA Memorandum Circular No. 2019-008).*	
12. Substantiation to Support Special Product Claims	Applicant or Manufacturer
13. Product Stewardship Program	Applicant
14. Submission of Actual Sample and Reference Standard	Applicant or Supplier/Manufacturer
15. Toxicity Data 15.1. Acute Toxicity 15.2. Corrosion / Irritation 15.3. Allergy / Sensitization 15.4. Sub-chronic Toxicity 15.5. Reproduction Effects 15.6. Teratogenicity 15.7. Neurotoxicity 15.8. Mutagenicity 15.9. Carcinogenicity and Chronic (Long Term) Toxicity Studies in Rats	Toxicity Testing Laboratory or Supplier/Manufacturer
16. Bio-efficacy Data	3rd Party Testing Laboratory
17. Human Exposure and Safety	Manufacturer or Supplier

17.1. Operators Exposure Data 17.2. Bystanders Exposure Data 17.3. Medical Data / Poisoning Symptoms / Antidote 17.4. Permissible Exposure Level 17.5. Personal Protective Equipment 17.6. Other Precautions	
18. Environmental Data	
19. Labeling / Packaging	

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant sends a request for schedule of submission of application requirements to FDAC (fdac@fda.gov.ph). Requests for schedule may be submitted from **Monday to Friday**.	1. Schedules the submission of application requirements for pre-assessment on **Thursdays**, except for Holidays, from **8AM to 12NN.**		FDAC Personnel
2. Applicant submits the application requirements for pre-assessment to FDAC (fdac.pacd@fda.gov.ph) on the day of the schedule, from **8AM to 12NN**.	2. Forwards the received application requirements for pre-assessment to CCHUHSRR from **1PM to 2PM.**		FDAC Personnel
	2.1. Pre-assesses the submitted application for completeness of requirements. Only applications		Food-Drug Regulation Officer CCHUHSRR

	with complete requirements shall proceed to payment.		
3. Applicant pays the fee.	3. Verifies the payment		FDA Cashier Personnel
4. Applicant submits the paid application (electronic copies of the complete requirements) to FDAC (fdac.pacd@fda.gov.ph).	4. Receives the lodged application.		FDAC Personnel
	4.1. Forwards the application to CCHUHSRR.		FDAC Personnel
	4.2. Receives the application and updates the database.	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
	4.3. Evaluates the correctness of documents.	10 Working Days	Food-Drug Regulation Officer / Consultant CCHUHSRR
	4.4. Reviews the bio-efficacy study and/or toxicity study.	7 Working Days	
	4.5. Reviews the recommendation of the consultant and prepares the overall recommendation.	2 Working Days	
	4.6. Checks if the recommendation is appropriate.	6 Hours	Food-Drug Regulation Officer CCHUHSRR
	4.7. Renders the final decision on the recommendation.	1 Hour	Director IV CCHUHSRR
	4.8. Updates the database and forwards the final issued document/s to records section.	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR

5. Applicant receives the final issued document.	5. Releasing		Releasing Personnel Records Section
TOTAL:		**20 Working Days**[5]	

3.3.RENEWAL OF PRODUCT REGISTRATION

CHECKLIST OF REQUIREMENTS[6]	**WHERE TO SECURE**
1. Integrated Application Form with Declaration	FDA website (https://www.fda.gov.ph/downloadables/)
2. Post-Market Surveillance Monitoring Report	Applicant
3. Unattached Legible, Comprehensive and Indelible Specimen of All Labeling Materials per Pack Size (Including Outer, Immediate, Package Inserts, if any) in English and/or Filipino Language with Local Dialects, As Applicable	
4. Copy of Official Receipt	FDA Cashier

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant sends a request for schedule of submission of application requirements to FDAC (fdac@fda.gov.ph).	1. Schedules the submission of application requirements for pre-assessment on **Thursdays**,		FDAC Personnel

[5] CCHUHSRR reserves the right to avail of the extension of the prescribed timeline by the same number of working days provided in Republic Act (RA) No. 11032 on the condition that the Center adheres to the provisions given in the IRR of RA No. 11032.

[6] For formulated products (HUP products) previously evaluated and issued with initial or renewed CPR based on earlier repealed registration guidelines, e.g. Administrative Order No. 2014-0038, selected documentary requirements for initial product registration under Administrative Order No. 2019-0008 may be requested during the renewal of the product registration.

Requests for schedule may be submitted from **Monday to Friday**.	except for Holidays, from **8AM to 12NN.**		
2. Applicant submits the application requirements for pre-assessment to FDAC (fdac.pacd@fda.gov.ph) on the day of the schedule, from **8AM to 12NN**.	2. Forwards the received application requirements for pre-assessment to CCHUHSRR from **1PM to 2PM.**		FDAC Personnel
	2.1. Pre-assesses the submitted application for completeness of requirements. Only applications with complete requirements shall proceed to payment.		Food-Drug Regulation Officer CCHUHSRR
3. Applicant pays the fee.	3. Verifies the payment		FDA Cashier Personnel
4. Applicant submits the paid application (electronic copies of the complete requirements) to FDAC (fdac.pacd@fda.gov.ph).	4. Receives the lodged application.		FDAC Personnel
	4.1. Forwards the application to CCHUHSRR.		FDAC Personnel
	4.2. Receives the application and updates the database.	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR

	4.3. Evaluates the correctness of documents and prepares the recommendation[7].	19 Working Days	Food-Drug Regulation Officer CCHUHSRR
	4.4. Checks if the recommendation is appropriate.	6 Hours	Food-Drug Regulation Officer CCHUHSRR
	4.5. Renders the final decision on the recommendation.	1 Hour	Director IV CCHUHSRR
	4.6. Updates the database and forwards the final issued document/s to records section.	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
5. Applicant receives the final issued document	5. Releasing		Releasing personnel Records Section
TOTAL:		**20 Working Days[8]**	

3.4.VARIATION OF PRODUCT REGISTRATION

CHECKLIST OF REQUIREMENTS (*Refer to AO 2019-0008 Annexes A and B for the specific data on the following requirements to amend the product registration of an active ingredient and formulated product, respectively)*	**WHERE TO SECURE**
1. Integrated Application Form	FDA website (https://www.fda.gov.ph/downloadables/)
2. Letter of Request	Applicant
3. Valid LTO	FDA-CCHUHSRR

[7] Highly technical bio-efficacy and/or toxicity data may be referred to the consultants for review.
[8] CCHUHSRR reserves the right to avail of the extension of the prescribed timeline by the same number of working days provided in Republic Act (RA) No. 11032 on the condition that the Center adheres to the provisions given in the IRR of RA No. 11032.

4. Valid Original CPR	
5. Copy of Official Receipt	FDA cashier
Specific Requirements: Major Variation	
1. Change in Product Name (Brand Name/Variant Name) a. Notarized Affidavit/Declaration of No Change in the Formulation b. Extension of Use or Claim and New Bio-efficacy Study, If There Is Request To Include Additional Target Pests c. Complete Labeling Requirements Reflecting the Change (Primary, Secondary and Inserts, If Any) in English and/or Filipino Language With Local Dialects, As Applicable	 Applicant 3rd Party Testing Laboratory Applicant
2. Change in Rate, Timing or Frequency of Application or Method of Application a. Extension of Use or Claim and New Bio-efficacy Study, If There Is Request To Include Additional Target Pests b. Study or Studies That Shall Justify Request for Change in Rate, Timing or Frequency of Application or Method of Application c. Complete Labeling Requirements Reflecting the Change (Primary, Secondary and Inserts, If Any) in English and/or Filipino Language With Local Dialects, As Applicable	 3rd party testing laboratory 3rd party testing laboratory Applicant
3. Change in Label Claim / Request for Additional Target Pests a. Extension of Use or Claim and New Bio-efficacy Study, If There Is Request To Include Additional Target Pests b. Complete Labeling Requirements Reflecting the Change (Primary, Secondary and Inserts, If Any) in English and/or Filipino Language With Local Dialects, As Applicable	 3rd party testing laboratory Applicant
4. Change in GHS Category / Hazard Class a. Copy of Safety Data Sheet b. Copy of Complete Toxicity Studies, If Request is For Change in	 Manufacturer Toxicity Testing Laboratory or Supplier/Manufacturer

Hazard Class c. Complete Labeling Requirements Reflecting the Change (Primary, Secondary and Inserts, If Any) in English and/or Filipino Language With Local Dialects, As Applicable	Applicant
Specific Requirements: Minor Variation	
1. Change in Business Name of the Manufacturer or Distributor a. Complete Labeling Requirements Reflecting the Change (Primary, Secondary and Inserts, If Any) in English and/or Filipino Language With Local Dialects, As Applicable	Applicant
2. Change in Product Ownership a. Copy of Termination Contract / Deed of Assignment b. Copy of the Agreement of the New Market Authorization Holder and Manufacturer c. Complete Labeling Requirements Reflecting the Change (Primary, Secondary and Inserts, If Any) in English and/or Filipino Language With Local Dialects, As Applicable	 Applicant Applicant Applicant
3. Change of Address of the Distributor of the Product a. Any Valid Document/s Showing Proof of Transfer b. Complete Labeling Requirements Reflecting the Change (Primary, Secondary and Inserts, If Any) in English and/or Filipino Language With Local Dialects, As Applicable	 Applicant Applicant
4. Addition or Deletion of Packaging of the Product a. Notarized Affidavit/Declaration of No Change in the Formulation b. Complete Labeling Requirements Reflecting the Change (Primary, Secondary and Inserts, If Any) in English and/or Filipino Language With Local Dialects, As Applicable	 Applicant Applicant

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant sends a request for schedule of submission of application requirements to FDAC (fdac@fda.gov.ph). Requests for schedule may be submitted from **Monday to Friday**.	1. Schedules the submission of application requirements for pre-assessment on **Thursdays**, except for Holidays, from **8AM to 12NN.**		FDAC Personnel
2. Applicant submits the application requirements for pre-assessment to FDAC (fdac.pacd@fda.gov.ph) on the day of the schedule, from **8AM to 12NN**.	2. Forwards the received application requirements for pre-assessment to CCHUHSRR from **1PM to 2PM.**		FDAC Personnel
	3. Pre-assesses the submitted application for completeness of requirements. Only applications with complete requirements shall proceed to payment.		Food-Drug Regulation Officer CCHUHSRR
3. Applicant pays the fee.			FDA Cashier Personnel
4. Applicant submits the paid application (electronic copies of the complete requirements) to FDAC (fdac.pacd@fda.gov.ph).	4.1. Receives the lodged application.		FDAC Personnel
	4.2. Forwards the application to CCHUHSRR.		FDAC Personnel

	4.3. Receives the application and updates the database.	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
	4.4. Evaluates the correctness of documents and prepares the recommendation.	19 Working Days	Food-Drug Regulation Officer CCHUHSRR
	4.5. Checks if the recommendation is appropriate.	6 Hours	Food-Drug Regulation Officer CCHUHSRR
	4.6. Renders the final decision on the recommendation.	1 Hour	Director IV CCHUHSRR
	4.7. Updates the database and forwards the final issued document/s to records section.	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
5. Applicant receives the final issued document.	5. Releasing		Releasing Personnel Records Section
TOTAL:		**20 Working Days**[9]	

[9] CCHUHSRR reserves the right to avail of the extension of the prescribed timeline by the same number of working days provided in Republic Act (RA) No. 11032 on the condition that the Center adheres to the provisions given in the IRR of RA No. 11032.

4.ISSUANCE OF COSMETIC AND TOYS AND CHILDCARE ARTICLES (TCCA) NOTIFICATION USER ACCOUNT AND PASSWORD

Issued to licensed establishments that will apply for product notification.

Center/Office/Division	**:**	Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research
Classification	**:**	Simple
Type of Transaction	**:**	G2B – Government to Business Entity
Who May Avail	**:**	Licensed Cosmetic and TCCA establishments (Distributor, Trader, Manufacturer)
Fees to be Paid	**:**	None

4.1.INITIAL APPLICATION

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Valid LTO	FDA-CCHUHSRR
2. QPIRA ID (for Cosmetics or TCCA) or Notarized authorization letter (Annex A of FMC 2015-010)	FDA Academy or FDA Memo Circular 2015-010

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant emails the request following the format stated in FMC 2015-010 to cchuhsrraseannotification2@fda.gov.ph		None		Applicant
	1. Verification of information sent. Data Controller verifies the information if correct and complete	None	3 working days	Administrative Assistant CCHUHSRR

	1.1. Data Controller creates username and password	None		
	1.2. Data Controller sends the username and password to applicant	None		
TOTAL:			**3 working days**	

4.2.RENEWAL APPLICATION

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
1. Valid LTO	FDA- CCHUHSRR
2. Letter of Request (Annex C of FMC 2015-010)	FDA Memo Circular 2015-010
3. QPIRA ID (for Cosmetics or TCCA) or Notarized authorization letter (Annex A of FMC 2015-010)	FDA Academy or FDA Memo Circular 2015-010

CLIENT STEPS	**AGENCY ACTION**	**FEED TO BE PAID**	**PROCESSING TIME**	**PERSON RESPONSIBLE**
1. Applicant emails the request following the format stated in FMC 2015-010 to cchuhsrraseannotification2@fda.gov.ph		None		Applicant
	1. Data Controller verifies the information if correct and complete	None	3 working days	Administrative Assistant CCHUHSRR
	1.1 Data Controller reactivates the username	None		

	and password and send it to applicant			
TOTAL:			**3 working days**	

4.3.CHANGE IN CREDENTIALS APPLICATION

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of Request	Applicant
2. QPIRA ID (for Cosmetics or TCCA) or Notarized authorization letter (Annex A of FMC 2015-010)	FDA Academy or FDA Memo Circular 2015-010

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant emails the request following the format stated in FMC 2015-010 to cchuhsrraseannotification2@fda.gov.ph	Data Controller verifies the information if correct and complete	None	3 working days	Administrative Assistant CCHUHSRR
	1.1. Data Controller sends the username and password to applicant	None	30 Minutes	
TOTAL:			**3 working days**	

5.ISSUANCE OF COSMETIC PRODUCT NOTIFICATION

Issued to licensed establishments that will place a cosmetic product in the market.

Center/Office/Division	**:**	Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B – Government to Business Entity
Who May Avail	**:**	Licensed Cosmetic establishments (Distributor, Trader, Manufacturer)
Fees to be Paid	**:**	Php 500.00 + 1% LRF not less than Php 10.00 for 1 year validity Additional Php 100.00 per variant

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
1. Cosmetic e-portal user account	CCHUHSRR
2. Valid LTO	FDA- CCHUHSRR
3. Substantiation (for further clarifications)[10] 3.1. Artwork of the Product labeling 3.2. Instructions for use 3.3. Mechanism of action of the product 3.4. Certificate of Origin of the ingredient 3.5. Safety Data Sheet 3.6. Certificate of Analysis	Source / Applicant

[10] Submission of the said documents shall not guarantee approval or issuance of a Certificate of Product Notification (CPN)

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant requests for e-portal username and password		None		Applicant
2. Applicant accomplishes the application form and declaration in the e-portal		None		Applicant
3. Applicant generates order of payment and pays the fee through a Landbank Branch or through Systems/Means prescribed by the FDA Cashier	3.1. Posting of payment. Payment will be posted after bank clearing	Php 510.00 Additional Php 100.00 per variant	refer to the FDA Cashier's Citizen's Charter	FDA Cashier personnel or Landbank Personnel
	3.2. Evaluator checks the correctness of the application *Substantiation may be asked if there will be further clarifications	None	18 working days[11]	Food Drug Regulation Officer CCHUHSRR
	3.3. CCHUHSRR Director gives the final decision on the application	None	2 working days	Director IV CCHUHSRR
	3.4. Acknowledgement or disapproval will be forwarded to applicants e-portal account	None		Applicant

[11] Applications shall be acted upon within the processing time indicated from the date the complete application or request was received.

TOTAL:	Php 510.00 Additional Php 100.00 per variant	**20 working days**[12]

[12] CCHUHSRR reserves the right to avail of the extension of the prescribed timeline by the same number of working days provided in Republic Act (RA) No. 11032 on the condition that the Center adheres to the provisions given in the IRR of RA No. 11032.

6.ISSUANCE OF GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE

Issued to a licensed manufacturer that is at least one year operational.

Center/Office/Division	**:**	Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research
Classification	**:**	Complex
Type of Transaction	**:**	G2B – Government to Business Entity
Who May Avail	**:**	Licensed Cosmetic Manufacturer
Fees to be Paid	**:**	Php 1,000.00 + 1% LRF (validity of 2 years)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of intent	Applicant
2. Copy of Valid LTO as Cosmetic/HUHS Manufacturer	FDA- CCHUHSRR
3. Copy of official receipt	FDA Cashier

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant submits the requirements to Letters Section in FDAC	1. Checks completeness of documents	None		FDAC officer of the day
2. Applicant pays the fee through a Landbank Branch or through Systems/Means prescribed by the FDA Cashier	2. Verifies payment	Php 1,010.00	Refer to FDA Cashier's Citizen's Charter	FDA Cashier personnel or Landbank Personnel

3. Applicant submits requirements (hard copy)	3.1. Receives complete requirements	None		FDAC officer of the day
	3.2. Application is forwarded to CCHUHSRR	None		FDAC personnel
	3.3. Data Controller receives the application and update the database	None	30 Minutes	Administrative Assistant VI CCHUHSRR
	3.4. Evaluator checks the correctness of documents. **Proceed to no.9 if inspection is not required* **Proceed to no. 6 if inspection is required*	None	6.5 working days	Food Drug Regulation Officer CCHUHSRR
	3.5. Data Controller updates the database and forwards the application to FROO	None	30 Minutes	Administrative Assistant VI CCHUHSRR
	3.6. FROO INSPECTION		Please refer to FROO Citizen's Charter	Field Regulatory Operations Office
	3.7. Data Controller receives the report and update the database then forwards to CCHUHSRR Evaluator	None	30 Minutes	Administrative Assistant VI CCHUHSRR
	3.8. Evaluator checks the correctness of documents.	None	6.5 working days	Food Drug Regulation Officer CCHUHSRR
	3.9. Checks if the recommendation is appropriate	None	2 Hours	Food Drug Regulation Officer

				CCHUHSRR
	3.10. CCHUHSRR Director signs the final authorization (may be approved or disapproved)	None	30 Minutes	Director IV CCHUHSRR
	3.11. Data Controller updates the database and forwards the final authorization to records section	None	1 Hour	Administrative Assistant VI CCHUHSRR
	3.12. Releasing			AFS-Releasing personnel
TOTAL:		Php 1,010.00	**7 working days**[13]	

[13] CCHUHSRR reserves the right to avail of the extension of the prescribed timeline by the same number of working days provided in Republic Act (RA) No. 11032 on the condition that the Center adheres to the provisions given in the IRR of RA No. 11032.

7.ISSUANCE OF IMPORT CLEARANCE

Issued to licensed establishments that will import products that are not yet notified but will be used for testing, research and development, clinical trial, exhibition, and so forth.

Center/Office/Division	**:**	Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research
Classification	**:**	Complex
Type of Transaction	**:**	G2B – Government to Business Entity
Who May Avail	**:**	Licensed Cosmetic, HUHS, HUP, TCCA Establishments with activity as importer of finished products (Distributor, Trader, Manufacturer)
Fees to be Paid	**:**	Php 500.00 + 1% LRF not less than Php 10.00

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
1. Letter of intent stating the purpose of importation	Applicant
2. Airway Bill or Bill of Lading	Designated courier
3. Packing List	Applicant
4. Proforma Invoice	Applicant
5. For Exhibition 5.1. Notarized affidavit of undertaking 5.2. Product Information (brochure, leaflet, label)	Applicant
6. For clinical trial/research 6.1. Copy of protocol	Applicant
7. For Donation 7.1. Letter of endorsement from DOH-BIHC 7.2. Deed of donation	 DOH-BIHC Applicant
8. For Household/Urban Pesticide Products (for analysis/ testing and/or submission sample)	Applicant

8.1 Safety Data Sheet of Product	
9. Copy of valid LTO	FDA- CCHUHSRR
10. Copy of official receipt	FDA cashier

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant submits the requirements to Letters Section in FDAC	1. Checks the completeness of documents	None		FDAC officer of the day
2. Applicant pays the fee	2. Verifies the payment	Php 510.00	Refer to FDA Cashier's Citizen's Charter	FDA Cashier personnel
3. Applicant submits requirements (hard copy)	3.1 Receives complete requirements	None		FDAC officer of the day
	3.2. Application is forwarded to CCHUHSRR	None		FDAC personnel
	3.3. Data Controller receives the application and update the database	None	30 Minutes	Administrative Assistant VI CCHUHSRR
	3.4. Evaluator checks the correctness of documents	None	6.5 working days	Food Drug Regulation Officer CCHUHSRR
	3.5. Checks if the recommendation is appropriate	None	2 Hours	
	3.6. CCHUHSRR Director signs the final authorization	None	30 Minutes	Director IV CCHUHSRR

	3.7. Data controller updates the database and forwards the authorization to records section	None	1 Hour	Administrative Assistant VI CCHUHSRR
	3.8. Releasing			AFS-Releasing personnel
TOTAL:		**Php 510.00**	**7 working days**[14]	

[14] CCHUHSRR reserves the right to avail of the extension of the prescribed timeline by the same number of working days provided in Republic Act (RA) No. 11032 on the condition that the Center adheres to the provisions given in the IRR of RA No. 11032.

8.ISSUANCE OF OFF-LABEL USE / PUBLIC HEALTH EMERGENCY EXEMPTION PERMIT FOR A HOUSEHOLD URBAN PESTICIDES (HUP)

Authorization issued during emergency conditions declared by the Department of Health (DOH) or Local Government Unit (LGU) such as pest/disease outbreak or epidemic for either a registered or unregistered HUP product to permit its use against pest/s that have not been previously approved by the FDA.

Center/Office/Division	**:**	Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B – Government to Business Entity
Who May Avail	**:**	Licensed HUP Establishments (Distributor, Trader, Manufacturer)
Fees to be Paid	**:**	Php 500.00 + 1% LRF not less than Php 10.00

CHECKLIST OF REQUIREMENTS (*Refer to AO 2019-0008 Annex C for the specific data on the following requirements)*	**WHERE TO SECURE**
1. Letter of Request	Applicant
2. Information Required for Public Health Exemption	
3. Description of the HUP Product	
4. Description of the Proposed Use	
5. Alternate Methods of Control	
6. Bio-efficacy Study	3rd Party Testing laboratory
7. Toxicity Study	Toxicity Testing Laboratory or Supplier/Manufacturer
8. Description of the Proposed Enforcement Program	Applicant
9. Copy of Official Receipt	FDA Cashier

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant sends a request for schedule of submission of application requirements to FDAC (fdac@fda.gov.ph). Requests for schedule may be submitted from **Monday to Friday**.	1. Schedules the submission of application requirements for pre-assessment on **Thursdays**, except for Holidays, from **8AM to 12NN.**		FDAC Personnel
2. Applicant submits the application requirements for pre-assessment to FDAC (fdac.pacd@fda.gov.ph) on the day of the schedule, from **8AM to 12NN**.	2.1. Forwards the received application requirements for pre-assessment to CCHUHSRR from **1PM to 2PM.**		FDAC Personnel
	2.2. Pre-assesses the submitted application for completeness of requirements. Only applications with complete requirements shall proceed to payment.		Food-Drug Regulation Officer CCHUHSRR
3.1. Applicant pays the fee.			FDA Cashier Personnel
3.2.Applicant submits the paid application (electronic copies of the complete requirements) to FDAC (fdac.pacd@fda.gov.ph).	3.1. Receives the lodged application.		FDAC Personnel
	3.2. Forwards the application to CCHUHSRR.		FDAC Personnel

	3.3. Receives the application and updates the database.	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
	3.4. Evaluates the correctness of documents.	10 Working Days	Food-Drug Regulation Officer / Expert Panel CCHUHSRR
	3.5. Reviews the bio- efficacy study and/or toxicity study.	7 Working Days	
	3.6. Reviews the recommendation of the expert panel and prepares the overall recommendation.	2 Working Days	
	3.7. Checks if the recommendation is appropriate.	6 Hours	Food-Drug Regulation Officer CCHUHSRR
	3.8. Renders the final decision on the recommendation.	1 Hour	Director IV CCHUHSRR
	3.9. Updates the database and forwards the final issued document/s to records section.	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
4. Applicant receives the final issued document.	4. Releasing		Releasing personnel Records Section
TOTAL:		**20 Working Days**[15]	

[15] CCHUHSRR reserves the right to avail of the extension of the prescribed timeline by the same number of working days provided in Republic Act (RA) No. 11032 on the condition that the Center adheres to the provisions given in the IRR of RA No. 11032.

9.ISSUANCE OF PRE-APPROVAL OF MODIFIED AND NON-STANDARD BIO-EFFICACY TEST PROTOCOLS

An authorization issued to licensed establishments of household pesticide product/s that are planning to conduct a bio-efficacy study using modified[16] or non-standard[17] test protocols to generate efficacy data in support of household pesticide registration. This authorization will not apply to test protocols that strictly adhere to accepted test protocols as listed in FDA Circular No. 2023-003.

Center/Office/Division	:	Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	Licensed HUP Establishments (Manufacturer, Trader, Distributor)
Fees to be paid	:	Php 500.00 + 1% LRF not less than Php 10.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of Intent specifying the reason for utilizing a non-standard or modified bio-efficacy test protocol	FDA website (https://www.fda.gov.ph/downloadables/)
2. Valid License to Operate	FDA-CCHUHSRR
3. Test Protocol **Refer to FDA Circular 2023-003 Annex C for Test Protocol Content**	Applicant
4. Official Receipt	FDA-Cashier

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE

[16] Modified test protocols are protocols that are based on accepted test protocols as listed in Annex A of FDA Circular No. 2023-003 but, for justifiable reasons/circumstances, deviates from the accepted protocol.
[17] Non-standard test protocols are protocols that are wholly developed/created for the purpose of testing the household pesticide product and, in no way, based on an accepted test protocol as listed in Annex A of FDA Circular No. 2023-003.

1. Applicant sends a request for schedule of submission of application requirements to FDAC (fdac@fda.gov.ph). Requests for schedule may be submitted **from Monday to Friday.**	1. Schedules the submission of application requirements for preassessment on **Thursdays, except for Holidays, from 8AM to 12NN.**		FDAC Personnel
2. Applicant submits the application requirements for pre-assessment to FDAC (fdac.pacd@fda.gov.ph) on the day of the schedule**, from 8AM to 12NN.**	2. Forwards the received application requirements for preassessment to CCHUHSRR **from 1PM to 2PM.**		FDAC Personnel
	2.1 Pre-assesses the submitted application for completeness of requirements. Only applications with complete requirements shall proceed to payment.		Food-Drug Regulation Officer CCHUHSRR
3. Applicant pays the corresponding fee.	3. Verifies and posts the payment details.		FDA Cashier
4. Applicant submits the paid application (electronic copies of the complete requirements) to FDAC (fdac.pacd@fda.gov.ph).	4. Receives the lodged application.		FDAC Personnel
	4.1 Forwards the application to CCHUHSRR.		FDAC Personnel
	4.2 Receives the application and updates the database.	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR

	4.3 Accomplishes Part I of the evaluation worksheet and endorses the application to the Consultant.	2 Hours	Food-Drug Regulation Officer CCHUHSRR
	4.4 Evaluates the correctness, accuracy, and compliance with administrative and technical standards of the test protocol.	18 Working Days	Consultant
	4.5 Forwards the recommendation on the application to CCHUHSRR.	30 Minutes	
	4.6 Prepares the draft FDA-issued document.	2 Hours	Food-Drug Regulation Officer CCHUHSRR
	4.6 Checks if the recommendation and draft document is appropriate	1 Working Day	Food-Drug Regulation Officer CCHUHSRR
	4.7 Renders the final decision on the recommendation and draft document.	2 Hours	Director IV CCHUHSRR
	4.8 Updates the database and forwards the final issued document to records section.	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
5. Applicant receives the final issued document.	5. Sends the electronic copy of the final issued document.	30 Minutes	Records Section
TOTAL		**20 Working Days**[18]	

[18] CCHUHSRR reserves the right to avail of the extension of the prescribed timeline by the same number of working days provided in Republic Act (RA) No. 11032 on the condition that the Center adheres to the provisions given in the IRR of RA No. 11032.

10.ISSUANCE OF SALES AND PROMOTION PERMIT

Issued to licensed establishments that intends to have broad consumer participation which contains promises of gain such as prizes, in cash or in kind, as a reward for the purchase of a product, security, service, or winning in a contest, game, tournament and other similar competitions which involve determination of winner/s and which utilize mass media or other widespread means of information.

Center/Office/Division	**:**	Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B – Government to Business Entity
Who May Avail	**:**	Licensed Cosmetic, HUHS, HUP, TCCA Establishments (Distributor, Trader, Manufacturer) or advertising agency representing the former
Fees to be Paid	**:**	Initial application *Based on the following promo size + 1% LRF: 1. Php 300,000 and below – Php 1,000 2. Php 300,001 to Php 500,000 – Php 2,000 3. Php 500,001 to Php 1 million – Php 3,000 4. Above Php 1 million – Php 5,000 Amendment application Php 300.00 + 1% LRF not less than Php 10.00

A. INITIAL APPLICATION

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Integrated application form	FDA website (https://www.fda.gov.ph/downloadables/)
2. Information Sheet and Mechanics of the sales promotion	FDA website (https://www.fda.gov.ph/downloadables/)
3. Copy of valid product registration/notification	FDA- CCHUHSRR
4. Copy of lay-out of any promo materials	Applicant
5. Copy of official receipt	FDA Cashier

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant requests for a schedule of submission of requirements	1. Checks the completeness of documents	None		FDAC personnel
2. Applicant pays the fee through a Landbank Branch or FDA Cashier	2. Verifies payment	Based on the following promo size + 1% LRF: 1. Php 300,000 and below – Php 1,000 2. Php 300,001 to Php 500,000 – Php 2,000 3. Php 500,001 to Php 1 million – Php 3,000 4. Above Php 1 million – Php 5,000	refer to the FDA Cashier's Citizen's Charter	FDA Cashier personnel or Landbank Personnel
3. Applicant submits requirements (electronic copies)	3.1. Receives complete requirements	None		FDAC officer of the day

	3.2. Application is forwarded to CCHUHSRR	None		FDAC personnel
	3.3. Data Controller receives the application and update the database	None	2 Hours	Administrative Assistant VI CCHUHSRR
	3.4. Evaluator checks the correctness of documents	None	15 working days	Food Drug Regulation Officer CCHUHSRR
	3.5. Checks if the recommendation is appropriate	None	3.5 working days	Food Drug Regulation Officer CCHUHSRR
	3.6. CCHUHSRR Director signs the final authorization	None	1 working day	Director IV CCHUHSRR
	3.7. Data Controller updates the database and forwards the final authorization to records section	None	2 Hours	Administrative Assistant VI CCHUHSRR
	3.8. Releasing			AFS-Releasing personnel
TOTAL:			**20 working days**[19]	

[19] CCHUHSRR reserves the right to avail of the extension of the prescribed timeline by the same number of working days provided in Republic Act (RA) No. 11032 on the condition that the Center adheres to the provisions given in the IRR of RA No. 11032.

B. AMENDMENT APPLICATION

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Integrated application form	FDA website (https://www.fda.gov.ph/downloadables/)
2. Letter of intent stating the type of amendment	Applicant
3. Copy of previously approved promo permit	Applicant
4. Copy of valid product registration/notification	FDA- CCHUHSRR
5. Copy of lay-out of any promo materials	Applicant
6. Copy of official receipt	FDA Cashier

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant requests for a schedule of submission of requirements	1. Checks the completeness of documents	None		FDAC personnel
2. Applicant pays the fee through a Landbank Branch or FDA Cashier	2. Verifies Payment	Php 310.00	refer to the FDA Cashier's Citizen's Charter	FDA Cashier personnel or Landbank Personnel
3. Applicant submits requirements (electronic copies)	3.1. Receives complete requirements	None		FDAC officer of the day
	3.2. Application is forwarded to CCHUHSRR	None		FDAC personnel

	3.3. Data Controller receives the application and update the database	None	2 Hours	Administrative Assistant VI CCHUHSRR
	3.4. Evaluator checks the correctness of documents	None	15 working days	
	3.5. Checks if the recommendation is appropriate	None	3.5 working days	Food Drug Regulation Officer CCHUHSRR
	3.6. CCHUHSRR Director signs the final authorization (may be approved or disapproved)	None	1 working day	Director IV CCHUHSRR
	3.7. Data Controller updates the database and forwards the final authorization to records section	None	2 Hours	Administrative Assistant VI CCHUHSRR
	3.8. Releasing			AFS-Releasing personnel
TOTAL:		**Php 310.00**	**20 working days**[20]	

[20] CCHUHSRR reserves the right to avail of the extension of the prescribed timeline by the same number of working days provided in Republic Act (RA) No. 11032 on the condition that the Center adheres to the provisions given in the IRR of RA No. 11032.

11.ISSUANCE OF TOYS AND CHILDCARE ARTICLES PRODUCT NOTIFICATION

Issued to licensed establishments that will place a toy or childcare article product in the market.

Center/Office/Division	**:**	Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B – Government to Business Entity
Who May Avail	**:**	Licensed Toys and Childcare Article establishments (Distributor, Manufacturer)
Fees to be Paid	**:**	Php 100.00 + 1% LRF not less than Php 10.00 (maximum of five (5) SKUs)

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
1. TCCA e-portal user account	CCHUHSRR
2. Valid LTO	FDA- CCHUHSRR
3. Laboratory Test Report 3.1. For toys intended for children below 14 y/o 3.1.1. Parts 1 to 3 of the PNS/ISO 8124 and reports for phthalate testing if the toy product contains PVC 3.2. For swings, slides, and similar activity toys 3.1.2. Parts 1 to 4 of the PNS/ISO 8124 and reports for phthalate testing if the toy product contains PVC 3.3. For Childcare Articles 3.1.3. Laboratory reports for migration of elements (Antimony, Arsenic, Barium, Cadmium, Chromium, Lead, Mercury, Selenium) and phthalate testing	Supplier
4. Labeling and Packaging including other informative materials - Shall be submitted during the application or within thirty (30) calendar days upon acknowledgment of the application	Applicant

CLIENT STEPS	**AGENCY ACTION**	**FEES TO BE PAID**	**PROCESSING TIME**	**PERSON RESPONSIBLE**

1.1 Applicant requests for e-portal username and password		None		Applicant
1.2. Applicant accomplishes the application form and declaration in the e-portal		None		Applicant
1.3. Applicant generates order of payment and pays the fee through a Landbank Branch or through Systems/Means prescribed by the FDA Cashier	1.1.Posting of payment. Payment will be posted after bank clearing	Php 110.00	refer to the FDA Cashier's Citizen's Charter	FDA Cashier personnel or Landbank Personnel
	1.2.Evaluator checks the correctness of the application	None	11 working days[21]	Food Drug Regulation Officer CCHUHSRR
	1.3. CCHUHSRR Director gives the final decision on the application	None	1 working day	Director IV CCHUHSRR
	1.4. Acknowledgement or disapproval will be forwarded to applicant's e-portal account	None		Applicant
TOTAL:		Php 110.00	**12 Working Days[22]**	

[21] Applications shall be acted upon within the processing time indicated from the date the complete application or request was received.
[22] CCHUHSRR reserves the right to avail of the extension of the prescribed timeline by the same number of working days provided in Republic Act (RA) No. 11032 on the condition that the Center adheres to the provisions given in the IRR of RA No. 11032.

CENTER FOR COSMETICS AND HOUSEHOLD URBAN HAZARDOUS/SUBSTANCES REGULATION AND RESEARCH INTERNAL SERVICES

1.**ISSUANCE OF CERTIFICATE REQUESTED BY LAW ENFORCEMENT AGENCIES (LEAs) FOR VERIFICATION OF AUTHORIZATION OF PRODUCT/S AND ESTABLISHMENT/S**

A process carried out by the Product Research and Standards Development Division under the Post-Marketing Surveillance (PMS) system of the CCHUHSRR wherein the authorization of products under investigation and/or in question by the Law Enforcement Agencies (LEAs) such as cosmetics, household and urban hazardous substances (HUHS), toys and childcare articles (TCCAs), and household urban pesticides (HUPs) as well as the license to operate of the Marketing Authorization Holders are checked, verified, and reviewed to ensure continuous compliance with existing FDA laws, rules, and regulations.

Center/Office/Division	**:**	Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research – Product Research and Standards Development Division (CCHUHSRR-PRSDD)
Classification	**:**	Highly Technical Transaction
Type of Transaction	**:**	Government to Government - G2G
Who May Avail	**:**	FDA Centers- REU and FROO

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of request for Verification of the Authorization of Product and Establishment emanating from Law Enforcement Agencies	Requesting Party (LEAs)
2. Referral letter with request from LEAs for verification of Authorization of Product and Establishment	FROO/REU

INTERNAL CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING DAY (Per product/ establishment basis	PERSON RESPONSIBLE
1.Requesting Party (LEAs) through FROO/ REU	1. Refers to the request for verification of authorization of products and establishments.	None	N/A	Office of the Field Regulatory Operations Office FROO/REU
2.Receives the referral and request letter	2. Receives and checks the completeness of the submitted documents then encodes it to the database then decks the referral and request forms.	None	0.5 working day	CCHUHSRR PRSDD Admin
3.Evaluation and Verification of the referral/request letter	3.1 Evaluates and verifies the notification/registration of the product and the establishment.	None	15 working days	CCHUHSRR PRSDD Evaluator
	3.2 Reviews the evaluation and recommendation by the evaluator and forwards the draft certificate or response letter to the Senior Checker and Quality assurance.	None	2 working days	CCHUHSRR PRSDD Checker

	3.3 Recommends the approval of the certificate or response letter and forwards to the Center Director.	None	1 working day	CCHUHSRR PRSDD Division Chief
	3.4 Approves the certificate or response letter for releasing to the requesting party.	None	1 working day	CCHUHSRR Center Director
4.Releasing of Certificate or Response Letter	4. The PRSDD Admin shall release the certificate or Response Letter to the Requesting Party	None	0.5 working day	CCHUHSRR PRSDD Admin
		TOTAL:	**20 WORKING DAYS**	

2. REVIEW OF POLICIES ENDORSED BY OTHER CENTERS AND OFFICES

Policy-determining issuances emanating from Other Offices (e.g., request for comments/inputs on proposed DOH Administrative Orders, FDA Orders, FDA Circulars, FDA Memorandum, Memorandum Circulars, and FDA Advisories)

Center/Office/Division	**:**	Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) - Product Research and Standards Development Division (PRSDD)
Classification	**:**	Highly technical transaction
Type of Transaction	**:**	Government to Government - G2G
Who May Avail	**:**	FDA Centers/ Offices and External Offices

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Inter-Office Memorandum* from the Proponent/Requesting Office *To aid in conducting an ample review, the following relevant information are recommended to be provided: a. Background, including overview of policy issues being addressed, legal basis b. Description and rationale of the proposed policy c. Relevant references d. Deadline of comments e. Scope of comments being sought from CCHUHSRR f. Focal person handling the proposed policy	Proponent/Requesting Office
2. Copy of the draft issuance, in word format	Proponent/Requesting Office

INTERNAL CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Endorses request, including attachments, to FDA-CCHUHSRR	1.1 Receives request, update document tracking system, endorse request to CCHUHSRR-OD	None	15 minutes	Administrative Assistant VI CCHUHSRR Office
	1.2 Decks request to PRSDD and provide instructions	None	4 hours	Director IV CCHUHSRR Office
	1.3 Reviews request, provides preliminary comments, deck request to Policy Section	None	4 hours	PRSDD Chief CCHUHSRR Office
	1.4 Updates policy database and endorse to Policy Section head	None	15 minutes	Administrative Assistant VI CCHUHSRR Office
	1.5 Preliminary reviews, assigns review to Policy Staff	None	4 hours	Administrative Assistant IV CCHUHSRR Office
	1.6 Conducts review, including necessary consultations, and preparation of IOM-response	None	15 working days	Food and Drug Regulation Officer CCHUHSRR Office
	1.7 Review of IOM-response and applies necessary revisions, finalizes IOM-response	None	2 working days and 3 hours	Food and Drug Regulation Officer CCHUHSRR Office
	1.8 Updates of policy database	None	15 minutes	Administrative Assistant VI CCHUHSRR Office
	1.9 Clearance of IOM-response	None	4 hours	PRSDD Chief CCHUHSRR Office
	1.10 Clearance of IOM-response	None	4 hours	Director IV CCHUHSRR Office

2. Receives IOM-response	2. Updates, document tracking system, referral to requesting/ proponent Office	None	15 minutes	Administrative Assistant VI CCHUHSRR Office
TOTAL:	None	20 working days		

CENTER FOR DEVICE REGULATION, RADIATION HEALTH AND RESEARCH (CDRRHR)
EXTERNAL SERVICES

1.AMENDMENT APPLICATION OF SALES PROMO PERMIT

The application for the amendment in the permit for the conduct of sales promotion schemes for medical devices.

Center/Office/Division	:	Center for Device Regulation, Radiation Health and Research – Licensing and Registration Division
Classification	:	Complex
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php300.00 + Php10.00 LRF per certification

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Letter of Intent specifying the type of amendment	Applicant
Copy of previously issued valid promo permit	Applicant
Supporting documents for the requested amendment	Applicant
Proof of payment	FDA Cashier
Self-Assessment Form	Applicant
Accomplished Integrated Application Form	Applicant
List of participating products in Excel Format.	Applicant
Submission schedule is as follows: For companies with names beginning with numbers 0-9 and letters A-M: Every Thursday from 8:00 AM to 5:00 PM. For companies with names beginning with letters N-Z: Every Friday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their application to fdac.letters@fda.gov.ph following the correct schedule.	1. Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client	None	Timeline starts after posting of payment	FDAC Officer
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 24 hours.	2. FDA receives the payment from the applicant company for posting.	PHP310.00		FDA Cashier
3. The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email	3.1 FDAC forwards the application to CDRRHR.	None		FDAC Officer
	3.2 The CDRRHR assigns the application to the evaluator.	None	1 working day	CDRRHR Administrative Staff

	3.3 The technical evaluator reviews the application. Recommends approval/ disapproval.	None	2 working days	Technical Evaluator
.	3.4 Quality Assurance - Checking of recommendation of the Supervisor	None	1 working day	LRD Chief
	3.5 Final Approval/Disapproval and signature of the Director.	None	1 working day	CDRRHR Director
.	3.6 Assigning of number and printing of permit. Scanning and transmitting permit to the Records Section.	None	1 working day	CDRRHR Administrative Staff
4. Pick-up of Certificate	4.Queuing and endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	PHP 310.00 per certification	7 working days	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

2.APPLICATION FOR VARIATION OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF IN-VITRO DIAGNOSTIC DEVICES/REAGENTS (IVD) AND CERTIFICATE OF MEDICAL DEVICE REGISTRATION (CMDR)

The application for minor or major variations or amendments in the CPR of medical devices and in-vitro diagnostic devices or reagents.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php500.00 + Php10.00 = Php510.00 Other fees: Extension of shelf life: Php1,000.00 + Php10.00 = Php1,010.00 Change in brand name: Php2,500.00 + Php25.00 = Php2,525.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Change of Business Name and Address of Manufacturer/Trader/Importer/ Distributor	
1. Letter of request - Should indicate the current and proposed changes - Should include in the letter if there is a renewal application and indicate document tracking Number	Applicant
2.Valid License to Operate (LTO) reflecting the new business name and address of manufacturer/trader/importer/distributor with the source reflected in the LTO	Applicant

3. Original Certificate of Product Registration (CPR) - Should submit back and front sides	Applicant
4. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Applicant
Change in Ownership (Inclusion/Deletion or Change in Trader/Importer/Distributor)	
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Valid LTO reflecting the source	Applicant
3. Termination of Contract/Deed of Assignment	Applicant or Principal/Source/ Manufacturer
4. Agreement with the new company must be valid	Applicant or Principal/Source/ Manufacturer
5. Original CPR - Should submit back and front sides	Applicant
6. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Applicant

Request for Change of Shelf Life	Where to secure
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant

2. Previously submitted stability data	Principal/Source/ Manufacturer
3. Real time data supporting the change of shelf life - Must be signed by the person who performed the analysis	Principal/Source/ Manufacturer
4. Copy of CPR - Should submit back and front sides	Applicant
5. Complete labeling requirements - Submit current and proposed labels	Applicant or Principal/Source/ Manufacturer
Change of Manufacturing Site (Same Subsidiary) With No Change in The Formulation, Equipment, and Manufacturing Procedure	Where to Secure
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
. Submit justification or supporting documents to show that the proposed manufacturer is a subsidiary of the current or approved manufacturer	
Letter from the manufacturer stating that there is no change in the formulation, equipment and manufacturing procedure	Principal/Source/ Manufacturer
4. Valid LTO	Applicant
5. Copy of submitted Notification of Source - The list of sources should reflect the proposed manufacturing site	Applicant
6. Formulation (for solutions) or List of Raw Materials (with the corresponding amount of raw materials used, if applicable) issued by the current and proposed manufacturer	Principal/Source/ Manufacturer
7. Manufacturing flowchart (current and proposed) Include brief narrative description of the manufacturing flowchart	Principal/Source/ Manufacturer
8. Finished product specification (current and proposed)	Principal/Source/ Manufacturer

9. For Imported Products – authenticated or apostilled GMP/ISO Certificate reflecting the new manufacturing site The GMP/ISO certificate should be valid	Principal/Source/ Manufacturer
10. Sterilization process and latest result of sterilization validation conducted/issued by the new manufacturing site	Principal/Source/ Manufacturer
11. Valid ISO Certificate of the sterilizing company (if there is a change in sterilization company)	Principal/Source/ Manufacturer
12. Copy of CPR - Should include back and front sides	Applicant
13. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Applicant or Principal/Source/ Manufacturer
Change of Brand Name (From Generic to Brand, Change of Brand to Another, Deletion of Brand)	Where to Secure
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
Copy of CPR - Should include back and front sides	Applicant
Certificate from IPO for local brand name. For imported products, the manufacturer's declaration that allows the use of the brand name.	Applicant
Official letter from the product owner regarding the change of brand name and declaration that there is no other change to the product/label except for the brand name	Principal/Source/ Manufacturer
Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Applicant or Principal/Source/ Manufacturer

Change of Storage Condition	Where to Secure

Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant

Change/Additional Indications	Where to Secure
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
Copy of CPR Submit front and back sides	Applicant
Approval letter issued by a government agency or notified body	Principal/Source/ Manufacturer
Studies to support the additional indication	Principal/Source/ Manufacturer
Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Principal/Source/ Manufacturer

Change of Re-Packer/Packer	Where to Secure
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant

2. Termination of contract with the previous re-packer/packer	Applicant or Principal/Source/ Manufacturer
3. Agreement of with the new re-packer/packer	Applicant or Principal/Source/ Manufacturer
4. Copy of CPR - Submit front and back sides	Applicant
5. Complete labeling requirements (Primary, Secondary, and Inserts) - Submit current and proposed labels	Principal/Source/ Manufacturer

Change of Label Design	Where to Secure
Letter of request Should indicate the reason for change Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Currently approved label design	Applicant
4. Proposed label with the new design	Applicant or Principal/Source/ Manufacturer
Change of Packaging	Where to Secure
Letter of request Should indicate the reason for change Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant

Copy of CPR - Submit front and back sides	Applicant
3. Appropriate scientific data on new packaging	Principal/Source/ Manufacturer
4. Proof that no interaction between the product and packaging material occur	Principal/Source/ Manufacturer
5. Comparative tabulated format of specifications of currently approved and proposed packaging material	Applicant or Principal/Source/ Manufacturer
Additional Presentation [e.g. (1) Registered box x 100's, additional presentation of 1 box x 500's; (2) registered 60mL, additional of 120mL]	Where to Secure
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Currently approved and proposed presentation	Applicant
Re-classification (from other classification to Medical Device)	Where to Secure
1. Letter of request	Applicant
2. Letter from the other Center regarding re-classification of the product (if applicable)	Applicant
3. Original CPR issued by another Center	Applicant
4. Complete requirements for initial registration	Applicant
Addition of Codes/Reference Number/Article Number	Where to Secure
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant

2. Copy of CPR - Submit front and back sides	Applicant
3. Declaration from the manufacturer that there is no change in the manufacturing process, sterilization process and raw materials	Principal/Source/ Manufacturer
4. Provide previous list of raw materials and manufacturing flowchart of the previously approved codes	Principal/Source/ Manufacturer
5. List of raw materials and manufacturing flowchart for the proposed code/s	Principal/Source/ Manufacturer
6. Complete tabulated format of the finished product specification of the currently approved codes and proposed codes	Principal/Source/ Manufacturer
7. Colored photos of the current and proposed codes	Applicant or Principal/Source/ Manufacturer
8. Labels of the current and proposed codes	Applicant or Principal/Source/ Manufacturer
Deletion of Codes/Reference Number/Article Number	Where to Secure
Letter of request Indicate the reason for deletion Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
Official letter from the product owner regarding the deletion	Principal/Source/ Manufacturer
3. Copy of CPR - Submit front and back sides	Applicant

Additional Sterilization Site	Where to Secure

Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Sterilization procedure and revalidation protocol issued by the currently approved sterilizing company.	Principal/Source/ Manufacturer
4. Sterilization procedure and revalidation protocol issued by the proposed sterilizing company.	Principal/Source/ Manufacturer
5. Latest result of sterilization revalidation of the new sterilizing company	Principal/Source/ Manufacturer
6. ISO Certificate of the new sterilizing company	Principal/Source/ Manufacturer

Change in Instructions for Use	Where to Secure
Letter of request Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Previously approved instructions for use	Applicant or Principal/Source/ Manufacturer
4. Proposed instructions for use	Principal/Source/ Manufacturer

5. For technical changes, submit study to support the change in instructions for use	Principal/Source/ Manufacturer

Change/Addition of Source of Raw Materials	Where to Secure
Letter of request Indicate the reason for the change/addition of source of raw materials Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Comparative tabulated format of the analysis of raw materials of the currently approved and new source	Applicant or Principal/Source/ Manufacturer
4. Comparative tabulated format of finished product specification of the currently approved and new source	Applicant or Principal/Source/ Manufacturer

Change of Test Procedure	Where to Secure
Letter of request Indicate the reason for the change of test procedure Should indicate the current and proposed changes Should include in the letter if there is a renewal application and indicate document tracking number	Applicant
2. Copy of CPR - Submit front and back sides	Applicant
3. Description of the analytical methodology, a summary of validation data and comparative analytical results between the currently approved and proposed test	Principal/Source/ Manufacturer

Submission schedule is as follows: > For companies with names beginning with numbers 0-9 and letters A-M: Every Thursday from 8:00 AM to 5:00 PM. > For companies with names beginning with letters N-Z: Every Friday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing the PDF of their application to fdac.letters@fda.gov.ph following the correct schedule and pays the corresponding fee.	1. Receiving officer generates a Document Tracking Number (DTN) and send and acknowledgment email / order of payment to the client.			FDAC Officer
The applicant company receives the Order of Payment and pays the fee through the FDAC Cashier or through the other means prescribed by the FDA. The Order of Payment is only valid for 24 hours after issuance.	2. FDA receives the payment from the applicant company.	*Fees depend on the total amendment request of the client.	Timeline starts after posting of payment	FDA Cashier
The applicant company receives the official receipt and sends the proof of payment to the FDAC through email.	3.1 FDAC forwards the application to the CDRRHR.		1 working day	FDAC Officer

	3.2 Decking of the application to the evaluator.			CDRRHR Administrative Staff
	3.3 The technical evaluator reviews the application and recommends approval/disapproval.		11 working days**	CDRRHR Technical Evaluator
	3.4 Quality Assurance – checking and recommendation of the Supervisor.		3 working days	CDRRHR LRD Division Chief
	3.5 Preparation of Letter of Approval or Disapproval of Variation		1 working day	CDRRHR Technical Evaluator
	3.6 Final approval and disapproval and signature of the Center Director.		1 working day	CDRRHR Director
	3.7 Scanning of the approval letter. Transmitting of the approval letter to the Records Section. Queuing and endorsement to the FDA Releasing Section.		3 working days	Administrative Officer
	TOTAL	Php510.00/ Php1,010.00/ Php2,525.00	20 working days***	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

3.RE-APPLICATION FOR CMDR AND IVDR INITIAL APPLICATIONS

The client's response or compliance to the issued Letter of Disapproval following their initial registration application. Clients are given 60 calendar days to comply from the date of the LoD issuance.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php 1,000.00 + 1% LRF = Php1,010.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Letter of Intent	Applicant.
Copy of the Letter of Disapproval/Reapplication.	Applicant
Compliance Documents	Applicant/Principal/ Manufacturer
Payment	FDA Cashier
NOTES: Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements.	

Submission schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Client sends an email containing the PDF of their compliance to fdac.pacd@fda.gov.ph within the prescribed time period stipulated in the Letter of Disapproval/Reapplication.*	1.1 Receiving officer sends an acknowledgment email to the client and assigns a new DTN to the application. FDAC forwards the re-application file to CDRRHR.	Php1,010	1 working day	FDAC Officer
	1.2 CDRRHR receives the re-application file and decks to the evaluator	None	1 working day	CDRRHR Administrative Staff
	1.3 Technical evaluation of application. Recommendation of Approval or Final Disapproval	None	10 working days	CDRRHR Technical Evaluator
	1.4 Quality Assurance - Checking of	None	4 working days	CDRRHR LRD Division Chief

	recommendation of the Supervisor			
	1.5 Drafting and finalization of certificate/disapproval letter	None	1 working day	CDRRHR Technical Evaluator
	1.6 Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	1.7 Scanning and transmittal of certificate/disapproval letter to the FDA Records Section	None	1 working day	CDRRHR Administrative Staff
	1.8 Queuing and endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	P1,010.00	20 working days**	

*Submission period is within sixty (60) days from the issuance date of the Letter of Disapproval/Re-application.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

4.RE-APPLICATION FOR RENEWAL OF CMDR/CPR and IVDR

The client's response or compliance to the issued Letter of Disapproval following their renewal application. Clients are given 30 calendar days to comply from the date of the LoD issuance.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php 1,000.00 + 1% LRF = Php1,010.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Letter of Intent	Applicant
Copy of the Notice of Deficiencies	Applicant
Compliance Documents	Applicant / Principal/Manufacturer
Payment	FDA Cashier

NOTES: Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Submission schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Client sends an email containing the PDF of their compliance to fdac.pacd@fda.gov.ph within the prescribed time period stipulated in the notice of deficiency.*	1.1 Receiving officer sends an acknowledgment email to the client and assigns a new DTN to the application. FDAC forwards the re-application file to CDRRHR.	Php1,010.00	1 working day	FDAC Officer
	1.2 CDRRHR receives the re-application file and decks to the evaluator	None	1 working day	CDRRHR Administrative Staff
	1.3 Technical evaluation of application. Recommendation of Approval or Final Disapproval	None	10 working days	CDRRHR Technical Evaluator
	1.4 Quality Assurance - Checking of recommendation of the Supervisor	None	4 working days	CDRRHR LRD Division Chief

	1.5 Drafting and finalization of certificate or disapproval letter	None	1 working day	CDRRHR Technical Evaluator
	1.6 Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	1.7 Scanning and Transmittal of certificate or disapproval letter to the FDA Records Section.	None	1 working day	CDRRHR Administrative Staff
	1.8 Queuing and endorsement to the Releasing Section	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	Php1,010.00	20 working days**	

*Submission period is within thirty (30) days from the issuance date of the Letter of Disapproval/Re-application.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

5.COMPLIANCE FOR CMDR AND IVDR APPLICATIONS

The client's response or compliance to the issued Notice of Deficiencies following their initial registration application. Clients are given 90 calendar days to comply from the date of the NOD issuance.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	**G2B - Government-to-Businesses**
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of Intent	Applicant.
2. Copy of the Notice of Deficiency	Applicant
3. Compliance Documents	Applicant / Principal/Manufacturer

NOTES: • Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) • The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Submission schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their compliance to fdac.pacd@fda.gov.ph within the prescribed time period stipulated in the Notice of Deficiencies.*	1.1 Receiving officer sends an acknowledgment email to the client. FDAC forwards the compliance to CDRRHR.	None	1 working day	FDAC Officer
	1.2 CDRRHR receives the compliance and decks the file to the evaluator.	None	1 working day	CDRRHR Administrative Staff
	1.3 Technical evaluation of application. Recommendation of re-application or proceed to Approval.	None	10 working days	Technical Evaluator
	1.4 Quality Assurance - Checking of recommendation of the Supervisor	None	4 working days	LRD Chief
	1.5 Final Approval/Disapproval and signature of the Director	None	2 working days	CDRRHR Director

	1.6 Scanning and Transmittal of Re-application letter to Records Section	None	1 working day	CDRRHR Administrative Staff
	1.7 Queuing and Endorsement to Releasing Section	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL		20 working days**	

**Submission period is within ninety (90) days from the issuance date of the Notice of Deficiencies (NOD).*

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

6.COMPLIANCE FOR RENEWAL OF CMDR/CPR AND IVDR

The client's response or compliance to the issued Notice of Deficiencies following their renewal application. Clients are given 30 calendar days to comply from the date of the NOD issuance.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	**G2B - Government-to-Businesses**
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of Intent	Applicant
2. Copy of the Notice of Deficiencies.	Applicant

3. Compliance Documents	Applicant / Principal/Manufacturer
NOTES: • Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) • The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Submission schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their compliance to fdac.pacd@fda.gov.ph within the prescribed time period stipulated in the Notice of deficiencies.*	1.1 Receiving officer sends an acknowledgment email to the client. FDAC forwards the compliance document to CDRRHR.	None	1 working day	FDAC Officer
	1.2 CDRRHR receives the compliance and decks to the evaluator	None	1 working day	CDRRHR Admin Staff
	1.3 Technical evaluation of application and recommendation for approval or disapproval.	None	10 working days	Technical Evaluator
	1.4 Quality Assurance - Checking of recommendation of the Supervisor	None	4 working days	LRD Chief
	1.5 Final Approval/Disapproval and signature of the Director	None	2 working days	CDRRHR Director

	1.6 Scanning and transmittal of the certificate/disapproval letter to the Records Section.	None	1 working day	CDRRHR Administrative Staff
	1.7 Queuing and endorsement to the FDA Releasing Section	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL		**20 working days****	

**Submission period is within thirty (30) days from the issuance date of the Letter of Disapproval/Re-application.*

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

7.COMPLIANCE FOR VARIATION APPLICATIONS

The client's response or compliance to the issued Notice of Deficiencies following their CPR variation application. Clients are given 30 calendar days to comply from the date of the NOD issuance.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Letter of Intent	Applicant

Copy of the Notice of Deficiencies	Applicant
Compliance Documents	Applicant / Principal/Manufacturer
NOTES: Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Submission schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Client sends an email containing the PDF of their compliance to fdac.pacd@fda.gov.ph within the prescribed time period stipulated in the notice of deficiencies. *	1 Receiving officer sends an acknowledgment email to the client. FDAC forwards the compliance file to CDRRHR.	None	1 working day	FDAC Officer
	1.2 CDRRHR receives the compliance file and decks the file to the evaluator.	None	1 working day	CDRRHR Administrative Staff
	1.3 Technical evaluation of application. Recommendation for approval or disapproval.	None	10 working days	CDRRHR Technical Evaluator
	1.4 Quality Assurance - Checking of recommendation of the Supervisor.	None	4 working days	CDRRHR LRD Division Chief

	1.5 Final Approval/Disapproval and signature of the Director.	None	2 working days	CDRRHR Director
	1.6 Scanning and Transmittal of certificate or disapproval letter to the FDA Records Section.	None	1 working day	CDRRHR Administrative Staff
	1.7 Queuing and Endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL		20 working days**	

*Submission period is within thirty (30) days from the issuance date of the Notice of Deficiencies.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

8.ISSUANCE OF CERTIFICATE OF FREE SALES (CFS)

The application for certification that the medical device is registered and currently sold in the Philippines.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Complex
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php500.00 + Php10.00 LRF per product

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1 Letter of Intent regarding application for Certificate of Free Sale List of all devices must be enumerated in one letter only. If the application is more than one CMDR/CMDN or if the product contains codes. The client must submit a Word Copy of the Letter of Intent.	Applicant
1 copy of Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN). The CPR must be valid. For CMDR's/CMDN's currently undergoing the Amendment/Variation process, a letter of approval must be secured by the company prior to CFS application.	Applicant
License to Operate as Medical Device Manufacturer/ Exporter. Must be valid For cases that the company is not the Manufacturer or Trader, they must apply for additional activity as an Exporter For LTO currently undergoing the renewal process, submit proof of application for LTO renewal, including Official Receipt.	Applicant
Fee Computation of fee is per CPR as indicated in the letter of intent.	Applicant

5. If the Manufacturer/Trader is different from the Exporter, submit a copy of the agreement/authorization allowing them to export the medical device.	Applicant or Principal/Source/ Manufacturer
Submission schedule is as follows: For companies with names beginning with numbers 0-9 and letters A-M: Every Thursday from 8:00 AM to 5:00 PM. For companies with names beginning with letters N-Z: Every Friday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their application to fdac.letters@fda.gov.ph following the correct schedule.	1. Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client	None	Timeline starts after posting of payment	FDAC Officer
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 24 hours.	2. FDA receives the payment from the applicant company for posting	PHP510.00		FDA Cashier
3. The applicant company receives the official receipt and sends the proof of	3.1 FDAC forwards the application to CDRRHR.	None		FDAC Officer

payment to FDA Action Center (FDAC) through email.				
	3.2 CDRRHR assigns the application to evaluator	None	1 Working day	CDRRHR Admin Staff
	3.3 The technical evaluator reviews the application. Recommends approval or disapproval.	None	7 working days	Technical Evaluator
	3.4 Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief
	3.5 Assigning of numbers and Printing of certificates.	None	2 working days	Technical Evaluator
	3.6 Final Approval/Disapproval and signature of the Director.	None	2 working days	CDRRHR Director
	3.7 Scanning and transmitting of certificates to the Record Section.	None	2 working days	CDRRHR Administrative Staff
4. Pick-up of Certificate	4 Queuing and endorsement to FDA Releasing Section	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	PHP510.00	20 working days**	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

9.ISSUANCE OF CERTIFICATE OF MEDICAL DEVICE LISTING (CMDL)

The application for authorization issued for a medical device that is intended for research, clinical trial, exhibit, donation, etc. and that is not intended for sale.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Complex Transaction
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php 500.00 + 1% LRF per certificate Note: Fee is per product reflected in a single packing list or invoice. If the product is reflected on a separate packing list/invoice, an additional fee shall be required.

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
LEGAL REQUIREMENTS	
Duly notarized and completely filled-up scanned copy of the Application Form.	Applicant. Form may be downloaded from the FDA website.
Notarized letter addressed to the Director, Center for Device Regulation, Radiation Health, and Research, stating that the medical device will be used solely for the intended use (e.g., research, clinical investigation, exhibit, personal use, sample product for analysis/testing, or donated brand new medical devices) and is not intended for sale. The letter should contain the following information: Complete list of the devices indicating the quantity, brand and the name of the manufacturer of the product Declaration that the organization shall be the sole entity responsible for the medical devices and that the CDRRHR-FDA, DOH will not be held liable for any safety issue concerning the product.	Applicant company

3. Copy of Certificate of Product Notification or Certificate of Product Registration or any equivalent document attesting to the safety and effectiveness of the device issued by the regulatory agency in the country where the device will come from.	Principal/Source/Manufacturer
4 Copy of SEC or DTI registration, when applicable.	Applicant company
5 Details for Bill of Landing Number / Air Waybill; Container Numbers, Packing List Number/Invoice Number.	Principal/Source/Manufacturer
6 For donated medical device/s (brand new), a certified true copy of the deed of donation and the deed of acceptance.	Principal/Source/Manufacturer and Applicant Company
7 For research proposal, research approval from Ethics Committee and research protocol.	Applicant company
8 For clinical study, approval from the Ethics Committee and clinical study protocol.	Applicant company
6. Payment	Applicant company
Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The file name should consist of the name of the requirement.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. The applicant company sends an email to FDAC Letters. The e-mail should contain the complete application requirements.**	1. Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client.	None		FDAC Officer
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g.	FDA receives the payment from the applicant company for posting.	PHP 510.00 per product. Note: If the declared products for importation are	Timeline starts after posting of payment	FDA Cashier

BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 24 hours.		reflected on different or separate packing list/invoice, then an additional payment of PHP510.00 per invoice would be required.		
3. The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email.	3.1 FDAC forwards the application to CDRRHR.	None	1 working day	FDAC Officer
	3.2. CDRRHR assigns the application to evaluator	None	1 working day	CDRRHR Administrative Staff
	3.3. The technical evaluator reviews the application. Recommends approval or disapproval. Assigns the number and prints the CMDL.	None	8 working days	Technical Evaluator
	3.4. Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief
	3.5. Final Approval/Disapproval and signature of the Director.	None	2 working days	CDRRHR Director
	3.6. Scanning and transmitting of CMDL to the Records Section.	None	2 working days	CDRRHR Administrative Staff
4. Pick-up of certificate	4. Queuing and endorsement to the FDA Releasing Section	None	1 working day	AFS Records Officer

				/ Administrative Officer
	TOTAL	PHP510.00 per product/packing list/invoice	20 working days	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Refer to FDA Circular No. 2020-026 – Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA).

10.ISSUANCE OF CERTIFICATE OF MEDICAL DEVICE NOTIFICATION (INITIAL APPLICATION)

The application for authorization issued for medical devices that fall under Class A.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php7,500.00 + 1% LRF for initial with 5-year validity for Class A medical devices Php3,000.00 + 1% LRF for initial with 2-year validity for Class B, C, D medical devices not included in FDA Circular 2020-001-A

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
LEGAL REQUIREMENTS	
1 copy of Notarized Agreement / Letter of Authorization. Must be valid; The product being applied must be indicated. For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct. For imported medical devices but the agreements are signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period from the document's issuance, a re-issued agreement/authorization or a notarized attestation by the Principal that the agreement/authorization is still in effect must be submitted. For locally manufactured medical devices with an exclusive distributor, the agreement should be duly notarized. For locally manufactured medical devices with a toll manufacturer, the agreement between the trader and the manufacturer should be duly notarized.	Principal/Source/Manufacturer

2. For Imported Medical Devices - 1 copy of government-issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Must be valid Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. For products that are manufactured in multiple sites or toll manufacturers, identify or highlight the product source. The product being applied must be indicated in the scope. For locally manufactured products, submit the valid LTO of the manufacturer	Principal/Source/Manufacturer
For imported medical devices, 1 copy of Certificate of Product Notification, Certificate of Product Registration, or any equivalent document attesting to the safety and effectiveness of the device issued by the manufacturer (Self-Declaration), regulatory agency or accredited notified body in the country of origin. Must be valid The copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. Authenticated or apostilled document can be accepted if the document is authenticated or apostilled prior to September 2020.	Principal/Source/Manufacturer
4. 1 Clear colored picture of the actual commercial product sample of the device for all sides without its packaging. An actual representative sample or commercial presentation can be required by the CDRRHR for verification purposes. Picture should not pixelate when the view is increased in size	Principal/Source/Manufacturer
TECHNICAL REQUIREMENTS	

. Device Description consisting of the following: Intended use – this should include the specific use of the product being applied. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Instruction for use – this is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users. List of raw materials – this should include all the raw materials as a component of the medical device itself. For kits/sets: submit the raw materials used with specifications of all components in the kit/set. For machines/equipment: The list of raw materials is ONLY required for the machine parts/accessories that: 1) will have a direct contact with the patient; and/or 2) will serve as a channel/conduit for medical gases during infusion (i.e. ventilators) - parts that come in direct contact with medical gases for infusion. Technical specification of the finished product – This should include the technical specification of the finished products (physical, chemical, mechanical, electrical, etc.). This may be in the form of Certificate of Analysis or Test certificate. For locally manufactured devices, the hierarchy of product standards shall apply.	Principal/Source/Manufacturer
1 copy of Certificate of Conformity (issued by the government agency, or its equivalent, dealing with metrology) on the aspect of manufacture relating to metrology for devices with measuring functions, if applicable i.e. Thermometer, Weighing Scale, etc.	Principal/Source/Manufacturer
Declaration of Conformity with product standards (self-declaration by the manufacturer) with list of product standards. These are the standards used during the design, development, manufacture, testing of the medical devices. The following standards shall be considered: Philippine National Standards (PNS), international standards (ISO, IEC), other International Standard Bodies recognized by the DOH and other equivalent national standards (of these international standards).	Manufacturer

Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging) for all codes included in the application. Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable. For any additional product claims on the label, submit studies or tests supporting the claims. For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name and IPO approval of the said brand name. For local manufactured products, IPO approval of the brand name If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark. Pictures and text of the label should be clear and will not be pixelated when the view is increased in size. Lot No., Batch No., Serial No., whichever is applicable should be reflected. Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected. Storage condition, sterilization method should be reflected if applicable. Importer and distributor's name and address should be reflected in the label of the product together with the Product Notification Number Suggested Retail Price (SRP) in Philippine peso Note: The above requirements shall be superseded upon the approval of Administrative Order for the labeling requirements of medical devices.	Principal/Source/Manufacturer
9. Declaration of shelf life.	Manufacturer
10. Payment	FDA Cashier
All documents must be submitted in the English language. Documents submitted in any other foreign language not accompanied by a notarized English translation for legal documents and an English translation for technical documents shall be disapproved. Documents should be in PDF searchable format of at least 150 dpi. The file name should consist of the name of the requirement.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. The applicant company will request for the user account through email.	1.FDA issues user account	None		FDAC Officer
2. The authorized representative of the applicant company fills out the online form/e-notification through the portal (eportal.fda.gov.ph). Uploads all the documents indicated on the checklist.	2.The CDRRHR assigns the application to the evaluator for pre-assessment. Applications filed from 5:00 PM and beyond will be decked for pre-assessment the next working day (8:00 AM).	None		CDRRHR Administrative Staff
3. If all the requirements are deemed complete, the applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 5 working days.	3. Pre-assessment the application. The Client will receive either Order of Payment or Letter of Denial	None		CDRRHR Evaluator
4. The applicant company receives the official receipt.	4.1 FDA receives the payments from the applicant company. Posting of payment and automatic decking of the application to CDRRHR.	Php 7,575.00 or Php 3,030.00	Timeline starts after posting of payment	FDA Cashier

	4.2 Evaluation of application.	None	10 working days	
	4.3 Quality Assurance - Checking of recommendation of the Supervisor	None	10 working days	LRD Chief
	4.4 Final Approval/Disapproval with e-signature of the Director.	None	5 working days	CDRRHR Director
	TOTAL	PHP 7,575.00 or Php 3,030.00	25 working days**	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

11.ISSUANCE OF CERTIFICATE OF MEDICAL DEVICE REGISTRATION (CMDR) FOR CLASS B (ABRIDGED APPROVAL, INITIAL APPLICATION)

The registration of Class B medical devices with product approval issued by the NRA of any ASEAN-member country under the AMDD-CSDT requirements, and which are to be imported, distributed, and sold in the Philippines. This shall not cover medical devices with issued Certificate of Product Registration (CPR) based on abridged approval in other countries outside the ASEAN.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php7,500.00 + 1% LRF for initial with 5-year validity (Php. 7,575.00) per product

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Notarized Application Form Must be completely and correctly filled-up and signed Must use the latest form prescribed by the CDRRHR for the type of application Must submit one application form with attachment reflecting all the product codes being applied. Furthermore, the grouping of medical device family should be clearly specified. Only one condition should be considered in the multiple CPR application. Must be unedited, non-tampered; and must reflect the correct brand name, medical device name, and device risk-classification.	Applicant. Form may be downloaded from the FDA website.

1 copy of Notarized Agreement / Letter of Authorization. Must be valid; The product being applied must be indicated. For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct. For imported medical devices but the agreement is signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period from the document's issuance, a re-issued agreement/authorization or a notarized attestation by the Principal that the agreement/authorization is still in effect must be submitted. For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized. For locally manufactured medical devices with a toll manufacturer, the agreement between the trader and the manufacturer should be duly notarized.	Principal/Source/Manufacturer
For Imported Medical Devices - 1 copy of government-issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Must be valid Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. For products that are manufactured in multiple sites or toll manufacturers, identify or highlight the product source. The product being applied must be indicated in the scope. For locally manufactured products, submit the valid LTO of the manufacturer	Principal/Source/Manufacturer
For imported medical devices, 1 copy of the product approval issued by the NRA of any ASEAN-member country under the AMDD-CSDT requirements. ***** Must be valid	Principal/Source/Manufacturer

The copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.	
Clear colored picture of the actual commercial product sample of the device for all sides without its packaging, for all codes included in the application. An actual representative sample or commercial presentation can be required by the CDRRHR for verification purposes. Pictures should not be pixelated when the view is increased in size.	Principal/Source/Manufacturer
Technical Requirements	
Executive Summary. The executive summary shall include the following information: an overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features, and a synopsis of the content of the CSDT; the commercial marketing history; the list of regulatory approvals or marketing clearances obtained; the status of any pending request for market clearance; and the important safety/performance related information.	Applicant or Principal/Source/Manufacturer
Relevant essential principles and method/s used to demonstrate conformity. Must be completely filled-up	Principal/Source/Manufacturer

Device description with the following information: Intended use- this refers to the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Indications of use- this is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate; and includes a description of the target patient population for which the medical device is intended. Instruction for use- these are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale use of the medical device, instructions needed to use the medical device in a safe manner shall, to the extent possible, be included on the medical device itself and/or its packaging by other formats/forms. This is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users. Contraindications- This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit Warnings - This is the specific hazard alert information that the user needs to know before using the medical device.	Principal/Source/Manufacturer

Precautions-This alerts the user to exercise special care necessary for the safe and effective use of the medical device. This may include actions to be taken to avoid effects on patients/users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects. Potential adverse effects- These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions. Alternative therapy (practices and procedures) (if applicable) - This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the medical device is intended. Raw Materials or formulation. A description of the materials or formulation of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device. Should have a List of all raw materials used as a component of the product (specify for which product part or component the raw material is used) Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. If the device contains PVC, identify the PVC plasticizer used. For kits/sets: submit the raw materials used with specifications of all components in the kit/set. For machines/equipment: The list of raw materials is ONLY required for the machine parts/accessories that: 1) will have a direct contact with the patient; and/or 2) will serve as a channel/conduit for medical	

gases during infusion (i.e. ventilators) - parts that come in direct contact with medical gases for infusion. Other Relevant Specifications to include the following: The functional characteristics and technical performance specifications of the device including, as relevant: accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability, and other factors Other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging. May submit Certificate of Analysis or Test Certificate with finished product specification. For Stability, submit functionality and packaging/integrity test study of the product duly signed by the person who conducted the studies to justify the claimed expiration date. For accelerated study, submit computation to justify the storage conditions used. If no expiration, submit justification from the manufacturer why the device has no expiration. Submit in-use stability study, as applicable. (e.g. contact lens solution, disinfectant) Identify the product's storage condition. For products with special storage conditions, submit transport stability study. For packaging, clarify the type of packaging used. i.e. blister pack, carton box, etc. For medical devices with animal tissue origin, submit Certificate of Compliance with ISO 22442 - Medical devices utilizing animal tissues and their derivatives issued by Government Authority or notified body. Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)	

Summary of Design Verification and Validation Documents: The validation documents shall consist of the following: Declaration/Certificates of Conformity to the product standards issued by the manufacturer Summaries or reports of tests and evaluation based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance covering the following appropriate tests reports and evaluations, whichever is applicable: a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the medical device with reference to the Essential Principles; Engineering test Laboratory test Biocompatibility test Animal Test Simulated Use software validation Pre-clinical studies The following standards shall be considered: Philippine National Standards (PNS), international standards (ISO, IEC) and other equivalent national standards (of these international standards). Philippine National Standard (PNS) ISO Standard or IEC Standard (whichever is applicable) in the absence of PNS. Standard developed by other International Standard Bodies recognized by the DOH, in the absence of PNS, ISO Standard, and IEC Standard. Any foreign standard that may be recognized by the DOH for the purpose of registration in the absence of PNS, ISO Standard, and IEC Standard, and standard developed by other International Standard Bodies recognized by the DOH.	Principal/Source/Manufacturer

. Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging) Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable. For any additional product claims on the label, submit studies or tests supporting the claims. For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name and IPO approval of the said brand name. For local manufactured products, IPO approval of the brand name If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark. Pictures and text of the label should be clear and not be pixelated when the view is increased in size. Lot No., Batch No., Serial No., whichever is applicable, should be reflected. Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected. Storage condition, sterilization method should be reflected if applicable. Importer and distributor's name and address should be reflected in the label of the product together with the Registration Number. Suggested Retail Price (SRP) in Philippine peso. The above requirements shall be superseded upon the approval of Administrative Order for the labeling requirements for medical devices.	Applicant or Principal/Source/Manufacturer
. Risk Analysis to include the results Identify the risk Submit Failure Mode Effect Analysis / Risk Benefit Analysis	Principal/Source/Manufacturer

. Physical Manufacturer information Manufacturing process, including quality assurance measures. This should include the manufacturing methods and procedures, manufacturing environment or conditions, facilities and controls. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing, and packaging of finished medical device. A brief summary of the sterilization method should be included. Include sterilization standard parameters, sterilization procedures, validation protocol and results of latest sterilization revalidation. If the sterilization of the device is contracted out, submit a copy of valid ISO Certificate of the contracted sterilizing company. For non-sterile devices: a) submit Non-sterile declaration from the manufacturer; b) If the device is required to be sterilized prior to use, submit recommended sterilization guidelines from the manufacturer.	Principal/Source/Manufacturer
Payment	FDA Cashier
Documentary requirements must be arranged according to the CSDT format. All documents must be submitted in English language. Documents submitted in any other foreign language not accompanied by a notarized English translation for legal documents and an English translation for technical documents shall be disapproved. Documents to be uploaded should be in PDF searchable format of at least 150 dpi The file name to be uploaded should consist of the name of the requirements Provide table of contents with page number	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME**	PERSON RESPONSIBLE
1. Client sends an email containing the PDF file of their application to cdrrhr-productregistration@fda.gov.ph	1.1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR Officer

following the correct schedule of application.				
	1.2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		Technical Evaluator
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 3 working days.	2 FDA receives the payment from the applicant company for posting	Php 7,575.00	Timeline starts after posting of payment	FDA Cashier
3 The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph	3.1 CDRRHR assigns the application to evaluator	None	1 working day	CDRRHR Administrative Staff
	3.2 The technical evaluator reviews the application. Recommends approval or disapproval.	None	8 working days***	Technical Evaluator
	3.3 Quality Assurance - Checking of recommendation of the Supervisor	None	3 working days	LRD Chief
	3.4 Drafting and finalization of CPR.	None	2 working days	Technical Evaluator

	3.5 Final Approval/Disapproval and E-Signature	None	2 working days	CDRRHR Director
	3.6 Assigning of number and Printing of CMDR. Scanning, barcoding and transmitting of CMDR to the Records Section.		3 working days	CDRRHR Administrative Staff
	3.7 Queuing and endorsement to the FDA Releasing Section		1 working day	AFS Records Officer/Administrative Officer
	TOTAL	Php 7,575.00	20 working days****	

*Refer to the FDA Advisory No. 2021-3084 – Abridged Processing of Applications for Registration/Notification of Medical Devices Approved by the Regulatory Authority of any ASEAN Member Country.

**Day 1 commences upon the receipt of the proof of payment / posting of payment.

***Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

****Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

*****FDA Circular No. 2022-008: Abridged Processing of Application for Registration of Medical Devices Approved by the National Regulatory Authority of Any ASEAN Member Country

12.ISSUANCE OF CERTIFICATE OF MEDICAL DEVICE REGISTRATION (CMDR) FOR CLASS B (INITIAL APPLICATION)

The application for authorization issued for medical devices that fall under Class B.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php7,500.00 + 1% LRF for initial with 5-year validity (Php. 7,575.00) per product

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Notarized Application Form Must be completely and correctly filled-up and signed Must use the latest form prescribed by the CDRRHR for the type of application Must submit one application form with attachment reflecting all the product codes being applied. Furthermore, the grouping of medical device family should be clearly specified. Only one condition should be considered in the multiple CPR application. Must be unedited, non-tampered; and must reflect the correct brand name, medical device name, and device risk-classification.	Applicant. Form may be downloaded from the FDA website.

1 copy of Notarized Agreement / Letter of Authorization. Must be valid; The product being applied must be indicated. For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct. For imported medical devices but the agreement is signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period from the document's issuance, a re-issued agreement/authorization or a notarized attestation by the Principal that the agreement/authorization is still in effect must be submitted. For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized. For locally manufactured medical devices with a toll manufacturer, the agreement between the trader and the manufacturer should be duly notarized.	Principal/Source/Manufacturer
For Imported Medical Devices - 1 copy of government-issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Must be valid Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. For products that are manufactured in multiple sites or toll manufacturers, identify or highlight the product source. The product being applied must be indicated in the scope. For locally manufactured products, submit the valid LTO of the manufacturer	Principal/Source/Manufacturer

4 For imported medical devices, 1 copy of Certificate of Product Registration, CE Certificate or any equivalent document attesting to the safety and effectiveness of the device issued by regulatory agency or accredited notified body in the country of origin. Must be valid The copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.	Principal/Source/Manufacturer
Clear colored picture of the actual commercial product sample of the device for all sides without its packaging, for all codes included in the application. An actual representative sample or commercial presentation can be required by the CDRRHR for verification purposes. Pictures should not be pixelated when the view is increased in size.	Principal/Source/Manufacturer
Technical Requirements	
Executive Summary. The executive summary shall include the following information: an overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features, and a synopsis of the content of the CSDT; the commercial marketing history; the list of regulatory approvals or marketing clearances obtained; the status of any pending request for market clearance; and the important safety/performance related information.	Applicant or Principal/Source/Manufacturer
Relevant essential principles and method/s used to demonstrate conformity. Must be completely filled-up	Principal/Source/Manufacturer

Device description with the following information: Intended use- this refers to the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Indications of use- this is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate; and includes a description of the target patient population for which the medical device is intended. Instruction for use- these are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale use of the medical device, instructions needed to use the medical device in a safe manner shall, to the extent possible, be included on the medical device itself and/or its packaging by other formats/forms. This is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users. Contraindications- This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit. Warnings-This is the specific hazard alert information that the user needs to know before using the medical device.	Principal/Source/Manufacturer

Precautions-This alerts the user to exercise special care necessary for the safe and effective use of the medical device. This may include actions to be taken to avoid effects on patients/users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects. Potential adverse effects- These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions. Alternative therapy (practices and procedures) (if applicable) - This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the medical device is intended. Raw Materials or formulation. A description of the materials or formulation of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device. Should have a List of all raw materials used as a component of the product (specify for which product part or component the raw material is used) Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. If the device contains PVC, identify the PVC plasticizer used. For kits/sets: submit the raw materials used with specifications of all components in the kit/set. For machines/equipment: The list of raw materials is ONLY required for the machine parts/accessories that: 1) will have a direct contact with the patient; and/or 2) will serve as a	

channel/conduit for medical gases during infusion (i.e. ventilators) - parts that come in direct contact with medical gases for infusion. Other Relevant Specifications to include the following: The functional characteristics and technical performance specifications of the device including, as relevant: accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability, and other factors Other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging. May submit Certificate of Analysis or Test Certificate with finished product specification. For Stability, submit functionality and packaging/integrity test study of the product duly signed by the person who conducted the studies to justify the claimed expiration date. For accelerated study, submit computation to justify the storage conditions used. If no expiration, submit justification from the manufacturer why the device has no expiration. Submit in-use stability study, as applicable. (e.g. contact lens solution, disinfectant) Identify the product's storage condition. For products with special storage conditions, submit transport stability study. For packaging, clarify the type of packaging used. i.e. blister pack, carton box, etc. For medical devices with animal tissue origin, submit Certificate of Compliance with ISO 22442 - Medical devices utilizing animal tissues and their derivatives issued by Government Authority or notified body. Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)	

Summary of Design Verification and Validation Documents: The validation documents shall consist of the following: Declaration/Certificates of Conformity to the product standards issued by the manufacturer Summaries or reports of tests and evaluation based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance covering the following appropriate tests reports and evaluations, whichever is applicable: a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the medical device with reference to the Essential Principles; Engineering test Laboratory test Biocompatibility test Animal Test Simulated Use software validation Pre-clinical studies The following standards shall be considered: Philippine National Standards (PNS), international standards (ISO, IEC) and other equivalent national standards (of these international standards). Philippine National Standard (PNS) ISO Standard or IEC Standard (whichever is applicable) in the absence of PNS. Standard developed by other International Standard Bodies recognized by the DOH, in the absence of PNS, ISO Standard, and IEC Standard. Any foreign standard that may be recognized by the DOH for the purpose of registration in the absence of PNS, ISO Standard, and IEC Standard, and standard developed by other International Standard Bodies recognized by the DOH.	Principal/Source/Manufacturer

Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging) Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable. For any additional product claims on the label, submit studies or tests supporting the claims. For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name and IPO approval of the said brand name. For local manufactured products, IPO approval of the brand name If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark. Pictures and text of the label should be clear and not be pixelated when the view is increased in size. Lot No., Batch No., Serial No., whichever is applicable, should be reflected. Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected. Storage condition, sterilization method should be reflected if applicable. Importer and distributor's name and address should be reflected in the label of the product together with the Registration Number. Suggested Retail Price (SRP) in Philippine peso. The above requirements shall be superseded upon the approval of Administrative Order for the labeling requirements for medical devices.	Applicant or Principal/Source/Manufacturer
Risk Analysis to include the results Identify the risk Submit Failure Mode Effect Analysis / Risk Benefit Analysis	Principal/Source/Manufacturer

Physical Manufacturer information Manufacturing process, including quality assurance measures. This should include the manufacturing methods and procedures, manufacturing environment or conditions, facilities and controls. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing, and packaging of finished medical device. A brief summary of the sterilization method should be included. Include sterilization standard parameters, sterilization procedures, validation protocol and results of latest sterilization revalidation. If the sterilization of the device is contracted out, submit a copy of valid ISO Certificate of the contracted sterilizing company. For non-sterile devices: a) submit Non-sterile declaration from the manufacturer; b) If the device is required to be sterilized prior to use, submit recommended sterilization guidelines from the manufacturer.	Principal/Source/Manufacturer
Payment	FDA Cashier
Documentary requirements must be arranged according to the CSDT format. All documents must be submitted in English language. Documents submitted in any other foreign language not accompanied by a notarized English translation for legal documents and an English translation for technical documents shall be disapproved. Documents to be uploaded should be in PDF searchable format of at least 150 dpi The file name to be uploaded should consist of the name of the requirements Provide table of contents with page number	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends an email containing the PDF file of their application to cdrrhr-productregistration@fda.gov.ph	1.1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR Officer

following the correct schedule of application.				
	1.2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		Technical Evaluator
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL) The Order of Payment will only be valid for 3 working days.	2 The FDA receives the payment from the applicant company for posting	Php 7,575.00	Timeline starts after posting of payment	FDA Cashier
3 The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph	3.1 The CDRRHR assigns the application to evaluator	None	2 working days	CDRRHR Administrative Staff
	3.2 The technical evaluator reviews the application. Recommends approval or disapproval.	None	53 working days*	Technical Evaluator
	3.3 Quality Assurance - Checking of recommendation of the Supervisor	None	10 working days	LRD Chief
	3.4 Drafting and finalization of CPR.	None	3 working days	Technical Evaluator

	3.5 Final Approval/Disapproval and E-Signature	None	5 working days	CDRRHR Director
	3.6 Assigning of number and Printing of CMDR. Scanning, barcoding and transmitting of CMDR to the Records Section.		6 working days	CDRRHR Administrative Staff
	3.7 Queuing and endorsement to the FDA Releasing Section		1 working day	AFS Records Officer / Administrative Officer
	TOTAL:	Php 7,575.00	80 working days***	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

13.ISSUANCE OF CERTIFICATE OF MEDICAL DEVICE REGISTRATION (CMDR) FOR CLASS C AND D (ABRIDGED APPROVAL, INITIAL APPLICATION)

The registration of Class C and D medical devices with product approval issued by the NRA of any ASEAN-member country under the AMDD-CSDT requirements, and which are to be imported, distributed, and sold in the Philippines. This shall not cover medical devices with issued Certificate of Product Registration (CPR) based on abridged approval in other countries outside the ASEAN.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php7,500.00 + 1% LRF for initial with 5-year validity (Php. 7,575.00) per product

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Notarized Application Form Must be completely and correctly filled-up and signed Must use the latest form prescribed by the CDRRHR for the type of application Must submit one application form with attachment reflecting all the product codes being applied. Furthermore, the grouping of medical device family should be clearly specified. Only one condition should be considered in the multiple CPR application. Must be unedited, non-tampered; and must reflect the correct brand name, medical device name, and device risk-classification.	Applicant. Form may be downloaded from the FDA website.

1 Copy of Notarized Agreement / Letter of Authorization. Must be valid; For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct. For imported medical devices but the agreements are signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period from the document's issuance, a re-issued agreement/authorization or a notarized attestation by the Principal that the agreement/authorization is still in effect must be submitted. For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized. For locally manufactured medical devices with a toll manufacturer, the agreement between the trader and the manufacturer should be duly notarized.	Principal/Source/Manufacturer
For Imported Medical Devices - 1 copy of government-issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Must be valid. Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. For products that are manufactured in multiple sites or toll manufacturers, identify or highlight the product source. The product being applied must be indicated in the scope. For locally manufactured products, submit the valid LTO of the manufacturer.	Principal/Source/Manufacturer
For imported medical devices, 1 copy of the product approval issued by the NRA of any ASEAN-member country under the AMDD-CSDT requirements. ***** Must be valid. The copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.	Principal/Source/Manufacturer
Clear colored picture of the actual commercial product sample of the device for all sides without its packaging, for all the codes included in the application. An actual representative sample or commercial presentation can be required by the CDRRHR for verification purposes. Pictures should not be pixelated when the view is increased in size.	Applicant or Principal/Source/Manufacturer
Technical Requirements	

Executive Summary. The executive summary shall include the following information: an overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features and a synopsis of the content of the CSDT; the commercial marketing history; the list of regulatory approvals or marketing clearances obtained; the status of any pending request for market clearance; and the important safety/performance related information.	Applicant or Principal/Source/Manufacturer
Relevant essential principles and method/s used to demonstrate conformity. Must be completely filled-up.	Principal/Source/Manufacturer
Device description with the following information: Intended use- this refers to the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Indications of use- this is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the medical device is intended. Instruction for use- this are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale use of the medical device, instructions needed to use the medical device in a safe manner shall, to the extent possible, be included on the medical device itself and/or its packaging by other formats/forms. This is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users. Contraindications- This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit. Warnings-This is the specific hazard alert information that a user needs to know before using the medical device. Precautions-This alerts the user to exercise special care necessary for the safe and effective use of the medical device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life	Principal/Source/Manufacturer

threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects. Potential adverse effects- These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions. Alternative therapy (practices and procedures) (if applicable) - This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the medical device is intended. Raw Materials or formulation. A description of the materials or formulation of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device. Should have a List of all raw materials used as a component of the product (specify for which product part or component the raw material is used). Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. If the device contains PVC, identify the PVC plasticizer used. For kits/sets: submit the raw materials used with specifications of all components in the kit/set. For machines/equipment: The list of raw materials is ONLY required for the machine parts/accessories that: 1) will have a direct contact with the patient; and/or 2) will serve as a channel/conduit for medical gases during infusion (i.e. ventilators) - parts that come in direct contact with medical gases for infusion. Other Relevant Specifications to include the following: j.1 The functional characteristics and technical performance specifications of the device including, as relevant: accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability, and other factors j.2 Other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging. May submit Certificate of Analysis or Test Certificate with finished product specification. For Stability, submit functionality and packaging/integrity test study of the product duly signed by the person who conducted the studies to justify the claimed expiration date. For accelerated study, submit computation to justify the storage conditions used. If no expiration, submit justification from the manufacturer why the device has no expiration. Submit in-use stability study, as applicable. (e.g. contact lens solution, disinfectant) Identify the product's storage condition.	

For products with special storage conditions, submit transport stability study. For packaging, clarify the type of packaging used. i.e. blister pack, carton box, etc. For medical devices with animal tissue origin, submit Certificate of Compliance with ISO 22442 - Medical devices utilizing animal tissues and their derivatives issued by Government Authority or notified body. Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)	
Summary of Design Verification and Validation Documents: The validation documents shall consist of the following: Declaration/Certificates of Conformity to the product standards issued by the manufacturer Summaries or reports of tests and evaluation based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance, such as a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the medical device with reference to the Essential Principles; Data summaries or tests reports and evaluations covering the following appropriate test reports, whichever is applicable: Engineering test, including software validation studies, if applicable Laboratory test Biocompatibility test/biological evaluation Animal Test Simulated Use Clinical evidence Implantable devices Newly introduced devices Devices incorporating new materials coming into contact with the patient Existing materials applied in a body part not previously exposed to that material, and for which no prior chemical experience exists An existing device that is modified and the modification might affect the safety and effectiveness All other medical devices under Class D	Principal/Source/Manufacturer

Clinical evidence of the effectiveness may comprise of medical device-related investigations conducted domestically or other countries, or it may be derived from relevant publications in peer-reviewed scientific literature. The documented evidence submitted should include the objectives, methodology and results presented in context, clearly and meaningfully. The conclusions on the outcome of the clinical studies should be preceded by a discussion in context with the published literature. For Class D medical devices: A bibliography of all published reports dealing with the use, safety, and effectiveness of the device. Submit the most recent published reports for the medical device	
Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging): Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable. For any additional product claims on the label, submit studies or tests supporting the claims. For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name and IPO approval of the said brand name. For local manufactured products, IPO approval of the said brand name If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark. Pictures and text of the label should be clear and will not be pixelated when the view is increase in size Lot No., Batch No., Serial No., whichever is applicable should be reflected Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected Storage condition, sterilization method should be reflected if applicable Importer and distributor's name and address should be reflected in the label of the product together with the Registration Number. Suggested Retail Price (SRP) in Philippine peso. The above requirements shall be superseded upon the approval of Administrative Order for the labeling requirements for medical devices.	Applicant or Principal/Source/Manufacturer
. Risk assessment which consists of risk analysis, evaluation and reduction measures. Identify the risk Submit Failure Mode Effect Analysis (FMEA) / Risk Benefit Analysis Evaluation of the effectiveness of control measures	Principal/Source/Manufacturer
. Physical Manufacturer information:	Principal/Source/Manufacturer

Manufacturing process, including quality assurance measures. This should include the manufacturing methods and procedures, manufacturing environment or conditions, facilities and controls. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing, and packaging of finished medical device. A brief summary of the sterilization method should be included. Include sterilization standard parameters, sterilization procedures, validation protocol and results of latest sterilization revalidation. If the sterilization of the device is contracted out, submit copy of valid ISO Certificate of the contracted sterilizing company. For non-sterile devices: a) submit Non-sterile declaration from the manufacturer; b) If the device is required to be sterilized prior to use, submit recommended sterilization guidelines from the manufacturer.	
Documentary requirements must be arranged according to the CSDT format. Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Provide table of contents with page number	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME**	PERSON RESPONSIBLE
Client sends an email containing the PDF file of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application.	1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR officer
	2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		CDRRHR Evaluator
The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL).	. The FDA receives the payment from the applicant company for posting	PHP7,575.00	Timeline starts after posting of payment	FDA Cashier

The Order of Payment will only be valid for 3 working days.				
The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email.	1	CDRRHR assigns the application to evaluator	None	1 working day	CDRRHR Administrative Staff
	2	The technical evaluator reviews the application. Recommends approval or disapproval.	None	8 working days***	Technical Evaluator
	3	Quality Assurance - Checking of recommendation of the Supervisor	None	3 working days	LRD Chief
	4	Drafting and finalization of CPR.	None	2 working days	Technical Evaluator
	5	Final Approval/Disapproval and E-Signature	None	2 working days	CDRRHR Director
	6	Assigning of number and printing of CMDR. Scanning, barcoding, and transmitting of CMDR to the Records Section.	None	3 working days	CDRRHR Administrative Staff
	7	Queuing and endorsement to the FDA Releasing Section	None	1 working day	AFS Records Officer/ Administrative Officer
		TOTAL:	PHP7,575.00	20 working days****	

*Refer to the FDA Advisory No. 2021-3084 – Abridged Processing of Applications for Registration/Notification of Medical Devices Approved by the Regulatory Authority of any ASEAN Member Country.

**Day 1 commences upon the receipt of the proof of payment / posting of payment.
***Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.
****Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.
*****FDA Circular No. 2022-008: Abridged Processing of Application for Registration of Medical Devices Approved by the National Regulatory Authority of Any ASEAN Member Country

14.ISSUANCE OF CERTIFICATE OF MEDICAL DEVICE REGISTRATION (CMDR) FOR CLASS C AND D (INITIAL APPLICATION)

The application for authorization issued for medical devices that fall under Class C or D.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php7,500.00 + 1% LRF for initial with 5-year validity (Php. 7,575.00) per product

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Notarized Application Form Must be completely and correctly filled-up and signed Must use the latest form prescribed by the CDRRHR for the type of application Must submit one application form with attachment reflecting all the product codes being applied. Furthermore, the grouping of medical device family should be clearly specified. Only one condition should be considered in the multiple CPR application. Must be unedited, non-tampered; and must reflect the correct brand name, medical device name, and device risk-classification.	Applicant. Form may be downloaded from the FDA website.
1 Copy of Notarized Agreement / Letter of Authorization. Must be valid; For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct. For imported medical devices but the agreements are signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period from the document's issuance, a re-issued agreement/authorization or a notarized attestation by the Principal that the agreement/authorization is still in effect must be submitted. For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized.	Principal/Source/Manufacturer

For locally manufactured medical devices with a toll manufacturer, the agreement between the trader and the manufacturer should be duly notarized.	
For Imported Medical Devices - 1 copy of government-issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Must be valid. Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. For products that are manufactured in multiple sites or toll manufacturers, identify or highlight the product source. The product being applied must be indicated in the scope. For locally manufactured products, submit the valid LTO of the manufacturer.	Principal/Source/Manufacturer
For imported medical devices, 1 copy of Certificate of Product Registration, CE Certificate or any equivalent document attesting to the safety and effectiveness of the device issued by regulatory agency or accredited notified body in the country of origin. Must be valid. The copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. USA FDA 510K and PMA (Post Market Approval), Online registry from the Singapore HAS, and EC Full Quality Assurance and Design Verification Certificate	Principal/Source/Manufacturer
Clear colored picture of the actual commercial product sample of the device for all sides without its packaging, for all the codes included in the application. An actual representative sample or commercial presentation can be required by the CDRRHR for verification purposes. Pictures should not be pixelated when the view is increased in size.	Applicant or Principal/Source/Manufacturer
Technical Requirements	
Executive Summary. The executive summary shall include the following information: an overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features and a synopsis of the content of the CSDT; the commercial marketing history; the list of regulatory approvals or marketing clearances obtained; the status of any pending request for market clearance; and the important safety/performance related information.	Applicant or Principal/Source/Manufacturer

Relevant essential principles and method/s used to demonstrate conformity. Must be completely filled-up.	Principal/Source/Manufacturer
Device description with the following information: Intended use- this refers to the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Indications of use- this is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the medical device is intended. Instruction for use- this are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale use of the medical device, instructions needed to use the medical device in a safe manner shall, to the extent possible, be included on the medical device itself and/or its packaging by other formats/forms. This is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users. Contraindications- This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit. Warnings-This is the specific hazard alert information that a user needs to know before using the medical device. Precautions-This alerts the user to exercise special care necessary for the safe and effective use of the medical device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects. Potential adverse effects- These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions.	Principal/Source/Manufacturer

Alternative therapy (practices and procedures) (if applicable) - This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the medical device is intended. Raw Materials or formulation. A description of the materials or formulation of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device. Should have a List of all raw materials used as a component of the product (specify for which product part or component the raw material is used). Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. If the device contains PVC, identify the PVC plasticizer used. For kits/sets: submit the raw materials used with specifications of all components in the kit/set. For machines/equipment: The list of raw materials is ONLY required for the machine parts/accessories that: 1) will have a direct contact with the patient; and/or 2) will serve as a channel/conduit for medical gases during infusion (i.e. ventilators) - parts that come in direct contact with medical gases for infusion. Other Relevant Specifications to include the following: j.1 The functional characteristics and technical performance specifications of the device including, as relevant: accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability, and other factors j.2 Other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging. May submit Certificate of Analysis or Test Certificate with finished product specification. For Stability, submit functionality and packaging/integrity test study of the product duly signed by the person who conducted the studies to justify the claimed expiration date. For accelerated study, submit computation to justify the storage conditions used. If no expiration, submit justification from the manufacturer why the device has no expiration. Submit in-use stability study, as applicable. (e.g. contact lens solution, disinfectant) Identify the product's storage condition. For products with special storage conditions, submit transport stability study. For packaging, clarify the type of packaging used. i.e. blister pack, carton box, etc. For medical devices with animal tissue origin, submit Certificate of Compliance with ISO 22442 - Medical devices utilizing animal tissues and their derivatives issued by Government Authority or notified body.	

Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)	
Summary of Design Verification and Validation Documents: The validation documents shall consist of the following: Declaration/Certificates of Conformity to the product standards issued by the manufacturer Summaries or reports of tests and evaluation based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance, such as a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the medical device with reference to the Essential Principles; Data summaries or tests reports and evaluations covering the following appropriate test reports, whichever is applicable: Engineering test, including software validation studies, if applicable Laboratory test Biocompatibility test/biological evaluation Animal Test Simulated Use Clinical evidence: Implantable devices Newly introduced devices Devices incorporating new materials coming into contact with the patient Existing materials applied in a body part not previously exposed to that material, and for which no prior chemical experience exists An existing device that is modified and the modification might affect the safety and effectiveness All other medical devices under Class D	Principal/Source/Manufacturer

Clinical evidence of the effectiveness may comprise of medical device-related investigations conducted domestically or other countries, or it may be derived from relevant publications in peer-reviewed scientific literature. The documented evidence submitted should include the objectives, methodology and results presented in context, clearly and meaningfully. The conclusions on the outcome of the clinical studies should be preceded by a discussion in context with the published literature. For Class D medical devices: A bibliography of all published reports dealing with the use, safety, and effectiveness of the device. Submit the most recent published reports for the medical device	
Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging): Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable. For any additional product claims on the label, submit studies or tests supporting the claims. For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name and IPO approval of the said brand name. For local manufactured products, IPO approval of the said brand name If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark. Pictures and text of the label should be clear and will not be pixelated when the view is increase in size Lot No., Batch No., Serial No., whichever is applicable should be reflected Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected Storage condition, sterilization method should be reflected if applicable Importer and distributor's name and address should be reflected in the label of the product together with the Registration Number. Suggested Retail Price (SRP) in Philippine peso. The above requirements shall be superseded upon the approval of Administrative Order for the labeling requirements for medical devices.	Applicant or Principal/Source/Manufacturer
. Risk assessment which consists of risk analysis, evaluation and reduction measures. Identify the risk Submit Failure Mode Effect Analysis (FMEA) / Risk Benefit Analysis Evaluation of the effectiveness of control measures	Principal/Source/Manufacturer

. Physical Manufacturer information: Manufacturing process, including quality assurance measures. This should include the manufacturing methods and procedures, manufacturing environment or conditions, facilities and controls. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing, and packaging of finished medical device. A brief summary of the sterilization method should be included. Include sterilization standard parameters, sterilization procedures, validation protocol and results of latest sterilization revalidation. If the sterilization of the device is contracted out, submit copy of valid ISO Certificate of the contracted sterilizing company. For non-sterile devices: a) submit Non-sterile declaration from the manufacturer; b) If the device is required to be sterilized prior to use, submit recommended sterilization guidelines from the manufacturer.	Principal/Source/Manufacturer
Documentary requirements must be arranged according to the CSDT format. Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Provide table of contents with page number	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends an email containing the PDF file of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application.	1.1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR officer
	1.2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		CDRRHR Evaluator

2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 3 working days.	2 FDA receives the payment from the applicant company for posting	PHP7,575.00	Timeline starts after posting of payment	FDA Cashier
3 The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email.	3.1 CDRRHR assigns the application to evaluator.	None	2 working days	CDRRHR Administrative Staff
	3.2 The technical evaluator reviews the application. Recommends approval or disapproval.	None	83 working days**	Technical Evaluator
	3.3 Quality Assurance - Checking of recommendation of the Supervisor	None	10 working days	LRD Chief
	3.4 Drafting and finalization of CPR.	None	3 working days	Technical Evaluator
	3.5 Final Approval/Disapproval and E- Signature	None	5 working days	CDRRHR Director
	3.6 Assigning of number and printing of CMDR. Scanning, barcoding, and transmitting of CMDR to the Records Section.	None	6 working days	CDRRHR Administrative Staff

	3.7 Queuing and endorsement to FDA Releasing Section	None	1 working day	AFS Records Officer/ Administrative Officer
	TOTAL	PHP7,575.00	110 working days***	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

15.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR EQUIPMENT/DEVICES USED TO TREAT SHARPS, PATHOLOGICAL AND INFECTIOUS WASTES (INITIAL APPLICATION)

The application for authorization issued for equipment/devices used to treat sharps, pathological and infectious wastes.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Manufacturers/Distributors/TSD Facility A) Below Php 1,000,000.00: 5,000 + 1% LRF = Php5,050.00 B) Php 1,000,000 – Php 5,000,000: 8,000 + 1% LRF = Php8,080.00 C) Above Php 5,000,000: 10,000 + 1% LRF = Php10,100.00 Healthcare Waste Generators: 3,000 + 1% LRF = Php3,030.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Properly and completely filled-up application form Must be signed by the company representative and dated Location of Installation shall be filled-up since the equipment will be inspected and tested for performance evaluation.	Applicant. Form may be downloaded from the FDA website.

Copy of SEC Articles of Incorporation or DTI Certificate of Business Registration The activity of manufacturing, importing or distributing the equipment should be reflected in the Articles of Incorporation The DTI Certificate of Business Registration must be valid.	Applicant
Technology Approval from DOST-ITDI for new technologies	Applicant
Technical Report:	
4.1. Company profile;	Applicant
4.2. Characteristics and Sources of generated waste;	Applicant
4.3. Detailed description of treatment equipment to be tested including manufacturer's instructions and technical specifications;	Applicant
4.4. Operating procedures and conditions including as applicable treatment time, pressure, temperature, chemical concentration, doses, feed rates and waste load composition;	Applicant
4.5. Storage, handling and volume capacity;	Applicant
4.6. Applicable emission controls for suspected emissions;	Applicant
4.7. Potential hazards/toxicities of waste residues;	Applicant
4.8. Energy efficiency	Applicant
4.9. Occupational safety and health assurance.	Applicant
Copy of Operation Manual	Applicant
Layout / Plans	Applicant
6.1. Location of installation;	Applicant
6.2. Design / Drawing or picture of the device / equipment applied for;	Applicant
Supplementary requirements for equipment / devices used for chemical disinfection:	Applicant
7.1. Material Safety Data Sheet (MSDS) of the chemicals to be used for disinfection	Applicant
7.2. The chemical to be used should be registered with the DENR-EMB or must be compliant with the WHO guidelines for hazardous wastes.	Applicant

For healthcare waste generators (e.g. hospitals) and Treatment, Storage and Disposal (TSD) Facilities, the Environmental Compliance Certificate (ECC) issued by the Environmental Management Bureau-Department of Environment and Natural Resources (EMB-DENR) and the License to Operate issued by the Department of Health shall be submitted together with the above documentary requirements. - License to Operate should be valid	Applicant
Copy of valid License to Operate (LTO)	Applicant
Notes: . This office shall not accept applications with incomplete requirements. . All documents should be submitted in electronic copy format. . All information contained in this application form will be held strictly confidential.	
*Submission schedule is every Friday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule.	1.1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None	Timeline starts after posting of payment	CDRRHR Officer
	1.2 Pre-assessment and issuance of Order of Payment or Denial Letter. (10 working days)			Technical Evaluator

2 The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 3 working days.	2. FDA receives the payment from the applicant company for posting.	Below Php 1,000,000.00: 5,000 + 1% LRF = Php5,050.00 Php 1,000,000 – Php 5,000,000: 8,000 + 1% LRF = Php8,080.00 Above Php 5,000,000: 10,000 + 1% LRF = Php10,100.00 Healthcare Waste Generators: 3,000 + 1% LRF = Php3,030.00		FDA Cashier
3 The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email	3.1 The CDRRHR will assign the application to evaluator	None	2 working days	CDRRHR Admin Staff
.	3.2 Technical evaluation of application. Issuance of a Notice of Deficiencies or endorsement.	None	20 working days	Technical Evaluator

4. Client complies with the Notice of Deficiencies *Clients are given 30 days to comply with the NOD. Non-compliance would mean disapproval of the application.	4.1 Evaluator reviews compliance documents. Once fully complied, endorsed to NRL for Performance Evaluation.	None	11 working days	Technical Evaluator
	Performance Testing	c/o NRL	Timeline depends on the NRL Procedure	c/o EAMC-NRL
	4.2 Review of Performance Evaluation report	None	5 working days	Technical Evaluator
	4.3 Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief
	4.4 Drafting and finalization of CPR.	None	2 working days	Administrative Officer
	4.5 Final Approval/Disapproval and signature of the Director	None	2 working days	CDRRHR Director
	4.6 Assigning of number and printing of certificate. Transmital to Record Section	None	1 working day	CDRRHR Administrative Staff
	4.7 Scanning and Barcoding of CPR. Queuing and Endorsement to Releasing Section.	None	2 working days	AFS Records Officer / Administrative Officer
	TOTAL	Php5,050.00/ Php8,080.00/	50 working days**	

		Php10,100.00/ Php3,030.00		

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

16.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR IN-VITRO DIAGNOSTIC DEVICES/REAGENTS (IVD) (INITIAL APPLICATION)

The application for authorization issued for In Vitro Diagnostic Devices or Reagents.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php1,500.00 + 1% LRF for initial with 1-year validity* Additional Php1,000.00 + 1% LRF if the product is for the detection of HCG (pregnancy test kit), which requires performance evaluation testing *Cost does not include the performance evaluation test; cost of testing depends on the corresponding National Reference Laboratory (NRL).

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Table of Contents with correct page number	Applicant
Notarized Application Form Must be completely filled-up; Model / Reference Number / Sizes / Codes must be properly identified; Refrain from indicating the Brand name (if applicable) on the Name of the product and vice versa For kits/sets, identify the complete contents/inclusions on the space provided for device name; For multiple models / reference number / size / codes, an annex page may be attached; For multiple models / reference number / size / codes; a Word copy must be submitted Should be signed by the proper authority as indicated on the form; Re-using forms is not acceptable since this is a legal document.	Applicant Form may be downloaded from the FDA website.

License to Operate (LTO) as a Medical Device Distributor (Importer/ Exporter/ Wholesaler)/ Local Manufacturer/Trader. Shall be valid The principal shall be reflected on the list of sources.	Applicant
Government Certificate of Clearance and Free Sale/Registration approval from the country of origin issued by the Health Authority Shall be valid Shall be authenticated/apostilled by the territorial Philippine Consulate for Imported Product. For products with a trade name or reference code that differs per country, submit declaration or clarification from the manufacturer/principal. The product shall be stated on the list.	Principal/Source/ Manufacturer
For Imported Products - government issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Shall be valid Shall be authenticated/apostilled by the territorial Philippine Consulate For products that are manufactured in multiple sites or toll manufacturers, identify or highlight where the product will be sourced from. The product being applied must be indicated in the scope. For locally manufactured products, valid LTO of the manufacturer	Principal/Source/ Manufacturer

Foreign Agency Agreement / Letter of Authorization. Shall be valid. Shall be authenticated/apostilled by the territorial Philippine Consulate. The product being applied must be indicated. For imported medical devices but the agreements are signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period, a re-issued agreement/authorization must be submitted or a notarized attestation by the Principal that the agreement/authorization is still in effect. For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized. For locally manufactured medical devices with toll manufacturer, agreement between the trader and the manufacturer should be duly notarized.	Applicant or Principal/Source/Manufacturer
Technical Requirements	
Intended use and Directions for Use which includes the following Intended use - this refers to the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Indications of use - this is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the medical device is intended. Instruction for use - these are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale use of the	Principal/Source/Manufacturer

medical device, instructions needed to use the medical device in a safe manner shall, to the extent possible, be included on the medical device itself and/or its packaging by other formats/forms. This is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users. Contraindications - This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit. Warnings - This is the specific hazard alert information that a user needs to know before using the medical device. Precautions - This alerts the user to exercise special care necessary for the safe and effective use of the medical device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects. Potential adverse effects- These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions. Intended purpose, including the following information: Type of analyte or measure of the assay. Whether the test is quantitative or qualitative. Role of the test in the clinical use e.g. screening, diagnostic or detection, aid to diagnostic, monitoring. Disease or condition that the test is intended for. Type of specimen to be used e.g. serum, plasma etc. The intended users (e.g. Self-testing by lay person, near- patient by trained personnel or professionals). Assay type e.g. immunoassay, chemistry, cytochemistry, image analysis, immunohistochemistry. The specific name of the instrument required for the assay, if any.	

Test principle. Specimen type. Conditions for collection, handling, storage and preparation of the specimen. Reagent description and any limitation (e.g. use with a dedicated instrument only). Metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order. Assay procedure including calculations and interpretation of results. Information on interfering substances that may affect the performance of the assay. Performance characteristics (summarized analytical and diagnostic sensitivity, specificity, reproducibility, etc.) Reference intervals. Study design (population studies, N, type of sample, matrix, dilution, target concentrations, etc.).	
List of all raw materials used as components of the reagents/test kit Product part or component where the raw material is used shall be specified Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. If the product contains PVC, identify the PVC plasticizer used. For kits/sets submit all raw materials and specifications used.	Principal/Source/Manufacturer
Technical specifications of the Finished Product	Principal/Source/ Manufacturer

. Analytical and clinical performance studies to support IVD performance claims: Specimen type (suitability, collection, storage and transport stability) Equivalence between specimen types Analytical performance characteristics accuracy trueness and bias precision (repeatability and reproducibility) Analytical sensitivity (limit of detection, detection of variants) Analytical specificity (interference and cross-reactivity) Measuring range of the assay Validation of assay cut-off Validation of assay reading time Complete performance study to justify all the claims on the package insert	Principal/Source/Manufacturer
. Brief description of the manufacturing procedure/flowchart which shall include the ff: methods used in the facility controls in the manufacture processing packaging process flowchart showing an overview of production	Principal/Source/Manufacturer
. Risk Analysis to include the results Identify the risk Submit Failure Mode Effect Analysis	Principal/Source/Manufacturer
. Stability test data and results which shall include: shelf life study in-use stability study shipping stability studies to justify claimed shelf life Note: - Shall be performed on at least three (3) different product lots.	Principal/Source/Manufacturer

- For accelerated study, indicate storage conditions, duration of study and computation to justify the storage condition used.	
. Labeling materials Immediate label secondary packaging box label package insert/brochure. shall include blood sample collection and handling performance study results and summary cross reactivity and list of potential interfering substances (if applicable) warnings and precautions information of the manufacturer revision number	Principal/Source/ Manufacturer
. For pregnancy test kit, 15 samples of the same lot with at least nine (9) months expiration date. NOTE: For other IVD applications, samples will be submitted directly to the respective NRLs. Number of samples required will depend on the requirement of each NRL. Take note that the labeling materials for all the samples should be complete and the same.	Applicant
16. Evidence of registration fee/payment (charge slip/official receipt)	FDA Cashier
All documents shall be submitted in English language. Documents submitted in any other foreign language not accompanied by English Translation shall be disapproved. Submit an electronic/scanned copy (in PDF searchable format of at least 150dpi). The soft copy shall be arranged according to the checklist of requirements. The file name shall consist of the name of the requirement. The electronic copy shall be contained either in one single continuous file per requirement or single continuous file for all requirements. Bring hard copy of the assessment slip.	

Submission schedule will be generated by the FDA and sent thru email to client	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends and email containing the PDF file of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application.	1.1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR Officer
	1.2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		Technical Evaluator
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL) The Order of Payment will only be valid for 3 working days.	2 FDA receives the payment from the applicant company for posting.	Php1,500.00 + 1% LRF for initial with 1-year validity* Additional Php1,000.00 + 1% LRF if the product is for the detection of HCG (pregnancy test) which requires performance evaluation testing.	Timeline starts after posting of payment	FDA Cashier

		Cost does not include the performance evaluation test; cost of testing depends on the corresponding National Reference Laboratory (NRL)		
3. The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email.	3.1 CDRRHR assigns the application to the evaluator.	None	1 working day	CDRRHR Admin Staff
.	3.2 The technical evaluator reviews the application. Recommends approval, disapproval, or notice of deficiency.	None	80 working days**	Technical Evaluator
.	3.3 Endorsement of the application to NRL for performance evaluation.	None	1 working day	Technical Evaluator
.	3.4 Performance Testing	c/o NRL	*Timeline depends on the NRL Procedure	c/o the National Reference Laboratory
	3.5 Review of Performance Evaluation report.	None	5 working days	Technical Evaluator
.	3.6 Quality Assurance - Checking of recommendation of the Supervisor	None	10 working days	LRD Chief

	3.7 Drafting and finalization of CPR.	None	2 working days	Technical Evaluator
.	3.8 Final Approval /Disapproval and signature of the Director	None	2 working days	CDRRHR Director
	3.9 Transmittal to the Records Section.	None	1 working day	CDRRHR Administrative Staff
	3.10 canning and barcoding of CPR. Queuing and endorsement to the FDA Releasing Section.	None	3 working days	AFS Records Officer / Admin Officer
	TOTAL	PHP1,515.00 For HCG pregnancy test kits – additional PHP1,010.00	105 working days***	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

17.ISSUANCE OF CERTIFICATE OF REGISTRATION FOR WATER PURIFICATION DEVICES/SYSTEM (INITIAL APPLICATION)

The application for authorization issued for water purification devices or systems.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Water Treatment Devices: Php500.00 + Php10.00 (1%) LRF per product = Php510.00 Water Treatment System: Php1,000.00 + Php10.00 (1%) LRF per product = Php1,010.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Properly and completely filled-up application form Must be signed by the company representative with date when signed. Claims should only be either for safe drinking water of purified water. Claims such as alkaline, ionized, PI, oxygenated or energized are not acceptable. Latest form should be used.	Applicant. Form may be downloaded from the FDA website.
Copy of SEC Articles of Incorporation or DTI Certificate of Business Registration The activity of manufacturing, importing or distributing the device should be reflected in the Articles of Incorporation The DTI Certificate of Business Registration must be valid.	Applicant

Copy of Mayor's Permit Must be Valid Name and address in the Mayor's Permit should be the same in the application form	Applicant
4. Copy of Operation Manual - Name and model number of the device in the operation manual should be the same with the application form and label	
Layout of devices or flowchart of treatment process. - The lay out or flowchart should show every stage how the water is being treated. - Include a narrative description for every stage or step of the treatment process - Submit a clear and colored photo of the device.	Applicant
6. List of raw materials used as components of the water purification device/system. - Should have a list of the component parts with the corresponding raw material used in the device.	Applicant
Label/labelling/product insert of manufacturer's performance claim Should be clear and readable. Name of the product and model number in the label should be consistent with the name and model number in the application form and operation manual. Name and address of the manufacturer, importer and distributor should be reflected Provide provision for the registration number	Applicant
8. For special claims, data from scientific research and laboratory analysis supporting and proving the claims of the manufacturer of the product	Applicant
9. Copy of valid License to Operate (LTO)	Applicant

NOTE: Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. *Submission schedule is every Friday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application.	1.1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR Officer
	1.2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		Technical Evaluator
2. The applicant company receives the Order of Payment and pays the assessed fee through	2.1 FDA receives the payment from the applicant company for posting.	See above table	Timeline starts after posting of payment	FDA Cashier

	FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). *The Order of Payment will only be valid for 3 working days		Php510.00 / Php1,010.00		
	The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email	2.2 CDRRHR assigns the application to evaluator	None	2 Working days	CDRRHR Administrative Staff
		2.3 Technical evaluation of application. Issuance of a Notice of Deficiencies or endorsement.	None	20 working days	Technical Evaluator
3	Client complies with the Notice of Deficiencies *Clients are given 30 days to comply with the NOD. Non-compliance would mean disapproval of the application.	3.1 Evaluator reviews compliance documents.	None	10 working days	Technical Evaluator
.		3.2 Once fully complied, endorsed to NRL for Performance Evaluation	None	1 working day	Technical Evaluator

.	Performance Testing	c/o NRL	Timeline depends on the NRL procedure	c/o EAMC-NRL
	3.3 Review of Performance Evaluation report	None	5 working days	Technical Evaluator
	3.4 Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief
	3.5 Final Approval/Disapproval and signature of the Director	None	2 working days	CDRRHR Director
	3.6 Printing of CPR and assigning of number. Transmital to Records Section.	None	3 working days	CDRRHR Administrative Staff
.	3.7 Scanning and Barcoding of CPR. Releasing of CPR.	None	2 working days	AFS Records Officer / Administrative Officer
	TOTAL	Php510.00 / Php1,010.00	50 working days**	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

18.ISSUANCE OF CLEARANCE FOR DONATION

The application for FDA clearance to facilitate the requests for, acceptance of, and distribution of all donations (medical devices) to the health sector.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Complex
Type of Transaction	:	G2G - Government-to-Government
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Endorsement letter signed by the Director IV of the DOH-BIHC	Applicant
Folder containing the complete requirements submitted to the DOH-BIHC Letter of intent/request addressed to the BIHC Director Photocopy of the authenticated (or apostilled, if applicable) Deed of Donation by the Philippine Embassy/Consulate in the country of origin Detailed list of items to be donated, to include the following information: For devices- with detailed specifications, brand name, name of equipment, name and address of the manufacturer, expiry date if sterile Photocopy of pertinent certificates/documents, duly authenticated/apostilled from the country of origin, or notarized if locally executed, as required in Annex B (Criteria on the Acceptance of Foreign Donations) For devices- CFS, Certificate of Good Condition, if applicable	Applicant

Photocopy of the shipping documents- include packing list, bill of landing/air waybill/sea waybill, commercial invoice Letter of concurrence/acceptance from the recipient or consignee with strategic plans/development cooperation agenda of the recipient Certificate of no commercial use and given for free or Notarized Affidavit of Undertaking indicating “not for commercial distribution or sale” duly signed by the recipient/consignee Distribution/Allocation List/Plan	
NOTES: Reference: Administrative Order No. 2020-0001: Guidelines in the Importation, Facilitation and Management of Foreign Donations involving Health and Health-Related Products Clients must submit the complete requirements (AO 2020-001 – Annex C) to the Department of Health – Bureau of International Health Cooperation	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. The applicant sends an email containing the PDF of their application to fdac.letters@fda.gov.ph.	1.1 FDAC Receiving Officer sends an acknowledgment email to the client.	None	1 working day	FDAC Officer
	1.2 FDAC forwards the file to CDRRHR.	None		FDAC Officer
	1.3 CDRRHR receives the file and reviews the request. Prepares the certificate or disapproval letter.	None	2 working days	CDRRHR Administrative Staff
	1.4 Quality Assurance - Checking of recommendation of the Supervisor.	None	1 working day	LRD Chief
	1.5 Final Approval/Disapproval and signature of the Director.	None	1 working day	CDRRHR Director

	1.6 Scanning and Transmittal of certificate or disapproval letter to the FDA Records Section.	None	1 working day	CDRRHR Administrative Staff
	1.7 Queuing and Endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL		7 working days**	

19.ISSUANCE OF COMPASSIONATE SPECIAL PERMIT (CSP)

The application for the restricted use of medical devices which are not yet registered or are in the process of registration in the Philippines by patients in need of immediate medical attention.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader, Patient/End-User of Medical Device
Fees to be Paid	:	Php500.00 + Php10.00 LRF per permit

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of intent which will include a brief description of the patient, attending physician, list of specialists who will perform the administration of the medical device, the quantity of the medical device required to perform the treatment and the proposed schedule of the medical attention.	Applicant
Attending physician's profile.	Applicant
3. License to Operate as Medical Device Importer/Distributor if the product is to be supplied by a company.	Applicant
4. Letter of information regarding the importer if the medical device is to be imported by a private individual.	Applicant
5. Certificate of Product Registration from the country of origin of the medical device to be used. If the medical device is locally manufactured, copy of the License to Operate as Medical Device Manufacturer.	Principal/Source/Manufacturer
6. Technical description of the medical device from the manufacturer; not downloaded from the company's website.	Principal/Source/Manufacturer
7. Justification letter from the attending physician regarding the urgency of the use of the medical device.	Applicant
8. Medical abstract of the patient.	Applicant
9. A waiver of FDA responsibility from any damage or injury arising from the use of the unregistered medical device to be signed by the applicant company, a relative of the patient and the attending physician.	Applicant

10. A commitment letter from the applicant that a medical report shall be submitted after the operation or use of the medical device in the patient.	Applicant
Submission schedule is as follows: For companies with names beginning with numbers 0-9 and letters A-M: Every Thursday from 8:00 AM to 5:00 PM. For companies with names beginning with letters N-Z: Every Friday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their application to fdac.letters@fda.gov.ph following the correct schedule.	1 Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client	None	Timeline starts after posting of payment	FDA Officer
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL) The Order of Payment will only be valid for 24 hours.	2 FDA receives the payment from the applicant company for posting	PHP510.00		FDA Cashier
3. The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email.	3.1 FDAC forwards the application to CDRRHR.	None		FDAC Officer

	3.2 Data Controller assigns the application to evaluator.	None	1 working day	Data Controller
	3.3 The technical evaluator reviews the application. Recommends approval/disapproval.	None	2 working days	Technical Evaluator
	3.4 Quality Assurance - Checking of recommendation of the Supervisor	None	1 working day	LRD Chief
	3.5 Final Approval/Disapproval and signature of the Director.	None	1 working day	CDRRHR Director
	3.6 Assigning of number and printing of permit. Scanning and transmitting permit to Records Section.	None	1 working day	Administrative Officer
4 Pick-up of Certificate	4 Queuing and endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Admin Officer
	TOTAL	PHP510.00	7 working days**	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

20. ISSUANCE OF FDA CLEARANCE FOR CUSTOMS RELEASE

Clearance for Customs Release (CFCR) is a document issued upon approval of the CDRRHR allowing and informing the release of regulated imports by the Bureau of Customs.

Center/Office/Division	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	Simple
Type of Transaction	G2B- Government to Business
Who May Avail	Importer/Distributor of Radiation Emitting Devices
Fees to be Paid	PHP 310/ Unit

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1.Written request for issuance of CFCR addressed to the Director of CDRRHR containing the following information documents: Number of units to be imported; Intended use of unit; Name and address of the facility where the unit will be installed (if available)	Applicant
2. A duly notarized letter guaranteeing submission to the CDRRHR of the name and address of the buyer of the device within fifteen (15) days of the sale/transfer of ownership of the device (if name of buyer is unavailable upon application).	Applicant
3.For radiation device item to be used for medical applications, a Certificate of Product Registration (CPR) or any equivalent document certifying that the product is safe and allowed to be sold in the country of origin issued by the Ministry of Health of the country of origin; This document shall be duly authenticated by the Philippine Consulate if the country of origin is a non-apostille member; This document shall be Apostilled if the country of origin is part of the Apostille Convention;	 Philippine Embassy in the country of origin Philippine Embassy in the country of origin Applicant/ Legal Person

If the CPR is unavailable immediately, certificate of free sales and/or a duly notarized letter guaranteeing submission of this document to the CDRRHR, within sixty (60) days from receipt by the CDRRHR of the written request, shall be allowed in lieu of the CPR	

4.	Brochure/ Literature of the device/ devices.	Product Manufacturer
5.	Copy of importer's permit.	Local government where the office of the importer is located
6.	Copy of proforma invoice.	Importer

STEPS FOR THE ISSUANCE OF CLEARANCE FOR CUSTOM RELEASE

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits the required documents to FDA through email.	1.1. Decking of application to the assessor for pre-assessment.	-	-	CDRRHR-RRD Data controller
	1.2. Pre-assessment of the applications and attached documents. *If complete, issue order of payment. **If not complete, assessor will send a notification of lacking documents. ***If the noted deficiencies are not submitted on or before the deadline, the application is denied.	-	-	CDRRHR-RRD Assessor
2. The applicant/authorized officer downloads the issued order of payment and pays the corresponding fee to the FDA recognized payment centers.	2.1. The FDA will receive the payment from the applicant for validation and posting.	PHP 310.00/ unit	-	FDA Cashier
	2.2. Evaluation of application. *If correct, application is recommended for the issuance of CFCR.	-	1 working day	CDRRHR-RRD

	**If not, the evaluator shall notify the applicant of the lacking regulatory requirements. ***If the facility fails to comply within the prescribed period, a Letter of Disapproval shall be sent to the facility.			Evaluator
	2.3. Reviews and recommends the draft CFCR/LOD for printing and final approval/disapproval of the Center Director.	-	1 working day	CDRRHR-RRD QA
	2.4. Approves/disapproves and signs CFCR/LOD.	-	1 working day	CDRRHR Director
	2.5 Endorses the CFCR/LOD to the Records Section for release/for mailing.	-		CDRRHR-RRD Data Controller
	TOTAL:	PHP310.00/ unit	3 working days	
Please be advised that as per RA No.11032 IRR, page 22 of 48, Section 3, b) The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter. Note: *Day 1 commences upon posting of payment.				

21. PRE-OPERATIONAL PERMIT (POP) FOR THERAPEUTIC X-RAY FACILITIES

Pre-operational permit (POP) is an authorization prior to the construction of a therapeutic x-ray facility.

Center/Office/Division	:	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	:	Highly Technical
Type of Transaction	:	G2B- Government to Business
Who May Avail	:	All Therapeutic X-ray Facilities
Fees to be Paid	:	None

CHECKLIST OF REQUIREMENTS	Where to Secure
1. Proof of Business Name and Address of the facility (Mayor's Permit)	Mayor's office from the municipality where the facility is located
2. Design of the medical linear accelerator facility indicating shielding details duly evaluated, verified, and signed by a board-certified ROMP	Equipment Manufacturer
Technical description/specifications of the following equipment: Therapeutic X-ray Machine Treatment planning system Patient data management software if available Radiotherapy simulator or computed tomography simulator, All other equipment listed in Appendix V of AO 2013-0031 or as revised	Equipment Manufacturer
Certification issued by the equipment manufacturer That the Therapeutic X-ray machine in its present condition is compliant with the performance and safety requirements of the International Atomic Energy Agency (IAEA) and the International Organization for Standardization / International Electrotechnical Commission (ISO/IEC) On the availability of spare parts, maintenance, and repair services.	Equipment Manufacturer

Personnel requirements: Notarized contract of employment between the facility and: The radiation oncologist/s The certified radiation oncology medical physicist The radiation oncology medical physicist The four (4) radiologic technologists	Human Resource Department of the Applicant
Radiation Protection and Safety Program	Applicant (in coordination with the Radiation Protection Committee of the hospital)
Emergency procedures during testing, commissioning, internal, and external quality audit, and during clinical operation, including a system of reporting a radiological accident/incident	Applicant (in coordination with their in-house Radiation Oncology Medical Physicist)
Emergency preparedness and response plan in the event of radiological emergencies such as: Accident medical exposure of a patient Accident exposure of a worker Accident exposure of a member of a public	Applicant (in coordination with their in-house Radiation Oncology Medical Physicist)

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits the required documents to FDA through email.	1.1. Decking of application to the evaluator for evaluation.	-	-	CDRRHR-RRD Data controller

	1.2. Evaluates the application documents. *If complete and correct, draft POP for quality assurance. **If not, the evaluator shall notify the applicant of the lacking regulatory requirements. ***If the facility fails to comply within the prescribed period, a Letter of Disapproval (LOD) shall be sent to the facility.	-	5 working days	CDRRHR-RRD Evaluator/ Technical Officer
	1.3. Reviews and recommends the POP/LOD for approval to the Center Director.	-	10 working days	CDRRHR-RRD QA
	1.4. Approves/disapproves and signs POP/LOD.	-	3 working days	CDRRHR Director
	1.5 Encodes and endorses the approved POP/LOD to Records Section for releasing/for mailing.	-	2 working days	CDRRHR-RRD Data Controller/AFS Records Personnel
	TOTAL:	None	20 working days	
Please be advised that as per RA No.11032 IRR, page 22 of 48, Section 3, b) The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.				

22. ISSUANCE OF SALES PROMO PERMIT (INITIAL APPLICATION)

The application for permit for the conduct of sales promotion schemes for medical devices.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Complex
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	NCR and other regions with prize ranging from Php1.00 to Php 300,000: Php1,000.00 + 1% LRF per certification; NCR and other regions with prize ranging from above Php300,000 to Php500,000: Php2,000.00 + 1% LRF per certification; NCR and other regions with prize ranging from Php500,000 to 1M: Php3,000.00 + 1% LRF per certification; NCR and other regions with prize ranging from above 1M: Php5,000.00 + 1% LRF per certification

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Letter of Intent for application of Promo Permit Include in the letter if an FDA representative is needed during the raffle date	Applicant/Advertising Agency
Accomplished Information Sheet and Mechanics of the Promotion Detailed list of promo mechanics with date/venue of raffle, prizes, and number of winners if applicable Detailed description on how the winner shall be chosen Promo duration is a must, “while supplies last is unacceptable”	Applicant/Advertising Agency
Copy of the valid product notification/registration/exemption For CMDN’s/CMDR’s currently undergoing the Amendment/Variation process, a letter of approval must be secured by the company prior to promo application.	Distributor/Importer/Manufacturer
Advertising/ Collateral Materials to be used in the Promotion The DOH-FDA promo permit number must be indicated.	Applicant

Valid License to operate as distributor/importer/manufacturer	Distributor/Importer/Manufacturer
Proof of payment	FDA Cashier
Self-Assessment Form	Applicant
Accomplished Integrated Application Form.	Applicant
List of participating products in Excel Format.	Applicant
Submission schedule is as follows: > For companies with names beginning with numbers 0-9 and letters A-M: Every Thursday from 8:00 AM to 5:00 PM. > For companies with names beginning with letters N-Z: Every Friday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their application to fdac.pacd@fda.gov.ph following the correct schedule. Note: Refer to FDA Circular No. 2020-026	1 Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client	None	Timeline starts after posting of payment	FDAC Officer

2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL)*The Order of Payment will only be valid for 24 hours.	2 The FDA Personnel receives the payment from the applicant company for posting	See above table Php1,010.00/ Php2,020.00/ Php3,030.00/ Php5,050.00		FDA Cashier
3. The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email	3.1 FDAC forwards the application to CDRRHR.	None		FDAC Officer
	3.2 CDRRHR assigns the application to evaluator	None	1 working day	CDRRHR Administrative Staff
	3.3 The technical evaluator reviews the application. Recommends approval or disapproval.	None	2 working days	Technical Evaluator
	3.4 Quality Assurance - Checking of recommendation of the Supervisor	None	2 working days	LRD Chief
	3.5 Final Approval/Disapproval and signature of the Director.	None	1 working day	CDRRHR Director
	3.6 Assigning number and Printing of permit. Scanning and transmittal of the permit to the Records Section.	None	1 working day	CDRRHR Administrative staff
Pick-up of Certificate	4 Queuing and endorsement to the FDA Releasing Section	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	Php1,010.00/ Php2,020.00/ Php3,030.00/ Php5,050.00	7 working days	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

23. ISSUANCE OF SPECIAL COVID CERTIFICATION (INITIAL APPLICATION AND RE-ISSUANCE)

The application for special certificate issued for COVID-19 test kits.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php 500.00 + 1% LRF per certificate

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Letter of intent regarding exemption of the device/product from registration	Applicant
Valid License to Operate as a Medical Device Distributor/Importer/Exporter	Applicant
Product registration issued by the regulatory agency or their accredited third party from the countries with established regulation such as but not limited to US Food and Drug Administration, Therapeutic Goods Authority, European Union, Health Science Authority, Pharmaceutical and Medical Device Authority, Ministry of Food and Drug Safety (Korea), and Health Canada, or WHO pre-qualification or EUL.	Applicant / Principal/Manufacturer
Product profile/IFU indicating the specificity and sensitivity of the COVID-19 test kit.	Applicant / Principal/Manufacturer
NOTES: Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. The applicant company sends and email to fdac.letters@fda.gov.ph. The e-mail should contain the complete application requirements.	1. Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client.	None		FDAC Officer
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 24 hours. The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email.	2.1 FDAC receives the payment from the applicant company for posting. FDAC forwards the application to CDRRHR.	P510	Timeline starts after posting of payment	FDAC Officer
	2.2 CDRRHR receives the application and decks the file to the evaluator.	None	1 working day	CDRRHR Administrative Staff
	2.3 Technical evaluation of application. Recommendation for approval/disapproval/endorsement letter to the NRL for performance testing.	None	13 working days	Technical Evaluator

	2.4 Quality Assurance - Checking of recommendation of the Supervisor.	None	3 working days	LRD Chief
	2.5 Final Approval/Disapproval and signature of the Director.	None	2 working days	CDRRHR Director
	2.6 Scanning and transmittal of certificate or letter to the FDA Records Section.	None	1 working day	CDRRHR Administrative Staff
	2.7 Queuing and endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL		20 working days**	

24.MANUAL APPLICATION OF RADIATION FACILITIES

24.1. ISSUANCE OF CERTIFICATE OF COMPLIANCE (COC)

Certificate of Compliance (COC) is a form of authorization/permission granted by the FDA which serves as proof of the facility's compliance to the set technical requirements. It is a prerequisite for the issuance of the DOH-LTO.

Center/Office/Division	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	Highly Technical
Type of Transaction	G2B- Government to Business
Who May Avail	All Medical and Non-Medical X-ray Facilities under One-Stop-Shop Licensing System
Fees to be Paid	Refer to table below

mA RANGE	INITIAL (3 years)	RENEWAL (5 years)	Renewal of Expired Authorization				
			1st Month	2nd Month	3rd Month	4th Month	> 4 months
100 and below	2430.00	2050.00	6250.00	6450.00	6650.00	6850.00	7230.00
101 up to 300	3333.00	2800.00	8575.00	8575.00	9125.00	9400.00	9933.00
301 up to 500	4242.00	3550.00	10900.00	11250.00	11600.00	11950.00	12642.00
501 up to 700	5151.00	4300.00	13225.00	13650.00	14075.00	14500.00	15351.00
greater than 700	6060.00	5050.00	15550.00	16050.00	16550.00	17050.00	18060.00

CERTIFICATE OF COMPLIANCE DOCUMENTARY REQUIREMENTS

MEDICAL X-RAY FACILITY

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Duly accomplished medical x-ray license application form **(Initial/ Renewal)**	Applicant
2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
3. VALID Professional Regulation Commission (PRC) license of all the radiologist/s and radiologic/x-ray technologist/s. **(Initial & Renewal)**	Professional Regulation Commission
4. Certificate of all the radiologist/s for being a Fellow of the Philippine College of Radiology (FPCR) or Diplomate of the Philippine Board of Radiology (DPBR) **(Initial & Renewal)**	Philippine College of Radiology
5. For Radiologic/ X-ray Technologist who will act as the radiation protection officer, certificate of training on radiation protection as proof that he completed the RPO training. **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
6. For Medical Physicist who will act as the radiation protection officer (RPO), photocopy of the documentary evidence satisfying the provisions stated in section 2.29 of AO No. 35 s. 1994. **(Initial & Renewal with changes in RPO)**	Applicant
7. Photocopy of performance test report from FDA – CSL/DTI – PAB accredited testing body (CT-Scan and Mammography) **(Initial &** Amendment)	FDA – CSL/DTI – PAB accredited testing body service providers
8. Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
9. Machine Calibration Report duly signed by the Service Engineer **(Initial &** Major Variation)	Service Engineer of the facility/ supplier/ third party service providers
10. Photocopy of the latest DOH License to Operate (LTO) /Certificate of Accreditation (COA). **(Renewal Only)**	Applicant
11. Duly filled-up and notarized affidavit of continuous compliance. **(Renewal Only)**	Applicant

DENTAL X-RAY FACILITY

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Duly accomplished application form **(Initial & Renewal)**	Applicant
2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
3. Certificate of training of the dentist and/or radiologic/x-ray technologist in radiation protection for radiation safety officers of dental x-ray facilities conducted by an organization recognized by CDRRHR (Initial & Renewal Application with new/changed RPO)	Recognized training provider of FDA
4. VALID Professional Regulation Commission (PRC) license of all the radiologist/s and radiologic/x-ray technologist/s. **(Initial & Renewal)**	Professional Regulation Commission
5. Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
6. Machine Calibration Report duly signed by the Service Engineer **(Initial & Major Variation)** (except Periapical Machine)	Service Engineer of the facility/ supplier/ third party service providers
7. Photocopy of performance test report from FDA – CSL/DTI – PAB accredited testing body **(Initial Applications for CBCT)**	FDA – CSL/DTI – PAB accredited testing body service providers
8. Photocopy of the latest DOH License to Operate (LTO) /Certificate of Accreditation (COA). **(Renewal Only)**	Applicant
9. Duly filled-up and notarized affidavit of continuous compliance. **(Renewal Only)**	Applicant

24.2.ISSUANCE OF CERTIFICATE OF REGISTRATION (COR) FOR MAGNETIC RESONANCE IMAGING

Refers to Non-ionizing Radiation Facility and device that uses radiofrequency radiation devices that produces (either deliberately or incidentally) radiofrequency energy during the course of their operation. It uses strong magnetic fields, magnetic field gradients and radio waves to generate images of the organs of the body for diagnosis human diseases.

Center/Office/Division	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	Highly Technical
Type of Transaction	G2B- Government to Business
Who May Avail	All Magnetic Resonance Imaging (MRI) Facilities
Fees to be Paid	Refer to table below

INITIAL (3 years)	RENEWAL (5 years)	Renewal of Expired COR				
		1st Month	2nd Month	3rd Month	4th Month	> 4 months
6060.00	5050.00	15550.00	16050.00	16550.00	17050.00	18060.00

CERTIFICATE OF REGISTRATION (COR) DOCUMENTARY REQUIREMENTS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Duly accomplished MRI registration form **(Initial/ Renewal)**	Applicant
2. VALID Professional Regulation Commission (PRC) license of all the radiologist/s and radiologic technologist/s. **(Initial & Renewal)**	Professional Regulation Commission
3. Photocopy of the certificate of all the radiologist/s for being a Fellow of the Philippine College of Radiology (FPCR) or Diplomate of the Philippine Board of Radiology (DPBR)**. (Initial & Renewal)**	Philippine College of Radiology
4. Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
6. Radiofrequency/Magnetic Field map. **(Initial Only)**	Applicant
7. Photocopy of the latest Certificate of Registration. **(Renewal Only)**	Applicant

24.3.ISSUANCE OF LTO FOR THERAPEUTIC X-RAY FACILITY (Utilizing LINAC)

License to Operate issued to an x-ray facility utilizing Linear Accelerator, Tomotherapy, Intraoperative Radiation Therapy or any other radiation devices that are used for treatment of cancer diseases.

Center/Office/Division	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	Highly Technical
Type of Transaction	G2B- Government to Business
Who May Avail	All Therapeutic X-ray Facilities
Fees to be Paid	Refer to table below

INITIAL (3 years)	RENEWAL (5 years)	Renewal of Expired LTO				
		1st Month	2nd Month	3rd Month	4th Month	> 4 months
6060.00	5050.00	15550.00	16050.00	16550.00	17050.00	18060.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Pre-operational Permit (POP) **(Initial only)**	Applicant
2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
3. PROS or PBR-RO certificate/s and valid professional regulation commission (PRC) license/s of all the radiation oncologist/s working in the therapeutic x-ray facility **(Initial & Renewal)**	Philippine Radiation Oncology Society/ Philippine Board of Radiology in Radiation Oncology
4. PRC board certificates and valid PRC licenses of all the radiotherapy technologists and their certificates of training as prescribed in Section VI-A-4.3 of the A.O. No. 0031 series of 2013 or as revised **(Initial & Renewal)**	Professional Regulation Commission

5. Philippine Board of Medical Physics certificate/s of all the Radiation Oncology Medical Physicist (ROMP). For non-board ROMPs, documentary evidence satisfying the provisions stated in Section XV-C-2 of the A.O. No. 0031 series of 2013 **(Initial & Renewal)**	Training Certificates- Senior Radiotherapy Technologist/ Certified Medical Physicist- Radiation Oncology Medical Physicist of the facility, Supplier's application specialist, Professional Organization of Radiologic Technologists
6. Valid notarized contract of employment between the facility and the radiation oncologist/s, radiation oncology medical physicist/s, and radiotherapy technologists **(Initial & Renewal)**	Applicant
7. Notarized appointment of the Radiation Protection Officer (RPO) and Assistant RPO **(Initial & Renewal)**	Applicant
8. Where applicable, proof of qualification/recognition as a Qualified Expert (Initial & Renewal)	Philippine Board of Medical Physics
9. Acceptance Test Certificate signed by the technical representative of the equipment manufacturer/supplier and board-certified ROMP (if available upon filing of application) **(Initial Only)**	Applicant in coordination with their Equipment manufacturer/supplier
10. Commissioning report of the equipment duly signed by the facility's certified ROMP **(Initial Only)**	Applicant (in coordination with their in-house Certified Medical Physicist- Radiation Oncology Medical Physicist)
11. Performance testing report of the x-ray unit/s in the therapeutic x-ray facility. (Initial Only)	FDA – CSL/DTI – PAB accredited testing body service providers
12. LINAC output calibration report of the DOH-SSDL or of a third-party board-Certified ROMP **(Initial & Renewal)**	DOH- SSDL or of a third-party board-Certified ROMP
13. Copy of the latest License to Operate **(Renewal Only)**	Applicant

24.4. AMENDMENT OF COC, LTO (MANUAL) AND COR DOCUMENTARY REQUIREMENTS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHANGE OF AUTHORIZED PERSONNEL Letter request stating the changes of authorized personnel Duly accomplished x-ray application form Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider if applicable. Proof of qualification of the new personnel as required in the application from checklist of requirements Copy of existing DOH LTO/COA	Applicant DTI-PAB Accredited Personal Dosimetry Service Providers Applicant Applicant Applicant
CHANGE OF MANAGEMENT OR OWNERSHIP Letter request stating the changes of the management/ownership/legal person Duly accomplished x-ray application form DTI/SEC registration/MOA/ Resolution/Mayor's Permit under the name of the new owner/management Copy of existing DOH LTO/COA	Applicant Applicant Mayor's office from the municipality where the facility is located/ DTI/ Securities and Exchange Commission Applicant
REMOVAL OF MACHINE Duly accomplished x-ray application form Letter of request stating the reason/s for the removal of machine Copy of existing DOH LTO/COA	Applicant
CHANGE IN THE RADIATION FACILITY SERVICE CATEGORY Duly accomplished x-ray application form Letter request stating the change in the radiation facility service category For upgrading of facility service category, floor plan is required as proof that the x-ray room specifications are met Copy of existing DOH LTO/COA	Applicant

INCLUSION OF ADDITIONAL MACHINE/S Duly accomplished x-ray application form Letter request stating the changes of machine details and/or inclusion of additional machine Machine Calibration Report duly signed by the Service Engineer Photocopy of performance test report from FDA – CSL/DTI – PAB accredited testing body (CT-Scan and Mammography) Copy of existing DOH LTO/COA *Initial fee for the particular machine shall apply and may be subject to inspection as deemed necessary.	Applicant Service Engineer of the facility/ supplier/ third service party FDA – CSL/DTI – PAB accredited testing body service providers
CHANGE OF MACHINE OR REPLACEMENT OF MAJOR COMPONENTS OF X-RAY MACHINE Duly accomplished x-ray application form Letter request stating the changes in the machine and/or its parts Machine Calibration Report duly signed by the Service Engineer Photocopy of performance test report from FDA – CSL/DTI – PAB accredited testing body (CT-Scan and Mammography) Copy of existing DOH LTO/COA *Initial fee for the particular machine shall apply and may be subject to inspection as deemed necessary.	 Applicant Applicant Service Engineer of the facility/ supplier/ third service party FDA – CSL/DTI – PAB accredited testing body service providers Applicant

25.ONLINE APPLICATION OF RADIATION FACILITIES

25.1. ISSUANCE OF USER'S ACCOUNT

Radiation Regulation Division Portal (RRD Portal) User Account will be used as the log in credentials in applying authorizations covered in the RRD Portal. The user account applicant shall either be the owner or authorized person of the facility/company.

Center/Office/Division	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	Simple
Type of Transaction	G2B- Government-to-Business
Who May Avail	All Radiation Facilities applying through RRD Portal
Fees to be Paid	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of Intent or Authorization Letter	Authorized person/ Legal person/ Owner of the Facilities/Company
2. Sworn Undertaking Form (CSE only)	Authorized personnel of Telecommunication Companies, RADAR, AM/FM Broadcast Station, TV Station, Radiofrequen Radiation (RFR) facilities, Contractors and Subcontractors of telecommunications companies/ service providers

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Go to https://rrdportal.fda.gov.ph, click "Create User Account" then select the type of authorization and upload documentary requirements.	1. Validation of user's information and approval of registration. *If approved, client will receive a system generated user name and password in their email account.		2 working days	User Account Evaluator
	TOTAL:	None	Working days	

25.2.ISSUANCE OF CERTIFICATE OF SAFETY EVALUATION (CSE)

Certificate of Safety Evaluation (CSE) is an evaluation of the NIR Facility using specific NIR devices, based on the technical documents submitted regarding the NIR emitting device, nature of installation, location and site configuration of the facility.

Center/Office/Division	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	Highly Technical
Type of Transaction	G2B- Government-to-Business
Who May Avail	All Telecommunication Companies, RADAR, AM/FM Broadcast Station, TV Station, Radiofrequency Radiation (RFR) facilities, Contractors and Subcontractors of telecommunications companies/ service providers
Fees to be Paid	PHP 900/ Transmitter

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Conceptual/ Elevation drawing (Outdoor Antennas)	Licensed Engineer of Telecommunications Companies /Service providers /Contractors/Subcontractors
2. Floor Plan (Indoor Antennas)	Licensed Engineer of Telecommunications Companies /Service providers /Contractors/Subcontractors
3. NTC Permit (RADAR, AM/FM Broadcast Station, TV Station)	National Telecommunications Commission (NTC)
4. Brochure/ Literature of the Antenna (RADAR)	Supplier/ Manufacturer of Antenna

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Encode required fields in the on-line application and upload the documentary requirements.	1. Pre-assessment of the on-line applications and attached documents. *If complete, order of payment will be generated. **If not, a system generated notification will be sent to the facility stating that the application is hereby denied.		-	CDRRHR-RRD Assessor
2. Download, print order of payment, pay the corresponding fee at the FDA	2. Validation and posting of payment.	Php 900.00/ Transmitter	-	FDA Cashier
	2.2. Reviews and recommends the draft CSE/LOD to the Center Director for final approval/ disapproval.		12 working days	CDRRHR-RRD QA
	2.3. Approves/ disapproves CSE/LOD. *If approved, client will receive a system generated CSE in their email account. **If not, client will receive a disapproval letter in their email account.		8 working days	CDRRHR Director
3. Download and print the issued CSE/LOD.			-	Applicant
	TOTAL:	Php 900.00/ Transmitter	20 working days	

23.3.ISSUANCE OF LICENSE TO OPERATE (LTO) OF X-RAY FACILITIES

License to Operate (LTO) refers to an authorization or permission granted by the FDA to any natural or juridical person engaged in the use of radiation devices and operation of its facilities and activities, where the level of risk, potential magnitude of exposure and hazards of facilities and activities associated with the practice or use of radiation devices is high.

Center/Office/Division	:	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	:	Highly Technical
Type of Transaction	:	G2B- Government-to-Business
Who May Avail	:	Medical X-ray Facilities such as General Radiography/Fluoroscopy, Mammography, Interventional Radiography, Computed Tomography and Therapeutic X-ray facility Utilizing Linear Accelerator. Non-Medical X-ray Facilities such as Anti-Crime & Linear Accelerator for Anti-Crime Applications Industrial X-ray Facilities such as Open-type Industrial Radiography, Linear Accelerator for Industrial Application, Computed Tomography for Industrial Application, Non-destructive Testing. Dental X-ray Facilities such as Panoramic/Cephalometric, CBCT, Veterinary X-ray Facilities
Fees to be Paid	:	Refer to table below

mA RANGE	INITIAL (3 years)	RENEWAL (5 years)	Renewal of Expired Authorization				
			1st Month	2nd Month	3rd Month	4th Month	> 4 months
100 and below	2430.00	2050.00	6250.00	6450.00	6650.00	6850.00	7230.00
101 up to 300	3333.00	2800.00	8575.00	8575.00	9125.00	9400.00	9933.00
301 up to 500	4242.00	3550.00	10900.00	11250.00	11600.00	11950.00	12642.00
501 up to 700	5151.00	4300.00	13225.00	13650.00	14075.00	14500.00	15351.00
greater than 700	6060.00	5050.00	15550.00	16050.00	16550.00	17050.00	18060.00

LTO DOCUMENTARY REQUIREMENTS
MEDICAL X-RAY FACILITY

GENERAL RADIOGRAPHY / FLUOROSCOPY AND INTERVENTIONAL

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Valid professional regulation commission (PRC) license of all radiologist/s and radiologic/x-ray technologist/s **(Initial & Renewal)**	Professional Regulation Commission
Certificate for being a fellow of the Philippine College of Radiology (FPCR) or diplomate of the Philippine Board of Radiology (DPBR) of all Radiologist/s **(Initial & Renewal)**	Philippine College of Radiology
For Radiologic/ X-ray Technologist who will act as the radiation protection officer, certificate of training on radiation protection as proof that he completed the RPO training. **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
For Medical Physicist who will act as the radiation protection officer (RPO), photocopy of the documentary evidence satisfying the provisions stated in section 2.29 of AO No. 35 s. 1994. **(Initial & Renewal with changes in RPO)**	Applicant
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Machine Calibration Report duly signed by the Service Engineer **(Initial & Renewal)**	Service Engineer of the facility/ supplier/ third party service providers
Copy of the latest License to Operate **(Renewal Only)**	Applicant

COMPUTED TOMOGRAPHY / MAMMOGRAPHY

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Valid professional regulation commission (PRC) license of all radiologist/s and radiologic/x-ray technologist/s **(Initial & Renewal)**	Professional Regulation Commission
Certificate for being a fellow of the Philippine College of Radiology (FPCR) or diplomate of the Philippine Board of Radiology (DPBR) of all Radiologist/s **(Initial & Renewal)**	Philippine College of Radiology
For Radiologic/ X-ray Technologist who will act as the radiation protection officer, certificate of training on radiation protection as proof that he completed the RPO training. **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
For Medical Physicist who will act as the radiation protection officer (RPO), photocopy of the documentary evidence satisfying the provisions stated in section 2.29 of AO No. 35 s. 1994. **(Initial & Renewal with changes in RPO)**	Applicant
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Performance test report from FDA-CSL/DTI-PAB accredited testing body **(Initial & Major Variation)**	FDA – CSL/DTI – PAB accredited testing body/ service provider

Copy of the latest License to Operate **(Renewal Only)**	Applicant

MEDICAL X-RAY FACILITIES
ANTI-CRIME (Utilizing LINAC)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Certificate of training of the radiation protection officer (RPO) in an appropriate radiation protection training course conducted by an organization recognized by the CDRRHR **(Initial & Renewal)**	Recognized training provider of FDA
Provision of radiation survey meter **(Initial & Renewal)**	Supplier of Radiation Survey Meter/ Calibration Services Providers
Valid Radiation Survey Meter Calibration Certificate **(Initial & Renewal)**	
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Brochure/Literature of the machine **(Initial & Renewal)**	Machine Manufacturer/Supplier
Copy of the latest License to Operate **(Renewal Only)**	Applicant

EDUCATION, TRAINING AND RESEARCH

CHECKLIST OF	WHERE TO SECURE
Mayor's Permit as proof of facility business	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose	DTI- PAB
Valid professional regulation	Professional Regulation Commission
Certificate of training on	Recognized training provider of FDA
If transportable, valid vehicle	Land Transportation Office
Machine Calibration	Service Engineer of the facility/ supplier/ third party service providers

INDUSTRIAL (OPEN-TYPE INDUSTRIAL RADIOGRAPHY, NON-DESTRUCTIVE TESTING and APPLICATIONS UTILIZING LINAC and COMPUTED TOMOGRAPHY)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Certificate of training of the radiation protection officer (RPO) in an appropriate radiation protection training course conducted by an organization recognized by the CDRRHR **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
Provision of radiation survey meter **(Initial & Renewal)**	Supplier of Radiation Survey Meter Calibration Services providers
Valid Radiation Survey Meter Calibration Certificate **(Initial & Renewal)**	
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Brochure/Literature of the machine **(Initial & Renewal)**	Machine Manufacturer/Supplier
Periodic workplace area monitoring results within the validity period of the expired license **(For facilities with OSL exemption) (Renewal Only)**	Radiation Protection Officer of the facility
Copy of the latest License to Operate **(Renewal Only)**	Applicant

DENTAL (PANORAMIC/CEPHALOMETRIC AND CBCT)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Valid professional regulation commission (PRC) license of all dentist/s and radiologic/x-ray technologist/s **(Initial & Renewal)**	Professional Regulation Commission
Certificate of training of the radiation protection officer (RPO) on radiation protection for radiation safety officers of dental x-ray facilities conducted by an organization recognized by CDRRHR **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Machine Calibration Report duly signed by the Service Engineer **(Initial & Major Variation)**	Service Engineer of the facility/ supplier/ third party service providers
Copy of the latest License to Operate **(Renewal Only)**	Applicant

VETERINARY

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Valid professional regulation commission (PRC) license of all veterinarian/s and radiologic/x-ray technologist/s **(Initial & Renewal)**	Professional Regulation Commission
Certificate of training of the radiation protection officer (RPO) on radiation protection for radiation safety officers of veterinary x-ray facilities conducted by an organization recognized by CDRRHR **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
Machine Calibration Report duly signed by the Service Engineer **(Initial & Major Variation)**	Service Engineer of the facility/ supplier/ third party service providers
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Brochure/Literature of the machine **(Initial & Renewal)**	Machine Manufacturer/Supplier
Copy of the latest License to Operate **(Renewal Only)**	Applicant

23.4.ISSUANCE OF CERTIFICATE OF FACILITY REGISTRATION (CFR) OF X-RAY FACILITIES

Certificate of Facility Registration (CFR) refers to an authorization or permission granted by the FDA to any natural or juridical person engaged in the use of radiation devices and operation of its facilities and activities of medium risk.

Center/Office/Division	:	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	:	Highly Technical
Type of Transaction	:	G2B- Government-to-Business
Who May Avail	:	Medical X-ray Facilities such as Bone Densitometry (DEXA) Non-Medical X-ray Facilities such as Anti-Crime- Security and Baggage Inspection System Industrial X-ray Facilities such as Closed-type industrial radiography Dental X-ray Facilities such as Periapical.
Fees to be Paid	:	Refer to table below

mA RANGE	INITIAL (3 years)	RENEWAL (5 years)	Renewal of Expired Authorization				
			1st Month	2nd Month	3rd Month	4th Month	> 4 months
100 and below	2430.00	2050.00	6250.00	6450.00	6650.00	6850.00	7230.00
101 up to 300	3333.00	2800.00	8575.00	8575.00	9125.00	9400.00	9933.00
301 up to 500	4242.00	3550.00	10900.00	11250.00	11600.00	11950.00	12642.00
501 up to 700	5151.00	4300.00	13225.00	13650.00	14075.00	14500.00	15351.00
greater than 700	6060.00	5050.00	15550.00	16050.00	16550.00	17050.00	18060.00

MEDICAL X-RAY FACILITY (BONE DENSITOMETRY)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Valid professional regulation commission (PRC) license of all radiologist/s and radiologic/x-ray technologist/s **(Initial & Renewal)**	Professional Regulation Commission
Certificate for being a fellow of the Philippine College of Radiology (FPCR) or diplomate of the Philippine Board of Radiology (DPBR) of all Radiologist/s **(Initial & Renewal)**	Philippine College of Radiology
For Radiologic/ X-ray Technologist who will act as the radiation protection officer, certificate of training on radiation protection as proof that he completed the RPO training. **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
For Medical Physicist who will act as the radiation protection officer (RPO), photocopy of the documentary evidence satisfying the provisions stated in section 2.29 of AO No. 35 s. 1994. **(Initial & Renewal with changes in RPO)**	Applicant
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Copy of the latest Authorization **(Renewal Only)**	Applicant

NON-MEDICAL X-RAY FACILITY

ANTI-CRIME (SECURITY AND BAGGAGE INSPECTION SYSTEM)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Mayor's Permit as proof of facility business name and address **(Initial)**	Mayor's office from the municipality where the facility is located
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Certificate of training of the radiation protection officer (RPO) in an appropriate radiation protection training course conducted by an organization recognized by the CDRRHR **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
Provision of radiation survey meter **(Initial & Renewal)**	Supplier of Radiation Survey Meter/ Calibration Services providers
Valid Radiation Survey Meter Calibration Certificate **(Initial & Renewal)**	
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Brochure/Literature of the machine **(Initial & Renewal)**	Machine Manufacturer/Supplier
Periodic workplace area monitoring results within the validity period of the expired license **(For facilities with OSL exemption) (Renewal Only)**	Radiation Protection Officer of the facility
Copy of the latest Authorization **(Renewal Only)**	Applicant

INDUSTRIAL (CLOSED-TYPE INDUSTRIAL RADIOGRAPHY)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Proof of Business Name (SEC or DTI Registration or Mayor' Business Permit) **(Initial)**	Mayor's office from the municipality where the facility is located/ Department of Trade and Industry/ Securities and Exchange Commission
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Certificate of training of the radiation protection officer (RPO) in an appropriate radiation protection training course conducted by an organization recognized by the CDRRHR **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
Provision of radiation survey meter **(Initial & Renewal)**	Supplier of Radiation Survey Meter Calibration Services providers
Valid Radiation Survey Meter Calibration Certificate **(Initial & Renewal)**	
Periodic workplace area monitoring results within the validity period of the expired license **(For facilities with OSL exemption) (Renewal Only)**	Radiation Protection Officer of the facility
Brochure/Literature of the machine **(Initial & Renewal)**	Machine Manufacturer/Supplier
If transportable, copy of valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Copy of the latest Authorization **(Renewal Only)**	Applicant

DENTAL (PERIAPICAL)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Proof of Business Name (SEC or DTI Registration or Mayor' Business Permit) **(Initial)**	Mayor's office from the municipality where the facility is located/ Department of Trade and Industry/ Securities and Exchange Commission
Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider **(Initial & Renewal)**	DTI-PAB Accredited Personal Dosimetry Service Providers
Valid professional regulation commission (PRC) license of all dentist/s and radiologic/x-ray technologist/s **(Initial & Renewal)**	Professional Regulation Commission
Certificate of training of the radiation protection officer (RPO) on radiation protection for radiation safety officers of dental x-ray facilities conducted by an organization recognized by CDRRHR **(Initial & Renewal with changes in RPO)**	Recognized training provider of FDA
If transportable, valid vehicle LTO registration (OR/CR) **(Initial & Renewal)**	Land Transportation Office
Copy of the latest Authorization **(Renewal Only)**	Applicant

23.5.ISSUANCE OF MAJOR AND MINOR VARIATION OF LICENSE TO OPERATE (LTO) and CERTIFICATE OF FACILITY REGISTRATION (CFR)

Variation is a post-FDA approval changes in the status, condition or activity of an authorized radiation facility.

Center/Office/Division	:	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	:	Highly Technical
Type of Transaction	:	G2B- Government-to-Business
Who May Avail	:	Medical X-ray Facilities such as Bone Densitometry (DEXA) Non-Medical X-ray Facilities such as Anti-Crime- Security and Baggage Inspection System Industrial X-ray Facilities such as Closed-type industrial radiography Dental X-ray Facilities such as Periapical, General Radiography/Fluoroscopy, Mammography, Interventional Radiography, Computed Tomography and Therapeutic X-ray facility Utilizing Linear Accelerator. Non-Medical X-ray Facilities such as Anti-Crime & Linear Accelerator for Anti-Crime Applications Industrial X-ray Facilities such as Open-type Industrial Radiography, Linear Accelerator for Industrial Application, Computed Tomography for Industrial Application, Non-destructive Testing.
Fees to be Paid	:	Refer to table below

mA RANGE	INITIAL (3 years)	RENEWAL (5 years)	Renewal of Expired Authorization				
			1st Month	2nd Month	3rd Month	4th Month	> 4 months
100 and below	2430.00	2050.00	6250.00	6450.00	6650.00	6850.00	7230.00
101 up to 300	3333.00	2800.00	8575.00	8575.00	9125.00	9400.00	9933.00
301 up to 500	4242.00	3550.00	10900.00	11250.00	11600.00	11950.00	12642.00
501 up to 700	5151.00	4300.00	13225.00	13650.00	14075.00	14500.00	15351.00
greater than 700	6060.00	5050.00	15550.00	16050.00	16550.00	17050.00	18060.00

MAJOR VARIATION	
CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Physical transfer of the radiation facility Letter request stating the changes of location of the facility Mayor's Permit of the Facility	 Applicant Mayor's office from the municipality where the facility is located
Change of location of the machine within the facility Letter request stating the changes of location of the machine from one room to another. Machine Calibration Report duly signed by the Service Engineer	Applicant Service Engineer of the facility/ supplier/ third party service providers
Change of machine or inclusion of additional machine/s Letter request stating the changes of the machine and/or inclusion of additional machine. Machine Calibration Report duly signed by the Service Engineer	Applicant Service Engineer of the facility/ supplier/ third party service providers
Note: *For authorization with more than three years validity, initial fee for the first three years plus renewal fee for the remaining years shall apply for a particular machine and may be subject to inspection as deemed necessary. **For authorization with less than three years validity, initial fee per year shall apply for a particular machine and may be subject to inspection	

MINOR VARIATION	
CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Change of Business Name of the Radiation Facility Letter request stating the changes of the facility name Updated DTI/SEC registration/Mayor's Permit	 Applicant Mayor's office from the municipality where the facility is located/ Department of Trade and Industry/ Securities and Exchange Commission

Change of Management/Ownership/Legal Person Letter request stating the changes of the management/ownership/legal person DTI/SEC registration/MOA/ Resolution/Mayor's Permit under the name of the new owner/management	Applicant Mayor's office from the municipality where the facility is located/ Department of Trade and Industry/ Securities and
Change of Authorized Personnel Letter request stating the changes of authorized personnel Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider where applicable; Proof of qualification of the new personnel as required in the application form checklist of requirements; and	Applicant DTI-PAB Accredited Personal Dosimetry Service Providers Applicant
Removal of Machine Letter request stating the reason/s for the removal of the machine	Applicant
Change in the radiation facility service category Letter request stating the change in the radiation facility service category For upgrading of facility service category, floor plan is required as proof that the x-ray room specifications are met	Applicant Applicant
Correction of Details in the LTO Letter request stating the reason for correction Proof of correct details (i.e. photos of the stickers of the control console and x-ray tube indicating the serial numbers, installation report, preventive maintenance report, supporting documents etc.)	Applicant

STEPS FOR INITIAL APPLICATION FOR A LICENSE TO OPERATE (LTO) AND MAJOR VARIATION

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Encode required fields in the on-line application and upload the documentary requirements.	1. Pre-assessment of the on-line applications and attached documents. *If complete, order of payment will be generated. **If not, a system generated notification will be sent to the facility stating that the	-	-	CDRRHR-RRD Assessor
2. Download, print order of payment, pay the corresponding fee at the FDA recognized	2.1. Validation and posting of payment.	Refer to Table of Fees Above	-	FDA Cashier
	2.2. Queuing/ decking of application to the	-	5 working days	CDRRHR-RRD
3. Applicant upload the compliance documents from the noted deficiencies during inspection in the RRD portal.	3.1. Conducts pre-licensing inspection and upload inspection report in the RRD portal. *If compliant, application is recommended for the issuance of authorization. **If not, the assigned inspector shall notify the applicant of the lacking regulatory requirements. ***If the facility fails to comply within the prescribed period, a letter of disapproval shall be sent to the facility.	-	20 working days	CDRRHR-RRD Assigned Inspector

	3.2. Evaluates the compliance documents. *If compliant, application is recommended for the issuance of authorization. **If not, the evaluator shall notify the applicant of the lacking regulatory requirements. ***If the facility fails to comply within the prescribed period, a letter of disapproval shall be sent to the facility.		3 working days	CDRRHR-RRD Evaluator
	3.3. Reviews/ recommends the LTO/LOD for final approval/ disapproval to the center director.	-	7 working days	CDRRHR-RRD QA
	3.4. Approves/disapproves the LTO/LOD.	-	5 working days	CDRRHR Director
4. Download and print the issued LTO/LOD.		-	-	Applicant
	TOTAL:	Refer to Table of Fees Above	40 working days	

Please be advised that as per RA No.11032 IRR, page 22 of 48, Section 3, b) The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.

Note: *The processing of LTO initial application is a multistage system which involves pre-licensing inspection or radiation protection survey and evaluation (RPSE) of radiation facilities.

**Day 1 commences upon posting of payment.

STEPS FOR RENEWAL APPLICATION OF LICENSE TO OPERATE (LTO), INITIAL/ RENEWAL APPLICATION OF CERTIFICATE OF FACILITY REGISTRATION (CFR)

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Encode required fields in the on-line application and upload the documentary requirements.	1. Pre-assessment of the on-line applications and attached documents. *If complete, order of payment will be generated **If not, a system generated notification will be sent to the facility stating that the application is hereby denied.	-	-	CDRRHR-RRD Assessor
2. Download, print order of payment, pay the corresponding fee at the FDA recognized payment centers.	2.1. Validation and posting of payment.	Refer to Table of Fees Above	-	FDA Cashier
	2.2. Reviews/ recommends the LTO/CFR/LOD for final approval/ disapproval to the center director.	-	10 working days	CDRRHR-RRD QA
	2.3. Approves/ disapproves the LTO/CFR/LOD.	-	5 working days	CDRRHR Director
3. Download and print the issued LTO/CFR/LOD.		-	-	Applicant
	TOTAL:	Refer to Table of Fees Above	15 working days	
Please be advised that as per RA No.11032 IRR, page 22 of 48, Section 3, b) The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter. Note: **Day 1 commences upon posting of payment.				

STEPS FOR MINOR VARIATION APPLICATION OF LICENSE TO OPERATE (LTO) & CERTIFICATE OF FACILITY REGISTRATION (CFR)

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Encode required fields in the on-line application and upload the documentary requirements.	1.1. Evaluation of the on-line applications and attached documents. *If complete application is recommended for the issuance of authorization. **If not, a system generated notification will be sent to the facility stating that the application is hereby denied.	-	5 working days days	CDRRHR-RRD Evaluator
	1.2. Reviews/ recommends the LTO/CFR/LOD for final approval/ disapproval to the center director.	-	5 working days	CDRRHR-RRD QA
	1.3. Approves/ disapproves the LTO/CFR/LOD.	-	5 working days	CDRRHR Director
2. Download and print the issued LTO/CFR/LOD.		-	-	Applicant
	TOTAL:	None	15 working days	
Please be advised that as per RA No.11032 IRR, page 22 of 48, Section 3, b) The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.				

26.RE-APPLICATION FOR CMDR AND IVDR APPLICATIONS

The client's response or compliance to the issued Letter of Disapproval following their initial registration application. Clients are given 60 calendar days to comply from the date of the LoD issuance.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php 1,000.00 + 1% LRF = Php1,010.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Letter of Intent	Applicant.
Copy of the Letter of Disapproval/Reapplication.	Applicant
Compliance Documents	Applicant/Principal/ Manufacturer
Payment	FDA Cashier
NOTES: Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Submission schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Client sends an email containing the PDF of their compliance to fdac.pacd@fda.gov.ph within the prescribed time period stipulated in the Letter of Disapproval/Reapplication.*	1.1 Receiving officer sends an acknowledgment email to the client and assigns a new DTN to the application. FDAC forwards the re-application file to CDRRHR.	Php1,010	1 working day	FDAC Officer
	2 CDRRHR receives the re-application file and decks to the evaluator	None	1 working day	CDRRHR Administrative Staff
	3 Technical evaluation of application. Recommendation of Approval or Final Disapproval	None	10 working days	Technical Evaluator
	4 Quality Assurance - Checking of recommendation of the Supervisor	None	4 working days	LRD Chief
	5 Drafting and finalization of certificate/disapproval letter	None	1 working day	Technical Evaluator
	6 Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	7 Scanning and transmittal of certificate/disapproval letter to the FDA Records Section	None	1 working day	CDRRHR Administrative Staff
	8 Queuing and endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	P1,010.00	20 working days**	

*Submission period is within sixty (60) days from the issuance date of the Letter of Disapproval/Re-application.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

27.RE-APPLICATION FOR RENEWAL OF CMDR/CPR AND IVDR

The client's response or compliance to the issued Letter of Disapproval following their renewal application. Clients are given 30 calendar days to comply from the date of the LoD issuance.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	Php 1,000.00 + 1% LRF = Php1,010.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Letter of Intent	Applicant
Copy of the Notice of Deficiencies	Applicant
Compliance Documents	Applicant / Principal/Manufacturer
Payment	FDA Cashier
NOTES: Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Submission schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Client sends an email containing the PDF of their compliance to fdac.pacd@fda.gov.ph within the prescribed time period stipulated in the notice of deficiency.*	1.1 Receiving officer sends an acknowledgment email to the client and assigns a new DTN to the application. FDAC forwards the re-application file to CDRRHR.	Php1,010	1 working day	FDAC Officer
	2 CDRRHR receives the re-application file and decks to the evaluator	None	1 working day	CDRRHR Administrative Staff
	3 Technical evaluation of application. Recommendation of Approval or Final Disapproval	None	10 working days	Technical Evaluator
	4 Quality Assurance - Checking of recommendation of the Supervisor	None	4 working days	LRD Chief
	5 Drafting and finalization of certificate or disapproval letter	None	1 working day	Technical Evaluator
	6 Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	7 Scanning and Transmittal of certificate or disapproval letter to the FDA Records Section.	None	1 working day	CDRRHR Administrative Staff
	8 Queuing and endorsement to the Releasing Section	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	Php1,010.00	20 working days**	

*Submission period is within thirty (30) days from the issuance date of the Letter of Disapproval/Re-application.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

28.RENEWAL APPLICATION FOR CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR IN-VITRO DIAGNOSTIC DEVICES/REAGENTS (IVD)

The application for the renewal of CPR for IVD devices/reagents.

<table>
<tr><td>Center/Office/Division</td><td>:</td><td>CDRRHR-LRD</td></tr>
<tr><td>Classification</td><td>:</td><td>Highly technical</td></tr>
<tr><td>Type of Transaction</td><td>:</td><td>G2B - Government-to-Businesses</td></tr>
<tr><td>Who May Avail</td><td>:</td><td>Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader</td></tr>
<tr><td>Fees to be Paid</td><td>:</td><td>Php5,000.00 + 1% LRF for renewal with 5 years validity

Cost does not include the performance evaluation test; cost of testing depends on the corresponding National Reference Laboratory (NRL)

Late Renewal Fees (as per FDA Circular 2011-004)
<table>
<tr><th>Timeline (after expiry date of certificate)</th><th>Validity of certificate (in years)</th><th>Fee</th><th>Laboratory Fee (c/o NRL)</th><th>Surcharge</th><th>Penalty</th><th>LRF</th><th>Total</th></tr>
<tr><td>a. First month (10% penalty)</td><td>5</td><td>5,000.00</td><td></td><td>10,000.00</td><td>500.00</td><td>50.00</td><td>15550.00</td></tr>
<tr><td>b. 1st day of the second month (20% penalty)</td><td>5</td><td>5,000.00</td><td></td><td>10,000.00</td><td>1,000.00</td><td>50.00</td><td>16050.00</td></tr>
<tr><td>c. 1st day of the third month (30% penalty)</td><td>5</td><td>5,000.00</td><td></td><td>10,000.00</td><td>1,500.00</td><td>50.00</td><td>16550.00</td></tr>
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</td></tr>
</table>

		d. 1st day of the fourth month (40% penalty	5	5,000.00		10,000.00	2,000.00	50.00	17050.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Table of Contents with correct page number.	Applicant
Notarized Application Form Shall be completely filled-up; Model / Reference Number / Sizes / Codes shall be properly identified; Refrain from indicating the Brand name (if applicable) on the Name of the product and vice versa For kits/sets, identify the complete contents/inclusions on the space provided for device name; For multiple CPR schemes, an annex page may be attached. However, the product name and model / reference number / size/ code must be specified to which CPR it belongs to; For multiple models / reference number / size / codes, an annex page may be attached; The Product Registration Number must be indicated (RR/IVDR); Shall be signed by the proper authority as indicated on the form; Re-using forms is not acceptable since this is a legal document.	Applicant. Form may be downloaded on the FDA website
License to Operate (LTO) as a Medical Device Distributor (Importer/ Exporter/ Wholesaler)/ Local Manufacturer/Trader. Shall be valid The principal shall be reflected on the list of sources.	Applicant
Copy of the front and back pages of the latest Certificate of Product Registration	Applicant
Foreign Agency Agreement / Letter of Authorization. Shall be valid. Shall be authenticated/apostilled by the territorial Philippine Consulate. The product being applied must be indicated. For imported medical devices but the agreements are signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties.	Applicant or Principal/Source/Manufacturer

For open-dated agreements/authorizations, if the certificate is beyond the 5- year period, a re-issued agreement/authorization must be submitted or a notarized attestation by the Principal that the agreement/authorization is still in effect. For locally manufactured medical devices with exclusive distributor, the agreement should be duly notarized. For locally manufactured medical devices with toll manufacturer, agreement between the trader and the manufacturer should be duly notarized.	
Government issued a certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Shall be valid Shall be authenticated/apostilled by the territorial Philippine Consulate For products that are manufactured in multiple sites or toll manufacturers, identify or highlight where the product will be sourced from. The product being applied must be indicated in the scope. For locally manufactured products, valid LTO of the manufacturer.	Principal/Source/Manufacturer
Real time stability test data and results which shall include: shelf life study in-use stability study Note : Shall be performed on at least three (3) different product lots.	Principal/Source/Manufacturer
Clear and readable photos of actual labeling materials Immediate label secondary packaging box label package insert/brochure. shall include blood sample collection and handling performance study results and summary cross reactivity and list of potential interfering substances (if applicable) warnings and precautions information of the manufacturer	Applicant

revision number	
For pregnancy test kit, 15 samples of the same lot with at least nine (9) months expiration date. NOTE: For other IVD applications, samples will be submitted directly to the respective NRLs. No. of samples required will depend on the requirement of each NRL.	Applicant
Evidence of registration fee/payment (charge slip/official receipt)	FDA Cashier
All documents shall be submitted in English language. Documents submitted in any other foreign language not accompanied by English Translation shall be disapproved. Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Schedule of submission will be generated by the FDA and sent through email to the client. Endorsement to the NRL depends on the schedule performance re-evaluation which will be indicated at the back of the certificate.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing the PDF of their application to	Receiving officer generates a Document Tracking Number	None		FDAC Officer

fdac.letters@fda.gov.ph following the correct schedule.	(DTN) and sends an acknowledgment email / order of payment to the client			
The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL) The Order of Payment will only be valid for 24 hours.	2.FDA receives the payment from the applicant company for posting.	PHP5,050.00	Timeline starts after posting of payment	FDA Cashier
The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email	3.1 FDAC forwards the application to CDRRHR.	None	1 working day	FDAC Officer
	3.2 CDRRHR assigns the application to evaluator	None	1 working day	CDRRHR Administrative Staff
	3.3 The technical evaluator reviews the application. Recommends approval or disapproval. Includes endorsement to NRL if the product is scheduled for performance re-evaluation.	None	5 working days**	Technical Evaluator
	Performance Testing	c/o NRL	Timeline depends on the NRL procedure	c/o the National Reference Laboratory
	4 Review of Performance Evaluation report	None	2 working days	Technical Evaluator

	5 Quality Assurance - Checking of recommendation of the Supervisor	None	4 working days	LRD Chief
	6 Drafting and finalization of CPR.	None	2 working days	Technical Evaluator
	7 Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	8 Transmittal to Records Section.	None	1 working day	CDRRHR Administrative Staff
	9 Scanning and barcoding of CPR. Queuing and endorsement to the FDA Releasing Section.	None	2 working days	AFS Records Officer / Administrative Officer
	TOTAL	PHP5,050.00	20 working days***	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

29.TURNED INITIAL REGISTRATION OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR EQUIPMENT/DEVICES USED TO TREAT SHARPS, PATHOLOGICAL AND INFECTIOUS WASTES

The application for authorization issued for equipment and devices used to treat sharps, pathological and infectious wastes after the CPR has passed the certificate expiry date by 120 days and beyond.

<table>
<tr><td>Center/Office/Division</td><td>:</td><td>CDRRHR-LRD</td></tr>
<tr><td>Classification</td><td>:</td><td>Highly Technical</td></tr>
<tr><td>Type of Transaction</td><td>:</td><td>Government-to-Businesses</td></tr>
<tr><td>Who May Avail</td><td>:</td><td>Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader</td></tr>
<tr><td>Fees to be Paid</td><td>:</td><td>(4 Months and Above) – TURNED INITIAL
<table>
<tr><th>Manufacturers/ Distributors/ TSD Facility</th><th>Surcharge</th><th>Penalties 40%</th><th>Initial Fee</th><th>LRF 1%</th><th>Total</th></tr>
<tr><td>Below Php 1,000,000.00</td><td>6,000</td><td>2,000</td><td>5,000</td><td>50</td><td>Php13,050</td></tr>
<tr><td>Php 1,000,000 – Php 5,000,000</td><td>6,000</td><td>3,200</td><td>8,000</td><td>80</td><td>Php17,280</td></tr>
<tr><td>Above Php 5,000,000</td><td>6,000</td><td>4,000</td><td>10,000</td><td>100</td><td>Php20,100</td></tr>
<tr><td>Healthcare Waste Generators</td><td>4,000</td><td>1,200</td><td>3,000</td><td>30</td><td>Php8,230</td></tr>
</table></td></tr>
</table>

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Properly and completely filled-up application form Must be signed by the company representative with date when signed Location of Installation shall be filled-up since the equipment will be inspected and tested for performance evaluation.	Applicant. Form may be downloaded from the FDA website.
Copy of issued CPR	Applicant
Copy of valid License to Operate (LTO)	Applicant

Copy of SEC Articles of Incorporation or DTI Certificate of Business Registration The activity of manufacturing, importing or distributing the equipment should be reflected in the Articles of Incorporation The DTI Certificate of Business Registration must be valid.	Applicant
Technology Approval from DOST-ITDI for new technologies	Applicant
Technical Report:	
6.1. Company profile;	Applicant
6.2. Characteristics and Sources of generated waste;	Applicant
6.3. Detailed description of treatment equipment to be tested including manufacturer's instructions and technical specifications;	Applicant
6.4. Operating procedures and conditions including as applicable treatment time, pressure, temperature, chemical concentration, doses, feed rates and waste load composition;	Applicant
6.5. Storage, handling and volume capacity;	Applicant
6.6. Applicable emission controls for suspected emissions;	Applicant
6.7. Potential hazards/toxicities of waste residues;	Applicant
6.8. Energy efficiency	Applicant
6.9. Occupational safety and health assurance.	Applicant
7. Copy of Operation Manual	Applicant
8. Layout / Plans	Applicant
8.1. Location of installation;	Applicant
8.2. Design / Drawing or picture of the device / equipment applied for;	Applicant
9. Supplementary requirements for equipment / devices used for chemical disinfection:	Applicant
9.1. Material Safety Data Sheet (MSDS) of the chemicals to be used for disinfection	Applicant
9.2. The chemical to be used should be registered with the DENR-EMB or must be compliant with the WHO guidelines for hazardous wastes.	Applicant

For healthcare waste generators (e.g. hospitals) and Treatment, Storage and Disposal (TSD) Facilities, the Environmental Compliance Certificate (ECC) issued by the Environmental Management Bureau-Department of Environment and Natural Resources (EMB-DENR) and the License to Operate issued by the Department of Health shall be submitted together with the above documentary requirements. - License to Operate should be valid.	Applicant
Notes: .This office shall not accept applications with incomplete requirements. .All documents should be submitted in electronic copy format. .All information contained in this application form will be held strictly confidential.	
*Submission schedule is every Thursday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing the PDF of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule for application.	1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR Officer
	2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		Technical Evaluator
The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means	2 FDA receives the payment from the applicant company for posting.	Refer Table Above	Timeline starts after posting of payment	FDA Cashier

prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). *The Order of Payment will only be valid for 3 working days.		Php13,050/ Php17,280/ Php20,100/ Php8,230		
The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email.	1 CDRRHR assigns the application to an evaluator.	None	2 working days	CDRRHR Administrative Staff
.	2 Technical evaluation of application. Issuance of a Notice of Deficiencies or endorsement.	None	20 working days	Technical Evaluator
. Client complies with the Notice of Deficiencies *Clients are given 30 days to comply with the NOD. Non-compliance would mean disapproval of the application.	4.1 Evaluator reviews compliance documents.	None	10 working days	Technical Evaluator
	2 Once fully complied, endorsed to NRL for Performance Evaluation	None	1 working day	Technical Evaluator
.	Performance Testing	c/o NRL	Timeline depends on the NRL procedure	c/o EAMC-NRL
	3 Review of Performance Evaluation report	None	5 working days	Technical Evaluator
	4 Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief

	5 Drafting and finalization of CPR.	None	2 working days	CDRRHR Administrative Staff
	6 Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	7 Assigning of number. Transmittal to the Records Section.	None	2 working days	CDRRHR Administrative Staff
	8 Scanning and barcoding of CPR. Queuing and endorsement to the FDA Releasing Section.	None	2 working days	AFS Records Officer / Administrative Officer
	TOTAL	Php17,280/ Php20,100/ Php8,230	50 working days**	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

30.RENEWAL APPLICATION OF CERTIFICATE OF REGISTRATION FOR WATER PURIFICATION DEVICES/SYSTEM

The application for the renewal of CPR for water purification devices or systems.

<table>
<tr><td>Center/Office/Division</td><td>:</td><td>CDRRHR-LRD</td></tr>
<tr><td>Classification</td><td>:</td><td>Highly Technical</td></tr>
<tr><td>Type of Transaction</td><td>:</td><td>G2B - Government-to-Businesses</td></tr>
<tr><td>Who May Avail</td><td>:</td><td>Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader</td></tr>
<tr><td>Fees to be Paid</td><td>:</td><td>Water Treatment Devices: Php500.00 + Php10.00 LRF per product
Water Treatment System: Php1,000.00 + Php10.00 LRF per product

Late Renewal
(1 Day to 1 Month)

<table>
<tr><th></th><th>Surcharge</th><th>Penalties 10%</th><th>Renewal Fee</th><th>LRF</th><th>Total</th></tr>
<tr><td>Water Treatment Devices</td><td>1,000</td><td>50</td><td>500</td><td>10</td><td>Php1,560</td></tr>
<tr><td>Water Treatment System</td><td>2,000</td><td>100</td><td>1,000</td><td>10</td><td>Php3,110</td></tr>
</table>

(1 Month to 2 Months)

<table>
<tr><th></th><th>Surcharge</th><th>Penalties 20%</th><th>Renewal Fee</th><th>LRF</th><th>Total</th></tr>
<tr><td>Water Treatment Devices</td><td>1,000</td><td>100</td><td>500</td><td>10</td><td>Php1,610</td></tr>
<tr><td>Water Treatment System</td><td>2,000</td><td>200</td><td>1,000</td><td>10</td><td>Php3,210</td></tr>
</table>
</td></tr>
</table>

(2 Months to 3 Months)

	Surcharge	Penalties 30%	Renewal Fee	LRF	Total
Water Treatment Devices	1,000	150	500	10	Php1,660
Water Treatment System	2,000	300	1,000	10	Php3,310

(3 Months to 4 Months)

	Surcharge	Penalties 40%	Renewal Fee	LRF	Total
Water Treatment Devices	1,000	200	500	10	Php1,710
Water Treatment System	2,000	400	1,000	10	Php3,410

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Properly and completely filled-up application form -Must be signed by the company representative with date when signed -Use the official and latest form	Applicant. Form may be downloaded from the FDA website.
2. Affidavit of Continuous Compliance -Use the official and latest form	Applicant

Bacteriological, physical and chemical test report from any laboratory accredited by the DOH. Bacteriological tests should include the following: HPC, Total Coliform and Fecal Coliform. For safe drinking water, the physical and chemical test results should consist of the following: color, odor, turbidity, total chloride, total hardness, pH, total dissolved solids, fluoride, nitrate, nitrite, sulfate, arsenic, cadmium, chromium, iron, lead and manganese. For purified water, the physical and chemical test results should consist of the following: color, odor, turbidity, total chloride, total hardness, pH, total dissolved solids, fluoride, nitrate, nitrite, sulfate, arsenic, cadmium, chromium, copper, iron, lead and manganese. The sampling for laboratory testing should be performed within two (2) months upon filing of renewal or the guidelines set forth in the latest version of Philippine National Standards for Drinking Water. For guidelines, refer to the latest version of the PNS for drinking water.	Applicant
4. Copy of old Certificate of Health-Related Device Registration -Include in the submission page 2 of old CPR and/or layout of the device	Applicant
5.Copy of valid License to Operate (LTO)	Applicant
*Performance evaluation testing is not required to be submitted given that the previous test results are still valid.	
NOTES: • Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) • The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. * Application should be filed two (2) months prior to the expiration of the validity of the CPR. Submission schedule is every Thursday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing the PDF of their application to fdac.letters@fda.gov.ph following the correct schedule.	Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client.	None		FDAC Officer
The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL) *The Order of Payment will only be valid for 24 Hours.	2 The FDA will receive the payment from the applicant company for posting.	See above table	Timeline starts after posting of payment	FDA Cashier
The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email	1 FDAC will forward the application to CDRRHR.	None	1 working day	FDAC Officer
	2 The CDRRHR will assign the application to evaluator	None	1 working day	CDRRHR Administrative Staff
	3 Technical evaluation of application. Issuance of a Notice of Deficiencies or endorsement.	None	5 working days	Technical Evaluator
Client complies with the Notice of Deficiencies *Clients are given 30 days to comply with the NOD. Non-compliance would mean disapproval of the application.	4.1 Evaluator reviews submitted compliance documents.	None	5 working days	Technical Evaluator
	2 Quality Assurance - Checking of recommendation of the Supervisor	None	2 working days	LRD Chief
	3 Drafting and finalization of CPR.		1 working day	CDRRHR Administrative Staff

	4 Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	5 Assigning of number. Transmital to Records Section.	None	2 working days	CDRRHR Administrative Staff
	6 Scanning and Barcoding of CPR. Queuing and endorsement to the FDA Releasing Section.	None	2 working days	AFS Records Officer / Administrative Officer
	TOTAL	Php510.00/ Php1,010.00	20 working days**	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.
**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

31.RENEWAL APPLICATION OF MEDICAL DEVICES FOR ALL CLASSIFICATIONS (CMDN FOR CLASS A AND CMDR FOR CLASS B, C, D)

The application for the renewal of CPR (CMDN and CMDR) for medical devices.

<table>
<tr><td>Center/Office/Division</td><td>:</td><td>CDRRHR-LRD</td></tr>
<tr><td>Classification</td><td>:</td><td>Highly Technical</td></tr>
<tr><td>Type of Transaction</td><td>:</td><td>G2B - Government-to-Businesses</td></tr>
<tr><td>Who May Avail</td><td>:</td><td>Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader</td></tr>
<tr><td>Fees to be Paid</td><td>:</td><td>Php5,000.00 + 1% LRF for renewal with 5-year validity (Php 5,050.00) per product

Late Renewal Fees (as per FDA Circular 2011-004)
<table>
<tr><th>Timeline (after expiry date of certificate)</th><th>Validity of certificate (in years)</th><th>Fee</th><th>Surcharge</th><th>Penalty</th><th>LRF</th><th>Total</th></tr>
<tr><td>a. First month (10% penalty)</td><td>5</td><td>5,000.00</td><td>10,000.00</td><td>500.00</td><td>50.00</td><td>15,550.00</td></tr>
<tr><td>b. 1st day of the second month (20% penalty)</td><td>5</td><td>5,000.00</td><td>10,000.00</td><td>1,000.00</td><td>50.00</td><td>16,050.00</td></tr>
<tr><td>c. 1st day of the third month (30% penalty)</td><td>5</td><td>5,000.00</td><td>10,000.00</td><td>1,500.00</td><td>50.00</td><td>16,550.00</td></tr>
<tr><td>d. 1st day of the fourth month (40% penalty)</td><td>5</td><td>5,000.00</td><td>10,000.00</td><td>2,000.00</td><td>50.00</td><td>17,050.00</td></tr>
</table></td></tr>
</table>

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
. Notarized Application Form Must be completely and accurately filled-up; Model / Reference Number / Sizes / Codes must be properly identified; For kits/sets, identify the complete contents/inclusions on the space provided for device name; LTO must be valid. However, if it is for renewal, submit proof of renewal application including the payment; For multiple CPR scheme, an annex page may be attached. However, the product name and model / reference number / size / code must be specified to which CPR it belongs to; For multiple models / reference number / size / codes, an annex page must be attached; For multiple models / reference number / size / codes, a Word copy must be submitted The Product Registration Number must be indicated (DVR/MDR/CMDN/CMDR); Should be signed by the proper authority as indicated on the form; Re-using forms is not acceptable.	Applicant. Form may be downloaded from the FDA website.
. Payment	FDA Cashier

. 1 Copy of Notarized Agreement / Letter of Authorization. Must be valid; The product being applied for must be indicated; For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct; For local agreements, it must be notarized locally, with passport ID page and record of arrival in the Philippines of the signatory/ies, and must be signed by both parties; The issuing party and the local market authorization holder must bear their approved name and address as indicated in the CPR; For open-dated agreements/authorizations, if the certificate is beyond the 5-year period, a certificate to confirm that the agreement is still valid must be submitted; Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct; For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized. For locally manufactured medical devices with toll manufacturer, agreement between the trader and the manufacturer should be duly notarized. For Imported Medical Devices - valid government-issued certificate attesting to the status of the manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct; For products that are manufactured in multiple sites or toll manufacturers, identify or highlight where the product will be sourced from; The product being applied must be indicated in the scope. For locally manufactured medical devices, a valid LTO of the manufacturer must be submitted, a copy of valid ISO 13485 is also encouraged.	Principal/Source/Manufacturer
Colored picture of the device from all sides. However, the CDRRHR may require a representative sample or commercial presentation for verification purposes.	Principal/Source/Manufacturer

Must be removed from its packaging for clear visualization of the device.	
Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging) Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable; All the approved product model / reference number / sizes / codes must be submitted, indicating both the international and mandatory labeling requirements; For any additional product claim/s on the label, submit studies or tests to support the claim/s; For imported products, if the brand name is the product's local brand, submit a declaration from the manufacturer allowing use of the brand name and its corresponding IPO approval; If the CE marking is reflected on the label, submit valid certificate supporting the placement of the CE mark; Labels must be legible even after when zoom in; Actual commercial labels must be submitted. Artworks are not acceptable since this is already for renewal; Primary packaging must be identified. All documents must be submitted in English language. Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The file name should consist of the name of the requirement.	Principal/Source/Manufacturer
Submit Table of Contents with correct page number.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing the PDF of their application to fdac.letters@fda.gov.ph following the correct schedule.	Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client.	None	Timeline starts after posting of payment	FDAC Officer
The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL) The Order of Payment will only be valid for 24 hours.	FDA receives the payment from the applicant company for posting.	PHP5,050.00		FDA Cashier
The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email.	1 FDAC forwards the application to CDRRHR.	None		FDAC Officer
	2 CDRRHR assigns the application to evaluator.	None	1 Working day	CDRRHR Administrative Staff
	3 The technical evaluator reviews the application; Recommends approval or disapproval.	None	10 Working days**	Technical Evaluator

	4 Quality Assurance - Checking of recommendation of the Supervisor	None	4 working days	LRD Chief
	5 Drafting and finalization of CPR.		1 working day	Technical Evaluator
	6 Final Approval/Disapproval and signature of the Director.	None	1 working day	CDRRHR Director
	7 Assigning of number and printing of CMDN/CMDR. Transmittal of CMDN/CMDR to the Records Section.	None	2 working days	CDRRHR Administrative Staff
Pick-up of Certificate	Queuing and endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL	PHP5,050.00	20 working Days***	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.
**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.
***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

32.TURNED INITIAL APPLICATION FOR CERTIFICATE OF MEDICAL DEVICE REGISTRATION (CMDR) FOR CLASS B

The application for authorization issued for medical devices that fall under Class B after the CPR has passed the certificate expiry date by 120 days and beyond.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	

APPLICATION	VALIDITY	FEE	SURCHARGE	PENALTY	LRF	TOTAL
Turned Initial (120 days after certificate's expiry date)	5 years	7,500.00	10,000.00	2,000.00	75.00	PHP19,575.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Notarized Application Form Must be completely and correctly filled-up and signed Must use the latest form prescribed by the CDRRHR for the type of application Must submit one application form with attachment reflecting all the product codes being applied. Furthermore, the grouping of medical device family should be clearly specified. Only one condition should be considered in the multiple CPR application. Must be unedited, non-tampered; and must reflect the correct brand name, medical device name, and device risk-classification.	Applicant. Form may be downloaded from the FDA website.

1 copy of Notarized Agreement / Letter of Authorization. Must be valid; The product being applied must be indicated. For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct. For imported medical devices but the agreement is signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period from the document's issuance, a re-issued agreement/authorization or a notarized attestation by the Principal that the agreement/authorization is still in effect must be submitted. For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized. For locally manufactured medical devices with a toll manufacturer, the agreement between the trader and the manufacturer should be duly notarized.	Principal/Source/Manufacturer
For Imported Medical Devices - 1 copy of government-issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Must be valid Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. For products that are manufactured in multiple sites or toll manufacturers, identify or highlight the product source. The product being applied must be indicated in the scope. For locally manufactured products, submit the valid LTO of the manufacturer	Principal/Source/Manufacturer
For imported medical devices, 1 copy of Certificate of Product Registration, CE Certificate or any equivalent document attesting to the safety and effectiveness of the device issued by regulatory agency or accredited notified body in the country of origin. Must be valid The copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.	Principal/Source/Manufacturer

Clear colored picture of the actual commercial product sample of the device for all sides without its packaging, for all codes included in the application. An actual representative sample or commercial presentation can be required by the CDRRHR for verification purposes. Pictures should not be pixelated when the view is increased in size.	Principal/Source/Manufacturer
Technical Requirements	
Executive Summary. The executive summary shall include the following information: an overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features, and a synopsis of the content of the CSDT; the commercial marketing history; the list of regulatory approvals or marketing clearances obtained; the status of any pending request for market clearance; and the important safety/performance related information.	Applicant or Principal/Source/Manufacturer
Relevant essential principles and method/s used to demonstrate conformity. Must be completely filled-up	Principal/Source/Manufacturer

Device description with the following information: Intended use- this refers to the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Indications of use- this is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate; and includes a description of the target patient population for which the medical device is intended. Instruction for use- these are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale use of the medical device, instructions needed to use the medical device in a safe manner shall, to the extent possible, be included on the medical device itself and/or its packaging by other formats/forms. This is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users. Contraindications- This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit. Warnings-This is the specific hazard alert information that the user needs to know before using the medical device.	Principal/Source/Manufacturer

Precautions-This alerts the user to exercise special care necessary for the safe and effective use of the medical device. This may include actions to be taken to avoid effects on patients/users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects. Potential adverse effects- These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions. Alternative therapy (practices and procedures) (if applicable) - This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the medical device is intended. Raw Materials or formulation. A description of the materials or formulation of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device. Should have a List of all raw materials used as a component of the product (specify for which product part or component the raw material is used) Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. If the device contains PVC, identify the PVC plasticizer used. For kits/sets: submit the raw materials used with specifications of all components in the kit/set. For machines/equipment: The list of raw materials is ONLY required for the machine parts/accessories that: 1) will have a direct contact with the patient; and/or 2) will serve as a channel/conduit for medical gases during infusion (i.e. ventilators) - parts that come in direct contact with medical gases for infusion. Other Relevant Specifications to include the following:	

The functional characteristics and technical performance specifications of the device including, as relevant: accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability, and other factors Other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging. May submit Certificate of Analysis or Test Certificate with finished product specification. For Stability, submit functionality and packaging/integrity test study of the product duly signed by the person who conducted the studies to justify the claimed expiration date. For accelerated study, submit computation to justify the storage conditions used. If no expiration, submit justification from the manufacturer why the device has no expiration. Submit in-use stability study, as applicable. (e.g. contact lens solution, disinfectant) Identify the product's storage condition. For products with special storage conditions, submit transport stability study. For packaging, clarify the type of packaging used. i.e. blister pack, carton box, etc. For medical devices with animal tissue origin, submit Certificate of Compliance with ISO 22442 - Medical devices utilizing animal tissues and their derivatives issued by Government Authority or notified body. Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)	

Summary of Design Verification and Validation Documents: The validation documents shall consist of the following: Declaration/Certificates of Conformity to the product standards issued by the manufacturer Summaries or reports of tests and evaluation based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance covering the following appropriate tests reports and evaluations, whichever is applicable: a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the medical device with reference to the Essential Principles; Engineering test Laboratory test Biocompatibility test Animal Test Simulated Use software validation Pre-clinical studies The following standards shall be considered: Philippine National Standards (PNS), international standards (ISO, IEC) and other equivalent national standards (of these international standards). Philippine National Standard (PNS) ISO Standard or IEC Standard (whichever is applicable) in the absence of PNS. Standard developed by other International Standard Bodies recognized by the DOH, in the absence of PNS, ISO Standard, and IEC Standard. Any foreign standard that may be recognized by the DOH for the purpose of registration in the absence of PNS, ISO Standard, and IEC Standard, and standard developed by other International Standard Bodies recognized by the DOH.	Principal/Source/Manufacturer

Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging) * Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable. For any additional product claims on the label, submit studies or tests supporting the claims. For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name and IPO approval of the said brand name. For local manufactured products, IPO approval of the-brand name If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark. Pictures and text of the label should be clear and not be pixelated when the view is increased in size. Lot No., Batch No., Serial No., whichever is applicable, should be reflected. Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected. Storage condition, sterilization method should be reflected if applicable. Importer and distributor's name and address should be reflected in the label of the product together with the Registration Number. Suggested Retail Price (SRP) in Philippine peso. The above requirements shall be superseded upon the approval of Administrative Order for the labeling requirements for medical devices.	Applicant or Principal/Source/Manufacturer
Risk Analysis to include the results. Identify the risk Submit Failure Mode Effect Analysis / Risk Benefit Analysis	Principal/Source/Manufacturer

Physical Manufacturer information Manufacturing process, including quality assurance measures. This should include the manufacturing methods and procedures, manufacturing environment or conditions, facilities and controls. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing, and packaging of finished medical device. A brief summary of the sterilization method should be included. Include sterilization standard parameters, sterilization procedures, validation protocol and results of latest sterilization revalidation. If the sterilization of the device is contracted out, submit a copy of valid ISO Certificate of the contracted sterilizing company. For non-sterile devices: a) submit Non-sterile declaration from the manufacturer; b) If the device is required to be sterilized prior to use, submit recommended sterilization guidelines from the manufacturer.	Principal/Source/Manufacturer
Payment	FDA Cashier
Documentary requirements must be arranged according to the CSDT format. All documents must be submitted in English language. Documents submitted in any other foreign language not accompanied by a notarized English translation for legal documents and an English translation for technical documents shall be disapproved. Documents to be uploaded should be in PDF searchable format of at least 150 dpi The file name to be uploaded should consist of the name of the requirements Provide table of contents with page number	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing the PDF file of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application.	1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR Officer
	2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		CDRRHR Evaluator

The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 3 working days.	FDA receives the payment from the applicant company for posting	Php 7,575.00	Timeline starts after posting of payment	FDA Cashier
The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph	1 CDRRHR assigns the application to evaluator	None	2 working days	CDRRHR Administrative Staff
	2 The technical evaluator reviews the application. Recommends approval or disapproval.	None	53 working days**	Technical Evaluator
	3 Quality Assurance - Checking of recommendation of the Supervisor	None	10 working days	LRD Chief
	4 Drafting and finalization of CPR.	None	3 working days	Technical Evaluator
	5 Final Approval/Disapproval and E-Signature	None	5 working days	CDRRHR Director
	6 Assigning of number and Printing of CMDR. Scanning, barcoding and transmitting of CMDR to the Records Section.		6 working days	CDRRHR Administrative Staff
	7 Queuing and endorsement to the FDA Releasing Section		1 working day	Administrative Officer
	TOTAL	Php 7,575.00	80 working days***	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

33.TURNED INITIAL APPLICATION FOR CERTIFICATE OF MEDICAL DEVICE REGISTRATION (CMDR) FOR CLASS C AND D

The application for authorization issued for medical devices that fall under Class C or D after the CPR has passed the certificate expiry date by 120 days and beyond.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	

APPLICATION	VALIDITY	FEE	SURCHARGE	PENALTY	LRF	TOTAL
Turned Initial (120 days after certificate's expiry date)	5	7,500.00	10,000.00	2,000.00	75.00	19,575.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Notarized Application Form Must be completely and correctly filled-up and signed Must use the latest form prescribed by the CDRRHR for the type of application Must submit one application form with attachment reflecting all the product codes being applied. Furthermore, the grouping of medical device family should be clearly specified. Only one condition should be considered in the multiple CPR application. Must be unedited, non-tampered; and must reflect the correct brand name, medical device name, and device risk-classification.	Applicant. Form may be downloaded from the FDA website.

1 Copy of Notarized Agreement / Letter of Authorization. Must be valid; For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization / agreement is true and correct. For imported medical devices but the agreements are signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period from the document's issuance, a re-issued agreement/authorization or a notarized attestation by the Principal that the agreement/authorization is still in effect must be submitted. For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized. For locally manufactured medical devices with a toll manufacturer, the agreement between the trader and the manufacturer should be duly notarized.	Principal/Source/Manufacturer
For Imported Medical Devices - 1 copy of government-issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Must be valid. Copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. For products that are manufactured in multiple sites or toll manufacturers, identify or highlight the product source. The product being applied must be indicated in the scope. For locally manufactured products, submit the valid LTO of the manufacturer.	Principal/Source/Manufacturer
For imported medical devices, 1 copy of Certificate of Product Registration, CE Certificate or any equivalent document attesting to the safety and effectiveness of the device issued by regulatory agency or accredited notified body in the country of origin. Must be valid. The copy of the certificate shall be accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct. USA FDA 510K and PMA (Post Market Approval), Online registry from the Singapore HAS, and EC Full Quality Assurance and Design Verification Certificate	Principal/Source/Manufacturer

Clear colored picture of the actual commercial product sample of the device for all sides without its packaging, for all the codes included in the application. An actual representative sample or commercial presentation can be required by the CDRRHR for verification purposes. Pictures should not be pixelated when the view is increased in size.	Applicant or Principal/Source/Manufacturer
Technical Requirements	
Executive Summary. The executive summary shall include the following information: an overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features and a synopsis of the content of the CSDT; the commercial marketing history; the list of regulatory approvals or marketing clearances obtained; the status of any pending request for market clearance; and the important safety/performance related information.	Applicant or Principal/Source/Manufacturer
Relevant essential principles and method/s used to demonstrate conformity. Must be completely filled-up.	Principal/Source/Manufacturer
Device description with the following information: Intended use- this refers to the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Indications of use- this is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the medical device is intended. Instruction for use- this are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale use of the medical device, instructions needed to use the medical device in a safe manner shall, to the extent possible, be included on the medical device itself and/or its packaging by other formats/forms. This is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users.	Principal/Source/Manufacturer

Contraindications- This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit. Warnings-This is the specific hazard alert information that a user needs to know before using the medical device. Precautions-This alerts the user to exercise special care necessary for the safe and effective use of the medical device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects. Potential adverse effects- These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions. Alternative therapy (practices and procedures) (if applicable) - This is a description of any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the medical device is intended. Raw Materials or formulation. A description of the materials or formulation of the device and their physical properties to the extent necessary to demonstrate conformity with the relevant Essential Principles. The information shall include complete chemical, biological and physical characterization of the materials of the device. Should have a List of all raw materials used as a component of the product (specify for which product part or component the raw material is used). Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. If the device contains PVC, identify the PVC plasticizer used. For kits/sets: submit the raw materials used with specifications of all components in the kit/set.	

For machines/equipment: The list of raw materials is ONLY required for the machine parts/accessories that: 1) will have a direct contact with the patient; and/or 2) will serve as a channel/conduit for medical gases during infusion (i.e. ventilators) - parts that come in direct contact with medical gases for infusion. Other Relevant Specifications to include the following: j.1 The functional characteristics and technical performance specifications of the device including, as relevant: accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability, and other factors j.2 Other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging. May submit Certificate of Analysis or Test Certificate with finished product specification. For Stability, submit functionality and packaging/integrity test study of the product duly signed by the person who conducted the studies to justify the claimed expiration date. For accelerated study, submit computation to justify the storage conditions used. If the product has no expiration, submit justification from the manufacturer why the device has no expiration. Submit in-use stability study, as applicable. (e.g. contact lens solution, disinfectant) Identify the product's storage condition. For products with special storage conditions, submit transport stability study. For packaging, clarify the type of packaging used. i.e. blister pack, carton box, etc. For medical devices with animal tissue origin, submit Certificate of Compliance with ISO 22442 - Medical devices utilizing animal tissues and their derivatives issued by Government Authority or notified body. Other Descriptive Information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)	

Summary of Design Verification and Validation Documents: The validation documents shall consist of the following: Declaration/Certificates of Conformity to the product standards issued by the manufacturer Summaries or reports of tests and evaluation based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance, such as a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the medical device with reference to the Essential Principles; Data summaries or tests reports and evaluations covering the following appropriate test reports, whichever is applicable: Engineering test, including software validation studies, if applicable Laboratory test Biocompatibility test/biological evaluation Animal Test Simulated Use Clinical evidence Implantable devices Newly introduced devices Devices incorporating new materials coming into contact with the patient Existing materials applied in a body part not previously exposed to that material, and for which no prior chemical experience exists An existing device that is modified and the modification might affect the safety and effectiveness All other medical devices under Class D	Principal/Source/Manufacturer
Clinical evidence of the effectiveness may comprise of medical device-related investigations conducted domestically or other countries, or it may be derived from relevant publications in peer-reviewed scientific literature. The documented evidence submitted should include the objectives, methodology and results presented in context, clearly and meaningfully. The conclusions on the outcome of the clinical studies should be preceded by a discussion in context with the published literature.	

For Class D medical devices: A bibliography of all published reports dealing with the use, safety, and effectiveness of the device. Submit the most recent published reports for the medical device	
Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging): Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable. For any additional product claims on the label, submit studies or tests supporting the claims. For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name and IPO approval of the said brand name. For local manufactured products, IPO approval of the said brand name If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark. Pictures and text of the label should be clear and will not be pixelated when the view is increase in size Lot No., Batch No., Serial No., whichever is applicable should be reflected Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected Storage condition, sterilization method should be reflected if applicable Importer and distributor's name and address should be reflected in the label of the product together with the Registration Number. Suggested Retail Price (SRP) in Philippine peso. The above requirements shall be superseded upon the approval of Administrative Order for the labeling requirements for medical devices.	Applicant or Principal/Source/Manufacturer
Risk assessment which consists of risk analysis, evaluation and reduction measures. Identify the risk Submit Failure Mode Effect Analysis (FMEA) / Risk Benefit Analysis Evaluation of the effectiveness of control measures	Principal/Source/Manufacturer

Physical Manufacturer information: Manufacturing process, including quality assurance measures. This should include the manufacturing methods and procedures, manufacturing environment or conditions, facilities and controls. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing, and packaging of finished medical device. A brief summary of the sterilization method should be included. Include sterilization standard parameters, sterilization procedures, validation protocol and results of latest sterilization revalidation. If the sterilization of the device is contracted out, submit copy of valid ISO Certificate of the contracted sterilizing company. For non-sterile devices: a) submit Non-sterile declaration from the manufacturer; b) If the device is required to be sterilized prior to use, submit recommended sterilization guidelines from the manufacturer.	Principal/Source/Manufacturer
Documentary requirements must be arranged according to the CSDT format. Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements. Provide table of contents with page number	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing the PDF file of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application.	1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR officer
	2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		CDRRHR Evaluator
The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed	FDA receives the payment from the applicant company for posting	PHP7,575.00	Timeline starts after posting of payment	FDA Cashier

by FDA. (e.g. BANCNET, LANDBANK ONCOLL). The Order of Payment will only be valid for 3 working days.				
The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email.	1	CDRRHR assigns the application to evaluator	None	2 working days	CDRRHR Administrative Staff
	2	The technical evaluator reviews the application. Recommends approval or disapproval.	None	83 working days**	Technical Evaluator
	3	Quality Assurance - Checking of recommendation of the Supervisor	None	10 working days	LRD Chief
	4	Drafting and finalization of CPR.	None	3 working days	Technical Evaluator
	5	Final Approval/Disapproval and E-Signature	None	5 working days	CDRRHR Director
	6	Assigning of number and printing of CMDR. Scanning, barcoding, and transmitting of CMDR to the Records Section.	None	6 working days	CDRRHR Administrative Staff
	7	Queuing and endorsement to the FDA Releasing Section	None	1 working day	AFS Records Officer/ Administrative Officer
		TOTAL	PHP7,575.00	110 working days*** .	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

34.TURNED INITIAL APPLICATION FOR CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR IN-VITRO DIAGNOSTIC DEVICES/REAGENTS (IVD)

The application for authorization issued for In Vitro Diagnostic Devices or Reagents after the CPR has passed the certificate expiry date by 120 days and beyond.

<table>
<tr><td>Center/Office/Division</td><td>:</td><td>CDRRHR-LRD</td></tr>
<tr><td>Classification</td><td>:</td><td>Highly technical</td></tr>
<tr><td>Type of Transaction</td><td>:</td><td>G2B - Government-to-Businesses</td></tr>
<tr><td>Who May Avail</td><td>:</td><td>Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader</td></tr>
<tr><td>Fees to be Paid</td><td>:</td><td>
<table>
<tr><th>APPLICATION</th><th>VALIDITY</th><th>FEE</th><th>LABORATORY FEE</th><th>SURCHARGE</th><th>PENALTY</th><th>LRF</th><th>TOTAL</th></tr>
<tr><td>Turned Initial (120 days after certificate’s expiry date)</td><td>1 year</td><td>1,500.00</td><td>c/o NRL</td><td>10,000.00</td><td>2,000.00</td><td>15.00</td><td>13,515.00</td></tr>
</table>
Additional Php1,000.00 + 1% LRF if the product is for the detection of hCG (pregnancy test) which requires performance evaluation testing

*Cost does not include the performance evaluation test; cost of testing depends on the corresponding National Reference Laboratory (NRL)
</td></tr>
</table>

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Table of Contents with correct page number	Applicant
Notarized Application Form Must be completely filled-up; Model / Reference Number / Sizes / Codes must be properly identified; Refrain from indicating the Brand name (if applicable) on the Name of the product and vice versa For kits/sets, identify the complete contents/inclusions on the space provided for device name; For multiple models / reference number / size / codes, an annex page may be attached; For multiple models / reference number / size / codes; a Word copy must be submitted Should be signed by the proper authority as indicated on the form; Re-using forms is not acceptable since this is a legal document.	Applicant. Form may be downloaded from the FDA website.
License to Operate (LTO) as a Medical Device Distributor (Importer/ Exporter/ Wholesaler)/ Local Manufacturer/Trader. Shall be valid The principal shall be reflected on the list of sources.	Applicant
Government Certificate of Clearance and Free Sale/Registration approval from the country of origin issued by the Health Authority Shall be valid Shall be authenticated/apostilled by the territorial Philippine Consulate for Imported Product. For products with a trade name or reference code that differs per country, submit declaration or clarification from the manufacturer/principal. The product shall be stated on the list.	Principal/Source/ Manufacturer
For Imported Products - government issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. Shall be valid Shall be authenticated/apostilled by the territorial Philippine Consulate For products that are manufactured in multiple sites or toll manufacturers, identify or highlight where the product will be sourced from. The product being applied must be indicated in the scope. For locally manufactured products, valid LTO of the manufacturer	Principal/Source/ Manufacturer

Foreign Agency Agreement / Letter of Authorization. Shall be valid. Shall be authenticated/apostilled by the territorial Philippine Consulate. The product being applied must be indicated. For imported medical devices but the agreements are signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties. For open-dated agreements/authorizations, if the certificate is beyond the 5-year period, a re-issued agreement/authorization must be submitted or a notarized attestation by the Principal that the agreement/authorization is still in effect. For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized. For locally manufactured medical devices with toll manufacturer, agreement between the trader and the manufacturer should be duly notarized.	Applicant or Principal/Source/ Manufacturer
Technical Requirements	
Intended use and Directions for Use which includes the following Intended use - this refers to the use for which the medical device is intended, for which it is suited according to the data supplied by the product owner in the instructions as well as the functional capability of the medical device. If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system. Indications of use - this is a general description of the disease or condition that the medical device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the medical device is intended. Instruction for use - these are all necessary information from the product owner including the procedures, methods, frequency, duration, quantity and preparation to be followed for sale use of the medical device, instructions needed to use the medical device in a safe manner shall, to the extent possible, be included on the medical device itself and/or its packaging by other formats/forms. This is the detailed instruction for use for the users of the medical device. The instruction should be clear enough to guide its users.	Principal/Source/Manufacturer

Contraindications - This is a general description of the disease or condition and the patient population for which the medical device should not be used for the purpose of diagnosing, treating, curing or mitigating. Contraindications are conditions under which the medical device should not be used because the risk of use clearly outweighs any possible benefit. Warnings - This is the specific hazard alert information that a user needs to know before using the medical device. Precautions - This alerts the user to exercise special care necessary for the safe and effective use of the medical device. They may include actions to be taken to avoid effects on patients/users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Precautions may also alert the user to adverse effects on the medical device of use or misuse and the care necessary to avoid such effects. Potential adverse effects- These are potential undesirable and serious outcomes (death, injury, or serious adverse events) to the patient/user, or side effects from the use of the medical device, under normal conditions. Intended purpose, including the following information: Type of analyte or measure of the assay. Whether the test is quantitative or qualitative. Role of the test in the clinical use e.g. screening, diagnostic or detection, aid to diagnostic, monitoring. Disease or condition that the test is intended for. Type of specimen to be used e.g. serum, plasma etc. The intended users (e.g. Self-testing by lay person, near- patient by trained personnel or professionals). Assay type e.g. immunoassay, chemistry, cytochemistry, image analysis, immunohistochemistry. The specific name of the instrument required for the assay, if any. Test principle. Specimen type. Conditions for collection, handling, storage and preparation of the specimen. Reagent description and any limitation (e.g. use with a dedicated instrument only). Metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order. Assay procedure including calculations and interpretation of results. Information on interfering substances that may affect the performance of the assay. Performance characteristics (summarized analytical and diagnostic sensitivity, specificity, reproducibility, etc.) Reference intervals.	

Study design (population studies, N, type of sample, matrix, dilution, target concentrations, etc.).	
List of all raw materials used as components of the reagents/test kit Product part or component where the raw material is used shall be specified Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component. If the product contains PVC, identify the PVC plasticizer used. For kits/sets submit all raw materials and specifications used.	Principal/Source/Manufacturer
9. Technical specifications of the Finished Product	Principal/Source/ Manufacturer
. Analytical and clinical performance studies to support IVD performance claims: Specimen type (suitability, collection, storage and transport stability) Equivalence between specimen types Analytical performance characteristics accuracy trueness and bias precision (repeatability and reproducibility) Analytical sensitivity (limit of detection, detection of variants) Analytical specificity (interference and cross-reactivity) Measuring range of the assay Validation of assay cut-off Validation of assay reading time Complete performance study to justify all the claims on the package insert	Principal/Source/Manufacturer
. Brief description of the manufacturing procedure/flowchart which shall include the ff: methods used in the facility controls in the manufacture processing packaging process flowchart showing an overview of production	Principal/Source/Manufacturer

. Risk Analysis to include the results Identify the risk Submit Failure Mode Effect Analysis	Principal/Source/Manufacturer
. Stability test data and results which shall include: shelf life study in-use stability study shipping stability studies to justify claimed shelf life Note: - Shall be performed on at least three (3) different product lots. - For accelerated study, indicate storage conditions, duration of study and computation to justify the storage condition used.	Principal/Source/Manufacturer
. Labeling materials Immediate label secondary packaging box label package insert/brochure. shall include blood sample collection and handling performance study results and summary cross reactivity and list of potential interfering substances (if applicable) warnings and precautions information of the manufacturer revision number	Principal/Source/ Manufacturer
. For pregnancy test kits, 15 samples of the same lot with at least nine (9) months expiration date. NOTE: For other IVD applications, samples will be submitted directly to the respective NRLs. Number of samples required will depend on the requirement of each NRL. Take note that the labeling materials for all the samples should be complete and the same.	Applicant
16. Evidence of registration fee/payment (charge slip/official receipt)	FDA Cashier

All documents shall be submitted in English language. Documents submitted in any other foreign language not accompanied by English Translation shall be disapproved. Submit an electronic/scanned copy (in PDF searchable format of at least 150dpi). The soft copy shall be arranged according to the checklist of requirements. The file name shall consist of the name of the requirement. The electronic copy shall be contained either in one single continuous file per requirement or single continuous file for all requirements. Bring hard copy of the assessment slip. Submission schedule will be generated by the FDA and sent thru email to client	

CLIENT STEPS		AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends and email containing the PDF file of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application.	1	Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None	Timeline starts after posting of payment	CDRRHR Officer
	2	Pre-assessment and issuance of Order of Payment or Denial Letter.	None		Technical Evaluator

The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL) The Order of Payment will only be valid for 3 working days.	The FDA will receive the payment from the applicant company for posting	Php1,500.00 + 1% LRF for initial with 1-year validity* Additional Php1,000.00 + 1% LRF if the product is for the detection of hCG (pregnancy test) which requires performance evaluation testing. Cost does not include the performance evaluation test; cost of testing depends on the corresponding National Reference Laboratory (NRL).		FDA Cashier
The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email.	1 The CDRRHR will assign the application to evaluator	None	1 working day	CDRRHR Administrative Staff
.	2 The technical evaluator reviews the application. Recommends approval or disapproval. Endorsement of the	None	81 working days**	Technical Evaluator

	application to NRL for performance evaluation.			
.	Performance Testing	c/o NRL	Timeline depends on the NRL Procedure	c/o the National Reference Laboratory
	3 Review of Performance Evaluation report	None	5 working days	Technical Evaluator
.	4 Quality Assurance - Checking of recommendation of the Supervisor	None	10 working days	LRD Chief
	5 Drafting and finalization of CPR.	None	2 working days	CDRRHR Administrative Staff
.	6 Final Approval /Disapproval and signature of the Director	None	2 working days	CDRRHR Director
	7 Transmittal to Records Section.	None	1 working day	CDRRHR Administrative Staff
	8 Scanning and Barcoding of CPR. Queuing and endorsement to the FDA Releasing Section.	None	3 working days	AFS Records Officer / Administrative Officer
	TOTAL	PHP1,515.00 For HCG pregnancy test kits – additional PHP1,010.00	105 working days***	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Timeline provided is for applications that are complete and correct with no Notice of Deficiencies issued.

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

35.TURNED INITIAL REGISTRATION OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR EQUIPMENT/DEVICES USED TO TREAT SHARPS, PATHOLOGICAL AND INFECTIOUS WASTES

The application for authorization issued for equipment and devices used to treat sharps, pathological and infectious wastes after the CPR has passed the certificate expiry date by 120 days and beyond.

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	Government-to-Businesses
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	(4 Months and Above) – TURNED INITIAL

Manufacturers/ Distributors/ TSD Facility	Surcharge	Penalties 40%	Initial Fee	LRF 1%	Total
Below Php 1,000,000.00	6,000	2,000	5,000	50	Php13,050
Php 1,000,000 – Php 5,000,000	6,000	3,200	8,000	80	Php17,280
Above Php 5,000,000	6,000	4,000	10,000	100	Php20,100
Healthcare Waste Generators	4,000	1,200	3,000	30	Php8,230

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Properly and completely filled-up application form Must be signed by the company representative with date when signed Location of Installation shall be filled-up since the equipment will be inspected and tested for performance evaluation.	Applicant. Form may be downloaded from the FDA website.
Copy of issued CPR	Applicant
Copy of valid License to Operate (LTO)	Applicant

Copy of SEC Articles of Incorporation or DTI Certificate of Business Registration The activity of manufacturing, importing or distributing the equipment should be reflected in the Articles of Incorporation The DTI Certificate of Business Registration must be valid.	Applicant
Technology Approval from DOST-ITDI for new technologies	Applicant
Technical Report:	
6.1. Company profile;	Applicant
6.2. Characteristics and Sources of generated waste;	Applicant
6.3. Detailed description of treatment equipment to be tested including manufacturer's instructions and technical specifications;	Applicant
6.4. Operating procedures and conditions including as applicable treatment time, pressure, temperature, chemical concentration, doses, feed rates and waste load composition;	Applicant
6.5. Storage, handling and volume capacity;	Applicant
6.6. Applicable emission controls for suspected emissions;	Applicant
6.7. Potential hazards/toxicities of waste residues;	Applicant
6.8. Energy efficiency	Applicant
6.9. Occupational safety and health assurance.	Applicant
7. Copy of Operation Manual	Applicant
8. Layout / Plans	Applicant
8.1. Location of installation;	Applicant
8.2. Design / Drawing or picture of the device / equipment applied for;	Applicant
9. Supplementary requirements for equipment / devices used for chemical disinfection:	Applicant
9.1. Material Safety Data Sheet (MSDS) of the chemicals to be used for disinfection	Applicant
9.2. The chemical to be used should be registered with the DENR-EMB or must be compliant with the WHO guidelines for hazardous wastes.	Applicant

For healthcare waste generators (e.g. hospitals) and Treatment, Storage and Disposal (TSD) Facilities, the Environmental Compliance Certificate (ECC) issued by the Environmental Management Bureau-Department of Environment and Natural Resources (EMB-DENR) and the License to Operate issued by the Department of Health shall be submitted together with the above documentary requirements. - License to Operate should be valid.	Applicant
Notes: .This office shall not accept applications with incomplete requirements. .All documents should be submitted in electronic copy format. .All information contained in this application form will be held strictly confidential.	
*Submission schedule is every Thursday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing the PDF of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule for application.	Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR Officer
	Pre-assessment and issuance of Order of Payment or Denial Letter.	None	Timeline starts after posting of payment	Technical Evaluator
The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g. BANCNET, LANDBANK ONCOLL). *The Order of Payment will only be valid for 3 working days.	2 FDA receives the payment from the applicant company for posting.	Refer Table Above Php13,050/ Php17,280/ Php20,100/ Php8,230		FDA Cashier

The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email.	CDRRHR assigns the application to an evaluator.	None	2 working days	CDRRHR Administrative Staff
.	Technical evaluation of application. Issuance of a Notice of Deficiencies or endorsement.	None	20 working days	Technical Evaluator
Client complies with the Notice of Deficiencies *Clients are given 30 days to comply with the NOD. Non-compliance would mean disapproval of the application.	4.1 Evaluator reviews compliance documents.	None	10 working days	Technical Evaluator
	Once fully complied, endorsed to NRL for Performance Evaluation	None	1 working day	Technical Evaluator
.	Performance Testing	c/o NRL	Timeline depends on the NRL procedure	c/o EAMC-NRL
	Review of Performance Evaluation report	None	5 working days	Technical Evaluator
	Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief
	Drafting and finalization of CPR.	None	2 working days	CDRRHR Administrative Staff
	Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	Assigning of number. Transmittal to the Records Section.	None	2 working days	CDRRHR Administrative Staff
	Scanning and barcoding of CPR. Queuing and endorsement to the FDA Releasing Section.	None	2 working days	AFS Records Officer / Administrative Officer
	TOTAL	Php17,280/ Php20,100/ Php8,230	50 working days**	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

36.TURNED INITIAL REGISTRATION OF CERTIFICATE OF REGISTRATION FOR WATER PURIFICATION DEVICES/SYSTEM

The application for authorization issued for water purification devices or systems after the CPR has passed the certificate expiry date by 120 days and beyond.

<table>
<tr><td>Center/Office/Division</td><td>:</td><td>CDRRHR-LRD</td></tr>
<tr><td>Classification</td><td>:</td><td>Highly Technical</td></tr>
<tr><td>Type of Transaction</td><td>:</td><td>G2B - Government-to-Businesses</td></tr>
<tr><td>Who May Avail</td><td>:</td><td>Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader</td></tr>
<tr><td>Fees to be Paid</td><td>:</td><td>Note: For renewal applications that are filed 120 days after expiry date of certificate
<table>
<tr><th>Surcharge</th><th>Penalties 40%</th><th>Initial Fee</th><th>LRF</th><th>Total</th></tr>
<tr><td>1,000</td><td>200</td><td>500</td><td>10</td><td>Php1,710</td></tr>
<tr><td>2,000</td><td>400</td><td>1,000</td><td>10</td><td>Php3,410</td></tr>
</table>
</td></tr>
</table>

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Properly and completely filled-up application form Must be signed by the company representative with a date when signed. Claims should only be either for safe drinking water or purified water. Claims such as alkaline, ionized, PI, oxygenated or energized are not acceptable. Latest form should be used.	Applicant. Form may be downloaded from the FDA website.

Copy of SEC Articles of Incorporation or DTI Certificate of Business Registration The activity of manufacturing, importing or distributing the device should be reflected in the Articles of Incorporation The DTI Certificate of Business Registration must be valid.	Applicant
Copy of Mayor's Permit Must be Valid Name and address in the Mayor's Permit should be the same in the application form	Applicant
4. Copy of Operation Manual	Applicant
- Name and model number of the device in the operation manual should be the same with the application form and label	
.Layout of devices or flowchart of treatment process. - The lay out or flowchart should show every stage how the water is being treated. Include a narrative description for every stage or step of the treatment process Submit a clear and colored photo of the device. .List of raw materials used as components of the water purification device/system. Should have a list of the component parts with the corresponding raw material used in the device. .Label/labelling/product insert of manufacturer's performance claim Should be clear and readable. Name of the product and model number in the label should be consistent with the name and model number in the application form and operation manual. Name and address of the manufacturer, importer and distributor should be reflected Provide provision for the registration number .For special claims, data from scientific research and laboratory analysis supporting and proving the claims of the manufacturer of the product	Applicant
0. Copy of valid License to Operate (LTO)	Applicant

NOTES: • Submit an electronic/scanned copy (in PDF searchable format of at least 150 dpi) • The soft copy should be arranged according to the checklist of requirements. The file name should consist of the name of the requirement. The electronic copy should be contained either in one single continuous file per requirement or single continuous file for all requirements.	
*Submission schedule is every Friday from 8:00 AM to 5:00 PM. This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
Client sends an email containing their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule of application.	1 Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None	Timeline starts after posting of payment	CDRRHR Officer
	2 Pre-assessment and issuance of Order of Payment or Denial Letter.	None		Technical Evaluator
Payment of the approved application at the Cashier		See above table Php1,710/ Php3,410		Cashier
	1 Transmittal of applications to CDRRHR	None	1 working day	FDAC Officer
.	2 Decking of application	None	2 working days	Data Controller

	3 Technical evaluation of application. Issuance of a Notice of Deficiencies or endorsement.	None	20 working days	Technical Evaluator
Client complies with the Notice of Deficiencies *Clients are given 30 days to comply with the NOD. Non-compliance would mean disapproval of the application.	3.1 Evaluator reviews submitted compliance documents.	None	13 working days	Technical Evaluator
	2 Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief
	3 Drafting and finalization of CPR.	None	2 working days	Administrative Officer
	4 Final Approval/Disapproval and E-Signature	None	3 working days	CDRRHR Director
	5 Assigning of number. Transmital to Records Section.	None	2 working days	Administrative Officer
	6 Scanning and barcoding of CPR	None	1 working day	Records Section Officer
	7 Queuing and endorsement to the FDA Releasing Section	None	1 working day	Releasing Section Officer
	TOTAL	Php1,710/ Php3,410	50 working days**	

*Day 1 commences upon the receipt of the proof of payment / posting of payment.

**Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.

CENTER FOR DRUG REGULATION AND RESEARCH
EXTERNAL SERVICES

1.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR CANCER DRUGS (INITIAL)

This Certificate of Product Registration is granted to Marketing Authorization Holders of cancer drugs upon compliance to Quality, Safety, Efficacy standards. It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Cancer Drugs
Fees to be Paid	:	Initial Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2 or 5-year CPR validity (Based on Bureau Circular No. 5 s. 1997). 2 year-validity: Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF 5 year-validity: Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF PHARMACEUTICAL PRODUCTS (PRESCRIPTION – HUMAN CANCER DRUGS) ASEAN Common Technical Dossier Part I: Administrative Data and Product Information Sec. A Introduction Sec. B Overall ASEAN Common Technical Dossier Table of Contents Sec. C Guidance on the Administrative Data and Product Information	

Duly accomplished and notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) Letter of Authorization (where applicable) Certifications For contract manufacturing: License of pharmaceutical industries and contract manufacturer Contract manufacturing agreement GMP certificate of contract manufacturer For manufacturing “under-license” License of pharmaceutical industries GMP certificate of the manufacturer Copy of “under-license” agreement For locally manufactured products: . License of pharmaceutical industries . GMP certificate (country specific) For imported products . License of pharmaceutical industries/importer/wholesaler (country specific) . Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format . Foreign GMP Clearance Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Part II: Quality	Applicant Company/Manufacturer (For the whole Part I) FDA Website & Cashier

Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 5 Reference Standards or Materials S 7 Stability Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages	Applicant Company/Manufacturer (For the whole Part II): Quality Document

P 2.3.3. Physicochemical and Biological Properties P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Product Interchangeability/equivalence evidence (if applicable) Note: • ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions.	

CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE (MR)/MONITORED RELEASE EXTENSION (MRE) TO INITIAL APPLICATIONS: ACTD Parts I & II (same as above) Risk Management Plan Periodic Safety Update Report (PSUR) or Phase IV Clinical Study Report (whichever is applicable) Other post-approval commitments (if any, based on the Special Conditions at the back page of the CPR and accompanying letter)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Additional Requirement for Dangerous Drugs (as per RA 9165 and Dangerous Drugs Board): -License to Handle Dangerous Drugs	Philippine Drug Enforcement Agency (PDEA)
Note: As per FDA-Circular-No.2020-003 , Submission of Risk Management Plan for a generic drug is not required, but it is expected that the Marketing Authorization Holder (MAH) will continue to evaluate the safety of their products on a regular basis and must be readily available upon request of FDA in case-to-case basis, such as but not limited to: In response to a safety concern arising from a new route of administration; As a result of a new safety concern associated with a new indication that may require additional PV activities; If the innovator or reference product has safety concerns that have been identified to require additional local PV activities.	Applicant Company/Manufacturer

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1. Sends the scheduled date of submission for pre-assessment	None		FDAC Personnel
	Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR Personnel

2. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.BizPortal Sends proof of payment to the FDAC.	Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC Personnel
	Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving
	Queuing time of the application before decking to evaluators	None	21 working days	CDRR-CRR Unit Personnel
	Decks/Assigns the application to the assigned evaluator	None	1 working day	CDRR Director
	Evaluates the application according to requirements and prescribed standards	None	130 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)

If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (for major deficiencies) For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients	None		FDRO I/II/III
	Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	78 working days	FDRO III
	Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III or higher) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR. For Dangerous Drugs, prepares a letter/notification to PDEA to seek comments/ recommendations on the	None	1 working day	FDRO I/II

	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	FDRO IV (Supervisor)
	Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	1 working day (per batch of applications)	LRD Chief
	Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	FDA Records *Personnel*

3. Receives the CPR/LOD/letter	Releases the CPR/LOD/letter to the client	None	1 working day	AFS Releasing Section *Personnel*
TOTAL: (Service is covered under Republic Act No. 11215 Article VI, Section 23)			working days	

2.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF PHARMACEUTICAL PRODUCTS FOR HUMAN AND USE INCLUDING VACCINES AND BIOLOGICALS THROUGH THE WHO COLLABORATIVE REGISTRATION PROCEDURE (CRP)

This Certificate of Product Registration is granted to Marketing Authorization Holders of drug products upon compliance to the agency-prescribed Quality, Safety, Efficacy standards through the World Health Organization (WHO) **Collaborative Registration Procedure (CRP)** based on FDA-Circular-No.-2022-009. It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of WHO Pre-qualified Pharmaceutical Products Monitored Release (MR) and Initial for WHO Pre-qualified drug products for human use including vaccines and biologicals
Fees to be Paid	:	A.O. No.-50-2001 FDA-Advisory-No.2021-2904 New Drug/Monitored Release (for all types of products): Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + Php 2,500.00* [Post-Marketing Surveillance (i.e., Local Phase IV Clinical Trial) Protocol Review] + 1% LRF *If additional PV activity(ies) are necessary based on FDA-Circular-No.2021-020 Initial Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF

		The applicant may apply for 2/5-year CPR validity. 2 year-validity: Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF 5 year-validity: Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF

ELIGIBILITY CRITERIA **(provided under Sec. V.B. of FDA-Circular-No.-2022-009)**
1. Only FDA-licensed drug manufacturers, traders, and distributors with WHO-prequalified pharmaceutic products and vaccines may apply for registration through this procedure. 2. Prior to the submission of the registration application with the FDA, the applicant shall ensure that the form provided under Appendix 2 of WHO TRS 996 Annex 8, Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the Procedure (Annex A), has been duly accomplished and submitted by the Manufacturer or Prequalification Holder to the World Health Organization Prequalification Team (WHO/PQT). 3. The eligible product shall be the same as the product prequalified by the WHO/PQT. a. All aspects of the drug product's quality, including but not limited to the formulation, manufacturing site/s, release and shelf-life specifications, primary packaging, and commercial presentation must be the same as those currently approved by the WHO/PQT at the time of submission. b. The proposed indication/s, dosing regimen/s, patient group/s, and/or direction/s for use should be the same as those approved by the WHO/PQT. 4. For post-approval change/s, only applications submitted to FDA not later than thirty (30) calendar days after approval of the change/s by WHO/PQT may be applied through CRP of WHO-prequalified pharmaceutical products and vaccines. Applications for post approval change/s which have not undergone WHO prequalification shall be evaluated through the regular FDA registration pathway following FDA-Circular-No.-2014-008 , its amendment FDA-Circular-No.-2014-008-A , supplement FDA-Circular-No.-2016-017 , and succeeding issuances for the same purposes.

5. The applicant may choose to avail of the CRP of WHO-prequalified pharmaceutical products and vaccines only if the application has not been applied through other types of facilitated review pathway (i.e. abridged review and verification review). If any of the requirements of CRP of WHO-prequalified pharmaceutical products and vaccines cannot be complied with, the application shall not be accepted and the applicant shall be advised to submit their application following the regular review pathway.
GENERAL REQUIREMENTS
Accomplished application form as per FDA-Circular-No.-2014-003 , as prescribed in FDA-Advisory-No.2022-0001, or any future issuance providing for its amendment, repeal, or modification; Complete International Council for Harmonization of Technical Requirements for Pharmaceutical for Human Use (ICH) Common Technical Document (CTD) or ASEAN Common Technical Dossier (ACTD) data requirements following existing guidelines (Refer to Annex 8.2 Checklist of Requirements for MR/Initial Applications of Vaccines and Biologicals). Appendix 3, Part A of WHO TRS 996 Annex 8, Expression of interest to the national regulatory authorities (NRAs) in the assessment and accelerated national registration of a World Health Organization (WHO) prequalified pharmaceutical product or vaccine) (Annex B). If the applicant company is not the original WHO PQ holder, the applicant company must submit an authorization letter that indicates agreement of the original WHO PQ holder, following the prescribed format in Appendix 3, Part A of WHO TRS 996; Country-specific requirements such as: Current Good Manufacturing Practice (cGMP) Clearance of Foreign Drug Manufacturers issued by Philippine FDA; Labeling materials consistent with country-specific requirements; Stability studies conducted under Climatic Zone IVb (hot and humid) for applicable products; Tabulated summary of WHO/PQT post-approval change/s prior to the registration application through CRP of WHO-prequalified pharmaceutical products and vaccines, obtained by the manufacturer/prequalification holder; Risk Management Plan (RMP) and RMP Philippine-specific Annex, with Periodic Safety Update Reports (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER), as applicable; Representative sample with corresponding Certificate of Analysis (upon request of the evaluator); and Additional requirements for vaccines and biological products: Identification of the medical director who will monitor event/s reactions, and prepare appropriate report to be submitted to FDA; Person/s responsible for production and control of the product (Name/s, Position, Department, and Sample of Signature); Information/procedure on the numbering system of the lots or batches; System for the reprocessing of the product in event of rejection of the lot or batch by the manufacturer’s Quality Assurance/Quality Control; Demonstration of lot-to-lot consistency from three (3) consecutive lots or batches; Description of the cold-chain procedures employed from the origin to the port of entry and storage in the Philippines (how and where);

Summary Lot Protocol (for vaccines, toxoids, and immunoglobulins only); List of countries where the product is already licensed and the date of approval (for vaccines only); and Head-to-head comparability studies (for biosimilars only).

CHECKLIST OF REQUIREMENTS FOR NEW CHEMICAL ENTITIES/MONITORED-RELEASE REGISTRATION OF PHARMACEUTICAL PRODUCTS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information	Applicant
Sec. A Introduction	Company/Manufacturer
Sec. B Overall ASEAN Common Technical Dossier	(For the whole Part I)
Table of Contents	
Sec. C Guidance on the Administrative Data and Product Information	
Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment)	FDA Website & Cashier
Letter of Authorization (where applicable)	
Certifications	
For contract manufacturing:	
License of pharmaceutical industries and contract manufacturer	
Contract manufacturing agreement	
GMP certificate of contract manufacturer	
For manufacturing “under-license”	
License of pharmaceutical industries	
GMP certificate of the manufacturer	
Copy of “under-license” agreement	
For locally manufactured products:	
License of pharmaceutical industries	
GMP certificate (country specific)	
For imported products	

License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures	Applicant Company/Manufacturer (For the whole Part II: Quality)

S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures	Applicant Company/Manufacturer (For the whole Part III: Nonclinical Document)

P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Product Interchangeability/Equivalence Evidence (if applicable) Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1.General Aspect 2.Content and Structural Format Sec. C Nonclinical Written and Tabulated Summaries 1.Nonclinical Written Summaries 1.1.Introduction 1.2.General Presentation Issues 2.Content of Nonclinical Written and Tabulated Summaries 2.1.Pharmacology 2.1.1.Written Summary 2.1.1.1.Primary Pharmacodynamics 2.1.1.2.Secondary Pharmacodynamics 2.1.1.3.Safety Pharmacology 2.1.1.4.Pharmacodynamic Drug Interactions 2.1.2. Tabulated Summary 2.2.Pharmacokinetics 2.2.1.Written Summary 2.2.1.1.Absorption 2.2.1.2.Distribution 2.2.1.3.Metabolism 2.2.1.4.Excretion 2.2.1.5.Pharmacokinetic Drug Interaction (Nonclinical) 2.2.2. Tabulated Summary 2.3.Toxicology	Applicant Company/Manufacturer (For the whole Part IV: Clinical Document)

2.3.1.Written Summary 2.3.1.1.Single-Dose Toxicity 2.3.1.2.Repeat-Dose Toxicity 2.3.1.3.Genotoxicity 2.3.1.4.Carcinogenicity 2.3.1.5.Reproductive and Developmental Toxicity 2.3.1.5.1.Fertility and Early Embryonic Development 2.3.1.5.2.Embryo-Foetal Development 2.3.1.5.3.Prenatal and Postnatal Development 2.3.1.6.Local Tolerance 2.3.1.7.Other Toxicity Studies (if available) 2.3.2. Tabulated Summary 3.Nonclinical Tabulated Summaries Sec. D Nonclinical Study Reports 1.Table of Contents 2.Pharmacology 2.1.Written Study Reports 2.1.1.Primary Pharmacodynamics 2.1.2.Secondary Pharmacodynamics 2.1.3.Safety Pharmacology 2.1.4.Pharmacodynamic Drug Interactions 3.Pharmacokinetics 3.1.Written Study Reports 3.1.1.Analytical Methods and Validation Reports 3.1.2.Absorption 3.1.3.Distribution 3.1.4.Metabolism 3.1.5.Excretion 3.1.6.Pharmacokinetic Drug Interaction (Nonclinical) 3.1.7.Other Pharmacokinetic Studies 4.Toxicology 4.1Written Study Reports 4.1.1.Single-Dose Toxicity 4.1.2.Repeat-Dose Toxicity 4.1.3.Genotoxicity	

4.1.3.1.In vitro Reports	
4.1.3.2.In vivo Reports	
4.1.4.Carcinogenicity	
4.1.4.1.Long Term Studies	
4.1.4.2.Short- or Medium-Term Studies	
4.1.4.3.Other Studies	Applicant Company
4.1.5.Reproductive and Developmental Toxicity	/Manufacturer
4.1.5.1Fertility and Early Embryonic Development	
4.1.5.2.Embryo-Foetal Development	
4.1.5.3.Prenatal and Postnatal Development	Applicant Company
4.1.5.4.Studies in which the Offspring are Dosed and/or further Evaluated	/Manufacturer
4.1.6Local Tolerance	
4.1.7.Other Toxicity Studies (if available)	FDA (Applicant Company)
4.1.7.1.Antigenicity	
4.1.7.2.Immunotoxicity	
4.1.7.3.Dependence	
4.1.7.4.Metabolites	
4.1.7.5.Impurities	
4.1.7.6.Other	
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5.Overview of Safety	
6.Benefits and Risks Conclusions	
Sec. C Clinical Summary	
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1.1.Background and Overview	
1.2.Summary of Results of Individual Studies	

1.3.Comparison and Analyses of Results across Studies Appendix 1 2.Summary of Clinical Pharmacology Studies 2.Background and Overview 2.2.Summary of Results of Individual Studies 2.3.Comparison and Analyses of Results across Studies 2.4.Special Studies Appendix 2 3Summary of Clinical Efficacy 3.1Background and Overview of Clinical Efficacy 3.2.Summary of Results of Individual Studies 3.3Comparison and Analyses of Results across Studies 3.3.1.Study Populations 3.3.2.Comparison of Efficacy Results of all Studies 3.3.3.Comparison of Results in Sub-populations 3.4.Analysis of Clinical Information Relevant to Dosing Recommendations 3.5.Persistence of Efficacy and/or Tolerance Effects Appendix 3 4Summary of Clinical Safety 4.1.Exposure to the Drug 4.1.1.Overall Safety Evaluation Plan and Narratives of Safety Studies 4.1.2.Overall extent of Exposure 4.1.3.Demographic and Other Characteristics of Study Population 4.2.Adverse Events 4.2.1.Analysis of Adverse Events 4.2.1.1.Common Adverse Events 4.2.1.2Deaths 4.2.1.3.Other Serious Adverse Events 4.2.1.4.Other Significant Adverse Events 4.2.1.5.Analysis of Adverse Events by Organ System or Syndrome 4.2.2. Narratives 4.3.Clinical Laboratory Evaluations 4.4.Vital Signs, Physical Findings, and Other Observations Related to Safety 4.5.Safety in Special Groups and Situations 4.5.1.Patient Groups	

4.5.2.Drug Interactions 4.5.3.Use in Pregnancy and Lactation 4.5.4.Overdose 4.5.5Drug Abuse 4.5.6.Withdrawal and Rebound 4.5.7.Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability 4.6. Post-Marketing Data Appendix 4 5.Synopses of Individual Studies Sec. D Tabular Listing of All Clinical Studies Sec. E Clinical Study Reports (if applicable) 1.Reports of Biopharmaceutic Studies 1.1.Bioavailability (BA) Study Reports 1.2.Comparative BA or Bioequivalence (BE) Study Reports 1.3.In vitro-In vivo Correlation Study Reports 1.4.Reports of Bioanalytical and Analytical Methods for Human Studies 2.Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials 2.1.Plasma Protein Binding Study Reports 2.2.Reports of Hepatic Metabolism and Drug Interaction Studies 2.3.Reports of Studies Using Other Human Biomaterials 3.Reports of Human Pharmacokinetic (PK) Studies 3.1.Healthy Subject PK and Initial Tolerability Study Reports 3.2.Patient PK and Initial Tolerability Study Reports 3.3Population PK Study Reports 4.Reports of Human Pharmacodynamic (PD) Studies 4.1Healthy Subject PD and PK/PD Study Reports 4.2.Patient PD and PK/PD Study Reports 5.Reports of Efficacy and Safety Studies 5.1.Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2.Study Reports of Uncontrolled Clinical Studies 5.3.Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses 5.4.Other Clinical Study Reports 6.Reports of Post-Marketing Experience 7.Case Report Forms and Individual Patient Listing	

Sec. F List of Key Literature References Additional Requirements: 1.Risk Management Plan – which shall include the following: RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems RMP Philippine-Specific Annex (as applicable) RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted 2.Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA Circular No. 2021-020] Note: •ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions.	

CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF PHARMACEUTICAL PRODUCTS (PRESCRIPTION – HUMAN DRUGS)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
ASEAN Common Technical Dossier Part I: Administrative Data and Product Information Sec. A Introduction Sec. B Overall ASEAN Common Technical Dossier Table of Contents Sec. C Guidance on the Administrative Data and Product Information Duly accomplished and notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) 2.Letter of Authorization (where applicable) Certifications For contract manufacturing: License of pharmaceutical industries and contract manufacturer Contract manufacturing agreement	Applicant Company/Manufacturer (For the whole Part I)

GMP certificate of contract manufacturer For manufacturing “under-license” License of pharmaceutical industries GMP certificate of the manufacturer Copy of “under-license” agreement For locally manufactured products: License of pharmaceutical industries GMP certificate (country specific) For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information	FDA Website & Cashier Applicant Company/Manufacturer (For the whole Part II): Quality Document

S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 5 Reference Standards or Materials S 7 Stability Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula	

P 3.2. Manufacturing Process and Process Control P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Product Interchangeability/equivalence evidence (if applicable) Note: •ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions.	
CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE (MR)/MONITORED RELEASE EXTENSION (MRE) TO INITIAL APPLICATIONS: ACTD Parts I & II (same as above) Risk Management Plan Periodic Safety Update Report (PSUR) or Phase IV Clinical Study Report (whichever is applicable)	 Applicant Company/ Manufacturer Applicant Company/ Manufacturer

Other post-approval commitments (if any, based on the Special Conditions at the back page of the CPR and accompanying letter)	Applicant Company/ Manufacturer
Additional Requirement for Dangerous Drugs (as per RA 9165 and Dangerous Drugs Board): -License to Handle Dangerous Drugs	Philippine Drug Enforcement Agency (PDEA)
Note: As per FDA-Circular-No.2020-003, Submission of Risk Management Plan for a generic drug is not required, but it is expected that the Marketing Authorization Holder (MAH) will continue to evaluate the safety of their products on a regular basis and must be readily available upon request of FDA in case-to-case basis, such as but not limited to: In response to a safety concern arising from a new route of administration; As a result of a new safety concern associated with a new indication that may require additional PV activities; If the innovator or reference product has safety concerns that have been identified to require additional local PV activities.	Applicant Company/Manufacturer

CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE AND INITIAL REGISTRATION OF VACCINES AND BIOLOGICALS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
A.O. No.47-a s.2001 Rules and Regulations on the Registration, including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biological Products	Applicant Company
ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information	Applicant Company
Sec. A Introduction	Applicant Company
Sec. B Overall ASEAN Common Technical Dossier Table of Contents	Applicant Company
Sec. C Guidance on the Administrative Data and Product Information	Applicant Company
Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) Letter of Authorization (where applicable)	FDA Website Applicant Company/ Manufacturer
Certifications For contract manufacturing:	

. License of pharmaceutical industries and contract manufacturer . Contract manufacturing agreement . GMP certificate of contract manufacturer	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For manufacturing “under-license” . License of pharmaceutical industries . GMP certificate of the manufacturer . Copy of “under-license” agreement	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For locally manufactured products: . License of pharmaceutical industries . GMP certificate (country specific)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Risk Management Plan (RMP) which shall include the following: RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems RMP Philippine-Specific Annex (as applicable) RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report . List of Countries where the product is already licensed and the date of approval (for vaccines) . Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer

. Person/s responsible for production and control of the product (Name/s Position, Department, and sample of signature) . Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)	
Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials	Applicant Company/ Manufacturer (For whole Part II: Quality)

S 6 Container Closure System S 7 Stability	
Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control Information on the number system of the lots or batches System for the re-processing of the product in the event of rejection of the lot or batch by the manufacturer's QA/QC P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients	

P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses Summary Lot Protocol (for vaccines, toxoids and immunoglobulins) Lot to Lot Consistency from three (3) consecutive batches P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Head to Head Comparability – for Biosimilars	
Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1. General Aspect 2. Content and Structural Format Sec. C Nonclinical Written and Tabulated Summaries 1. Nonclinical Written Summaries 1.1. Introduction 1.2. General Presentation Issues 2.Content of Nonclinical Written and Tabulated Summaries 2.1.Pharmacology 2.1.1.Written Summary 2.1.1.1.Primary Pharmacodynamics 2.1.1.2.Secondary Pharmacodynamics 2.1.1.3.Safety Pharmacology 2.1.1.4.Pharmacodynamic Drug Interactions	Applicant Company/Manufacturer (For whole Part III: Nonclinical Document)

2.1.2. Tabulated Summary 2.2.Pharmacokinetics 2.2.1.Written Summary 2.2.1.1.Absorption 2.2.1.2.Distribution 2.2.1.3.Metabolism 2.2.1.4.Excretion 2.2.1.5.Pharmacokinetic Drug Interaction (Nonclinical) 2.2.2. Tabulated Summary 2.3.Toxicology 2.3.1.Written Summary 2.3.1.1.Single-Dose Toxicity 2.3.1.2.Repeat-Dose Toxicity 2.3.1.3.Genotoxicity 2.3.1.4.Carcinogenicity 2.3.1.5.Reproductive and Developmental Toxicity 2.3.1.5.1.Fertility and Early Embryonic Development 2.3.1.5.2.Embryo-Foetal Development 2.3.1.5.3.Prenatal and Postnatal Development 2.3.1.6.Local Tolerance 2.3.1.7.Other Toxicity Studies (if available) 2.3.2. Tabulated Summary 3.Nonclinical Tabulated Summaries Sec. D Nonclinical Study Reports 1. Table of Contents 2. Pharmacology 2.1. Written Study Reports 2.1.1. Primary Pharmacodynamics 2.1.2. Secondary Pharmacodynamics 2.1.3. Safety Pharmacology	

2.1.4. Pharmacodynamic Drug Interactions 3. Pharmacokinetics 3.1. Written Study Reports 3.1.1. Analytical Methods and Validation Reports 3.1.2. Absorption 3.1.3. Distribution 3.1.4. Metabolism 3.1.5. Excretion 3.1.6. Pharmacokinetic Drug Interaction (Nonclinical) 3.1.7. Other Pharmacokinetic Studies 4. Toxicology 4.1. Written Study Reports 4.1.1. Single-Dose Toxicity 4.1.2. Repeat-Dose Toxicity 4.1.3. Genotoxicity 4.1.3.1. In vitro Reports 4.1.3.2. In vivo Reports 4.1.4. Carcinogenicity 4.1.4.1. Long Term Studies 4.1.4.2. Short- or Medium-Term Studies 4.1.4.3. Other Studies 4.1.5. Reproductive and Developmental Toxicity 4.1.5.1. Fertility and Early Embryonic Development 4.1.5.2. Embryo-Foetal Development 4.1.5.3. Prenatal and Postnatal Development 4.1.5.4. Studies in which the Offspring are Dosed and/or further Evaluated 4.1.6. Local Tolerance 4.1.7. Other Toxicity Studies (if available) 4.1.7.1. Antigenicity 4.1.7.2. Immunotoxicity 4.1.7.3. Dependence	

4.1.7.4. Metabolites 4.1.7.5. Impurities 4.1.7.6. Other	
Sec. E List of Key Literature References Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Product Development Rationale 2. Overview of Biopharmaceutics 3. Overview of Clinical Pharmacology 4. Overview of Efficacy 5. Overview of Safety 6. Benefits and Risks Conclusions Sec. C Clinical Summary 1. Summary of Biopharmaceutic Studies and Associated Analytical Methods 1.1. Background and Overview 1.2. Summary of Results of Individual Studies 1.3. Comparison and Analyses of Results across Studies Appendix 1 2. Summary of Clinical Pharmacology Studies 2.1. Background and Overview 2.2. Summary of Results of Individual Studies 2.3. Comparison and Analyses of Results across Studies 2.4. Special Studies Appendix 2 3. Summary of Clinical Efficacy 3.1. Background and Overview of Clinical Efficacy 3.2. Summary of Results of Individual Studies 3.3. Comparison and Analyses of Results across Studies 3.3.1. Study Populations	Applicant Company/Manufacturer (For whole Part IV: Clinical Document)

3.3.2. Comparison of Efficacy Results of all Studies 3.3.3. Comparison of Results in Sub-populations 3.4. Analysis of Clinical Information Relevant to Dosing Recommendations 3.5. Persistence of Efficacy and/or Tolerance Effects Appendix 3 4. Summary of Clinical Safety 4.1. Exposure to the Drug 4.1.1. Overall Safety Evaluation Plan and Narratives of Safety Studies 4.1.2. Overall extent of Exposure 4.1.3. Demographic and Other Characteristics of Study Population 4.2. Adverse Events 4.2.1. Analysis of Adverse Events 4.2.1.1. Common Adverse Events 4.2.1.2. Deaths 4.2.1.3. Other Serious Adverse Events 4.2.1.4. Other Significant Adverse Events 4.2.1.5. Analysis of Adverse Events by Organ System or Syndrome 4.2.2. Narratives 4.3. Clinical Laboratory Evaluations 4.4. Vital Signs, Physical Findings, and Other Observations Related to Safety 4.5. Safety in Special Groups and Situations 4.5.1. Patient Groups 4.5.2. Drug Interactions 4.5.3. Use in Pregnancy and Lactation 4.5.4. Overdose 4.5.5. Drug Abuse 4.5.6. Withdrawal and Rebound 4.5.7. Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability 4.6. Post-Marketing Data Appendix 4 5. Synopses of Individual Studies	

Sec. D Tabular Listing of All Clinical Studies Sec. E Clinical Study Reports (if applicable) 1. Reports of Biopharmaceutic Studies 1.3. In vitro-In vivo Correlation Study Reports 1.4. Reports of Bioanalytical and Analytical Methods for Human Studies 2. Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials 2.1. Plasma Protein Binding Study Reports 2.2. Reports of Hepatic Metabolism and Drug Interaction Studies 2.3. Reports of Studies Using Other Human Biomaterials 3. Reports of Human Pharmacokinetic (PK) Studies 3.1. Healthy Subject PK and Initial Tolerability Study Reports 3.2. Patient PK and Initial Tolerability Study Reports 3.3. Population PK Study Reports 4. Reports of Human Pharmacodynamic (PD) Studies 4.1. Healthy Subject PD and PK/PD Study Reports 4.2. Patient PD and PK/PD Study Reports 5. Reports of Efficacy and Safety Studies 5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2. Study Reports of Uncontrolled Clinical Studies 5.3. Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses 5.4. Other Clinical Study Reports 6. Reports of Post-Marketing Experience 7. Case Report Forms and Individual Patient Listing Sec. F List of Key Literature References Additional Requirements: 1. For MR, Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020]	Applicant Company/Manufacturer

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	Sends the scheduled date of submission for pre-assessment	None		FDAC Personnel
	Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR Pre-assessor

2. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.bizPortal Sends proof of payment to the FDAC.	Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC Personnel
	Receives the application from FDAC and encodes/updates the database.	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3. Decks/Assigns the application to the assigned evaluators of Registration Section and/or Clinical Research Section*. *Decking to CRS is only applicable for Monitored release and Initial (Vaccines) applications	None	1 working day	CDRR Director

	Evaluator verifies the registration pathway of the application if indeed for Collaborative Review/Registration Procedure (CRP). The evaluator shall inform the WHO/PQT and the applicant of its consent to apply the procedure through Appendix 3, Part B of WHO TRS 996 Annex 8, Decision on acceptance by the NRA to apply the Procedure to a specified WHO-prequalified product and request for access to product-specific information and documentation (Annex C). The regulatory time is stopped (stop clock) until the WHO/PQT has provided the FDA with the requested product-related information and documentation, through the restricted-access website.	None	5 working days	FDRO I/II/III
	For human vaccines, toxoids and immunoglobulins, Summary Lot Protocol shall be referred to CSL.	None	31 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/FDRO III (Senior Evaluator)
	2.5 Evaluates the application according to requirements and prescribed standards	None		FDRO I/II/III

3. If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 a. Clinical Research Section (Safety and Efficacy evaluator) Prepares a worksheet with Recommendations on the evaluated safety and efficacy dossier, RMP, and PMS protocol (if any), then forwards this to the Quality evaluator of the Registration Section. b. Registration Section (Quality evaluator) Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS)	None		FDRO I/II/III
	Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS) *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication **step 8a is only applicable for Monitored Release and Initial (Vaccines) applications.			
	3.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	20 working days	FDRO III

	3.3 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR For Dangerous Drugs, prepares a letter/notification to PDEA for its recommendation on the application particularly on the formulation and labeling	None	2 working days	FDRO I/II/III
	3.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor.	None		FDRO III
	3.5 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None		FDRO IV (Supervisor)
	3.6 Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	1 working day	LRD Chief
	3.7 Signs and approves the final decision	None	1 working day	CDRR Director
	3.8 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	3.9 Scans, barcodes the final output document (CPR/LOD/Letter); and endorses the final output document to the FDAC Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel

4. Receives the CPR/LOD/Letter	4.1 Releases the CPR/LOD/Letter to the client	None	1 working day	AFS - Releasing Section Personnel
	4.2 Notifies the WHO/PQT of the regulatory decision (CPR/LOD/Letter)	None	Within 20 working days upon release of the regulatory decision (CPR/LOD/Letter)	FDRO I/II/III
(Service is covered under FDA-Circular-No.-2022-009).		TOTAL:	working days	

3.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR PRESCRIPTION GENERIC DRUGS (INITIAL)

This Certificate of Product Registration is granted to Marketing Authorization Holders of prescription generic drugs upon compliance to Quality, Safety, Efficacy standards. It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Initial Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2 or 5-year CPR validity (Based on Bureau Circular No. 5 s. 1997). 2 year-validity: Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF 5 year-validity: Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF PHARMACEUTICAL PRODUCTS (PRESCRIPTION – HUMAN DRUGS) ASEAN Common Technical Dossier Part I: Administrative Data and Product Information Sec. A Introduction Sec. B Overall ASEAN Common Technical Dossier Table of Contents Sec. C Guidance on the Administrative Data and Product Information Duly accomplished and notarized Integrated Application Form (in excel and pdf formats) (with proof of payment)	Applicant Company/Manufacturer

Letter of Authorization (where applicable) Certifications For contract manufacturing: License of pharmaceutical industries and contract manufacturer Contract manufacturing agreement GMP certificate of contract manufacturer For manufacturing “under-license” License of pharmaceutical industries GMP certificate of the manufacturer Copy of “under-license” agreement For locally manufactured products: License of pharmaceutical industries GMP certificate (country specific) For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Part II: Quality	(For the whole Part I) FDA Website & Cashier

Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 5 Reference Standards or Materials S 7 Stability Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages	Applicant Company/Manufacturer (For the whole Part II): Quality Document

P 2.3.3. Physicochemical and Biological Properties P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Product Interchangeability/equivalence evidence (if applicable) Note: • ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions.	

CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE (MR)/MONITORED RELEASE EXTENSION (MRE) TO INITIAL APPLICATIONS: ACTD Parts I & II (same as above) Risk Management Plan Periodic Safety Update Report (PSUR) or Phase IV Clinical Study Report (whichever is applicable) Other post-approval commitments (if any, based on the Special Conditions at the back page of the CPR and accompanying letter)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Additional Requirement for Dangerous Drugs (as per RA 9165 and Dangerous Drugs Board): -License to Handle Dangerous Drugs	Philippine Drug Enforcement Agency (PDEA)
Note: As per FDA-Circular-No.2020-003 , Submission of Risk Management Plan for a generic drug is not required, but it is expected that the Marketing Authorization Holder (MAH) will continue to evaluate the safety of their products on a regular basis and must be readily available upon request of FDA in case-to-case basis, such as but not limited to: In response to a safety concern arising from a new route of administration; As a result of a new safety concern associated with a new indication that may require additional PV activities; If the innovator or reference product has safety concerns that have been identified to require additional local PV activities.	Applicant Company/Manufacturer

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	Sends the scheduled date of submission for pre-assessment	None		FDAC Personnel
	Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR Personnel

2. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.BizPortal Sends proof of payment to the FDAC.	1 Endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC Personnel
	Receives the application from FDAC and encodes/updates the database	None	Day 1 1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	Queuing time of the application before decking to evaluators	None	Day 2-21 20 working days	CDRR-CRR Unit Personnel
	Decks/Assigns the application to the assigned evaluator	None	Day 22 1 working day	LRD Chief
	Evaluates the application according to requirements and prescribed standards	None	Day 23-72 50 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)

If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (for major deficiencies) For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None		FDRO I/II/III
	Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	Day 73-112 40 working days	FDRO III

	Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III or higher) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR. For Dangerous Drugs, prepares a letter/notification to PDEA to seek comments/ recommendations on the application.	None	Day 113 1 working day	FDRO I/II
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	Day 114 1 working day	FDRO III
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	Day 115 1 working day	FDRO IV (Supervisor)
	3.6 Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	Day 116 1 working day (per batch of applications)	LRD Chief
	Signs and approves the final decision	None	Day 117 1 working day (per batch of applications)	CDRR Director
	Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	Day 118 1 working day (per batch of applications)	CDRR-CRR Unit Personnel

	Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section	None	Day 119 1 working day (per batch of applications)	FDA Records *Personnel*
4. Receives the CPR/LOD/letter	Releases the CPR/LOD/letter to the client	None	Day 120 1 working day	AFS Releasing Section *Personnel*
TOTAL: (Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13 and Republic Act No. 7394 Article 31).			120 working days	

4.ISSUANCE OF ACCREDITATION CERTIFICATE FOR LOCAL BIOEQUIVALENCE (BE) TESTING CENTERS (INITIAL and RENEWAL)

This Accreditation Certificate in granted to Bioequivalence (BE) Testing Centers conducting the clinical and bioanalytical phases of a BE Study upon site inspection to confirm compliance with principles of Good Clinical (GCP) and Laboratory Practices (GLP).

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	Bioequivalence (BE) Testing Centers (Clinical & Bioanalytical facilities)
Fees to be Paid	:	Based on Administrative-Order-No.-2012-0024 All fees with additional 1% Legal Research Fee (LRF) Accreditation of BE testing center (3-year validity): Php 20,000.00 (per year) Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) audit of BE testing centers Local Within Metro Manila: Php 15,000 + Transportation Cost Outside Metro Manila: Php 15,000 + Per Diem/Per inspector + Transportation Cost Overseas ASEAN Countries: US$3,500 + UNDP Per Diem Rate* + Transportation Cost Asia Pacific Countries (other than ASEAN): US$7,000 + UNDP Per Diem Rate + Transportation Cost All Countries Outside of Asia Pacific: US$10,500 + UNDP Per Diem Rate + Transportation Cost

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Documents to be submitted based on FDA Circular No.2021-006, Subject: Interim Guidelines on the Issuance of Accreditation and Inspection of Bioequivalence (BE) Testing Centers	
Letter of Request	Applicant
Proof of Payment, i.e. copy of Official Receipt (OR) or Oncoll payment slip	FDA Cashier
Organizational Chart	Applicant
Certificates of Accreditation and/or Licenses-to-Operate from relevant agencies	Relevant Agencies

Quality Manual	Applicant
Personnel Records including curricula vitae and training records demonstrating sufficient qualifications based on educational background, training and work experience	Applicant
Standard Operating Procedures (SOPs), Work Instructions, and forms of all the critical processes and activities	Applicant
Records/logbooks of instrument and equipment usage, maintenance, calibration and standardization	Applicant
Records of environmental monitoring and control (e.g. temperature, relative humidity, pests, microbes)	Applicant
Memoranda of Understanding/Contracts of Agreement between the Bioequivalence testing center and: Duly licensed/accredited 3rd party Screening Laboratory (for hematology, urinalysis, X-ray, ECG, drug testing, etc.) (where applicable) Duly licensed/accredited 3rd party Clinical or Bioanalytical Facility (where applicable) Other relevant parties involved in biological sample transport, waste disposal, instrument calibration, maintenance and standardization	Applicant
List of BE Studies Completed for the Past Accreditation Period and/or schedule of on-going and future studies	Applicant
Full Report of at least 2 Most-Recently Completed Bioequivalence Studies (for renewal applications)	Applicant
Other relevant documents in fulfillment of applicable principles of Good Clinical (GCP) and Good Laboratory Practices (GLP)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1.1.Manual Submission to FDAC Submit the letter of request and all other supporting documents (see table above) at the FDAC-PACD.	1.1.Issues acknowledgement receipt with a corresponding Document Tracking Number to the applicant.	See Table Above	1 working day	FDAC Personnel
2.Pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.BizPortal				FDA Cashier/Landbank
	2.1.Endorses the received application to the Center	None	1 working day	FDAC Personnel

	2.2.Receives the application from FDAC and encodes /updates the database	None		Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit *Personnel*
	2.3 Decks/Assigns the application to the Bioequivalence (BE) Inspection Team Leader	None	1 working day	CDRR *Director*/Licensing and Registration Division (LRD) *Chief*
	2.4.Assigns co-inspectors and discusses the schedule of the desktop review	None	1 working day	BE Inspection *Team Leader* and *assigned members* of BE Inspection Team
	2.5.Conducts desktop review of the application based on the checklist of requirements	None	12 working days	BE Inspection Team
	2.6.Consolidates the evaluation findings of the Inspection Team	None	3 working days	BE Inspection Team
3.Submits any additional documents or clarifications requested by the BE Team	3.1..Sends the list of deficiencies to the applicant via email	None	20 working days	BE Inspection Team
	3.2.Evaluates the compliance documents submitted by the applicant	None	10 working days	BE Inspection Team
4.Confirms the schedule of virtual/remote inspection	4.Sends a proposed date of virtual/remote inspection to the applicant via email if necessary	None	1 working day	BE Inspection *Team Leader*
5.Participates in the opening and closing meetings at the BE Testing Center	5.1.Inspection Proper at the BE Testing Center, including conduct of opening and closing meetings, examination of	None	5 working days	BE Inspection Team

Provides overview of the BE Testing Center and conducts a brief tour at the site and its facilities Provides inspection-related documents and information as requested by the BE Inspection Team through observation and interview	documents with direct access, interviews, and observation of activities, equipment, and conditions in the inspected areas Provides the provisional list of inspection findings on the last day of inspection			
	5.2.Prepares the Official Inspection Report		Within 20 working days after the inspection	BE Inspection Team
	5.3.Reviews the Official Inspection Report, affixes initial on the draft document, and forwards it to the Section Supervisor		1 working day	BE Inspection Team
	5.4.Reviews and signs the Official Inspection Report, and forwards it to the Licensing and Registration (LRD) Chief			FDRO IV (Supervisor)
	5.5.Checks and endorses the recommendation of the inspectors and supervisor by affixing signature			LRD Chief
	5.6.Signs the Official Inspection Report		1 working day	CDRR Director
	5.7.Encodes/Updates the Database and Endorses the final output document to CDRR-Records	None	1 working day	CDRR-CRR Unit Personnel
	5.8.Scans and endorses the Inspection Report to the FDAC Releasing Section	None	1 working day (per batch of applications)	CDRR-Records *Personnel*

	5.9.Releases the Inspection Report to the client	None	1 working day	AFS Releasing Section *Personnel*
6.Submits the Corrective and Preventive Action (CAPA) Plan	6.1.Receives the Corrective and Preventive Action (CAPA) Plan and forwards it to the Center for Drug Regulation and Research (CDRR)	None	Client: Within 20 working days upon receipt of inspection report by the client. FDAC: 1 working day	FDAC Personnel
	6.2.Receives the Corrective and Preventive Action (CAPA) Plan from FDAC and encodes/updates the database and forwards it to the BE Inspection Team Leader	None	1 working day	CDRR-CRR Unit Personnel
	6.3.Evaluates the Corrective and Preventive Action (CAPA) Plan	None	Within 20 working days upon receipt of CAPA Plan	BE Inspection Team
7.Submits responses and documents requested by the BE Inspection Team, if applicable	7..1Prepares the Accreditation Certificate and Final Inspection Report if approval of the application is recommended Prepares and sends the Notice of Deficiencies (NOD) through email if information in the CAPA Plan or accompanying documents submitted are insufficient to make a final decision, then reviews the requested documents upon compliance by the BE Testing Center	None	Client: Within 20 working days upon receipt of NOD BE Inspection Team: 1 working day (for approval or disapproval); Within 20 working days upon receipt of	BE Inspection Team

	7.2.Prepares the Letter of Disapproval (LOD) and Final Inspection Report if approval of the application is not recommended		2nd compliance from the BE Testing Center, (for NOD)	
	7.3.Reviews the final output document (Accreditation Certificate or LOD), affixes initial on the draft document, and forwards it to the Section Supervisor	None		BE Inspection Team
	7.4.Reviews and signs the final output document, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	FDRO IV (Supervisor)
	7.5.Checks and endorses the recommendation of the inspectors and supervisor by affixing signature	None		LRD Chief
	7.6.Signs and approves the final decision	None	1 working day	CDRR Director
	7.7.Encodes/Updates the Database and Endorses the final output document to the FDA Records Section (for Accreditation Certificate) or Releasing Section (for LOD)	None	1 working day	CDRR-CRR Unit Personnel
	7.8.Scans the Accreditation Certificate, updates the database, and endorses the Accreditation Certificate to the FDAC Releasing Section	None	1 working day (per batch of applications)	FDA Records *Personnel*
8.Receives the Accreditation Certificate or LOD	8.Releases the Accreditation Certificate or LOD to the client	None	1 working day	FDAC Releasing Section *Personnel*
TOTAL: Service is covered under the ASEAN Mutual Recognition Arrangement for Bioequivalence Study Reports of Generic Medicinal Products			112 working days	

5.ISSUANCE OF ACKNOWLEDGEMENT TO MINOR VARIATION-NOTIFICATION APPLICATIONS

This acknowledgment is issued to any minor changes to a registered pharmaceutical finished product classified as minor-variation notification.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Simple
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Refer to FDA-Circular-No.-2014-008, Annex D Payment shall be on a per product, per change basis Link: https://www.fda.gov.ph/wp-content/uploads/2021/04/FDA-Circular-No.-2014-008.pdf Refer to FDA-Circular-No.-2014-008 , Annex D Payment shall be on a per product, per change basis Regular PACs: Php500.00 + LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
FDA-Circular-No.-2014-008-A	
Hard copy:	
Two (2) copies of notarized Annex B (see attached sample Annex B);	Applicant company/ Manufacturer
Original copy of the Official Receipt.	FDA Cashier
Soft copy:	
Notarized latest Annex C;	
Portable document format (PDF) copy of signed integrated application form (IAF);	Applicant Company/ Manufacturer
IAF in Microsoft Excel format;	
Scanned copy of Certificate of Product Registration (CPR) and/or proof of renewal;	

For Certificate of Listing of Identical Drug Product (CLIDP), a copy of Principal CPR (PCPR) variation approval (where applicable); Complete documentary requirements based on the ASEAN Variation Guidelines, FDA-Circular-No.-2014-008 , FDA-Circular-No.-2014-008-A , and FDA-Circular-No.-2016-017 and pertinent evidence supporting change/s	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. E-mail submission: Submits the application for pre-assessment through fdac.letters.cdrr@fda.gov.ph	1.1 Receives the application and forwards the application to CDRR pre-assessor	None	0	FDAC Personnel
	1.2 Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN)	None	0	CDRR Personnel

2. Submits application with complete documents and requirements through fdac.letters.cdrr@fda.gov.ph	2.1.Accepts the application with complete and correct requirements. 2.2.Assigns Document Tracking Number (DTN) and issues pre-assessment slip to the applicant indicating to proceed to payment	None	1 working day	FDAC Personnel
3.Pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.bizPortal Upon payment, the applicant shall send the copy of the Official Receipt to the FDAC through email.		See Table Above	1 working day	FDA Cashier/ Landbank
	3.1 Endorses the received applications (soft/hard copies) to the Center, including the soft copy of transmittal for post-acknowledgement	None	1 working day	FDAC Personnel
	Evaluates the application according to requirements and prescribed standards	None	2 working days	CDRR Personnel

	Acknowledges the notification, encodes and updates the database and Document Tracking System status For approved applications, revises Annex C then emails to the applicant company For disapproved applications, emails the signed grounds for disapproval to the applicant company	None	2 working days	CDRR-CRR Personnel
Service covered under FDA-Circular-No.-2020-026.		TOTAL:	7 working days	

Note: Day 1 strictly refers to Tuesdays and Wednesdays which are the Notification days following FDA-Circular-No.-2014-008-A.

6.ISSUANCE OF BUREAU OF CUSTOMS (BOC) CLEARANCE [IMPORT PERMIT AND EXPORT PERMIT)

The BOC Clearance is granted to establishments with:

A. Valid LTO as drug Importer/Exporter to allow importation or exportation of drug products used as samples for registration, product development studies, and as test samples or reference products for Bioavailability/Bioequivalence studies, Comparative Dissolution Profile, Biowaiver, return of complaint samples.

B. Valid LTO as drug Sponsor/CRO for the return of unused Investigational Product/s and/or Ancillary supplies in an approved clinical trial conducted in the Philippines to the Sponsor or as specified by applicant, e.g. Global Depot.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Simple
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	AO No.-50-2001 Php 500.00/product + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Checklist of Requirements for Bureau of Customs Clearance [Import Permit and Export Permit]	
Letter of Application. It should include the following: Name of requesting party and position Purpose of application Itemized, detailed description of the drug product: Generic Name Brand Name (*if applicable*) Dosage Strength and Form Packaging/Availability Manufacturer Manufacturing Data *If the exact manufacturing data of the drug product is unavailable at the time of application, the applicant shall include in their letter a commitment on their part to submit the information once it became available. ·An estimated quantity/ volume needed ·Country of Origin (Indicate the country where the drug product will be shipped from) Receiving company and complete address (include name of representative if available) (*for export*)	Applicant Company/Manufacturer
·A waiver of FDA Philippines responsibility from any damage or injury arising from the use of the unregistered drug or device to be signed by the responsible official of the Institution.	Applicant
Proof of payment (Php 500 + LRF) per product	Company/Landbank/FDA Cashier
Certificate of Analysis (*for import*) / Actual photo of the drug product to be exported (*for export*)	
Proforma Invoice (includes batch number & expiry date)	Applicant Company/Manufacturer
Proof of Purchase (i.e. Official Receipt) from a reputable local source of the product (for export except for products which will be shipped by the MAH or for products intended for clinical trial use)	Applicant Company/Manufacturer
References: Republic Act No. 9711 – Food and Drug Administration Act of 2009 Customs Memorandum Circular No. 54-2014 – Matrix on Appropriate Requirements on the Release of Products under FDA Jurisdiction	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an application email containing the requirements to fdac.letters.cdrr@fda.gov.ph following the correct submission schedule	1.Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgement email with the order of payment to the applicant	None		FDAC Personnel
2.Pay for the required fee through any of the following: FDA Cashier BANCNET Landbank OnColl Then send the proof of payment to the FDAC.	2.1.Receives the payment from the applicant for posting Upon receipt of the proof of payment, endorses the application to CDRR for evaluation	See Table Above	*Timeline starts after posting of payment	FDA Cashier/ Landbank FDAC Personnel
	2.2.Receives the application from FDAC and encodes/updates the database and FIS	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3.Decks/Assigns the application to the assigned evaluator	None	1 working day	CRS Administrative Staff

	2.4.Evaluates the application for completeness according to requirements and prescribed standards *Any minor deficiencies/ clarifications will be communicated to the client through electronic communication (3 calendar days to respond to the queries)	None	3 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
	2.5.Reviews the evaluated application bearing the recommendation of the Evaluator	None	1 working day	Clinical Research Section *Supervisor*
	2.6.Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD) Chief	None	1 working day	FDRO I/II/III
	2.7.Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	PRSDD Chief
	2.8.Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	2.9.Encodes/Updates the Database and endorses the final response to the AFS Releasing Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
3. Receives the permit or final response	3.Releases the permit or final response to the client	None	1 working day	AFS Releasing Section *Personnel*
TOTAL:		PHP510.00 per product	7 Working Days	

7.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION FOR MAJOR VARIATION - STRAIN CLEARANCE (MAV-SC) AND MINOR VARIATION – STRAIN CLEARANCE (MIV-SC) OF HUMAN INFLUENZA VACCINES

This Certificate of Product Registration is granted to Marketing Authorization Holders once the proposed change in the strains has been approved (MaV-SC)/to continue the manufacture, distribution and sale of Seasonal Influenza Vaccines based on compliance with quality, safety and efficacy standards (MiV-SC).

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Human Influenza Vaccines
Fees to be Paid	:	Major Variation – Strain Clearance (MaV-SC) Php 20,000 + LRF Minor Variation – Strain Clearance (MiV-SC) Php 500 + LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR MAJOR VARIATION – STRAIN CLEARANCE (MaV-SC) OF HUMAN INFLUENZA VACCINES FDA Circular 2020-002: Guidelines on the Registration of Human Influenza Vaccines (Only relevant and adequate sections of the ACTD/CTD should be submitted. All sections not felt to be necessary should however be justified adequately in the Summary/Overview) Part I: Administrative Data and Product Information Sec. A Introduction Sec. B Table of Contents Sec. C Guidance on the Administrative Data and Product Information	Applicant Company

For contract manufacturing:	
License of pharmaceutical industries and contract manufacturer	Applicant Company/Manufacturer
Contract manufacturing agreement	Applicant Company/Manufacturer
GMP certificate of contract manufacturer	Applicant Company/Manufacturer
For manufacturing “under-license”	
License of pharmaceutical industries	Applicant Company/Manufacturer
GMP certificate of the manufacturer	Applicant Company/Manufacturer
Copy of “under-license” agreement	Applicant Company/Manufacturer
For locally manufactured products:	
License of pharmaceutical industries	Applicant Company/Manufacturer
GMP certificate (country specific)	Applicant Company/Manufacturer
For imported products	
Foreign GMP Clearance	
License of pharmaceutical industries/importer/wholesaler (country specific)	Applicant Company/Manufacturer
Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin	Applicant Company/Manufacturer
according to the current WHO format	Applicant Company/Manufacturer
If the product is not marketed in the country of origin the following should be submitted:	
CPP indicating that the product is for export only or Certificate of Export; and	
Authenticated Certificate of Free Sale (CFS) or CPP where it is marketed;	Applicant Company/Manufacturer
If the country of origin does not issue a CPP the following should be submitted:	Applicant Company/Manufacturer
Justification that the country of origin does not issue a CPP; and	
Authenticated CFS or CPP where it is marketed	Applicant Company/Manufacturer
	Applicant Company/Manufacturer
Labeling (new strains)	

Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary (addendum to “previous” QOS) Sec. C Body of Data Drug Substance (S) S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials - seed lots: history: - passage level - characterization of Haemagglutinin and Neuraminidase - analytical protocols (including test results on seed lots)* S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation - monovalent bulks: - manufacturing process strain specific changes - validation of critical manufacturing steps (e.g. inactivation, splitting efficiency) (new strains) S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures - validation study reports and summaries of test method [e.g. validation of Single Radial Diffusion (SRD) test for the new strain(s)] S 4.4. Batch Analyses - results of monovalent bulks: results (including test for neuraminidase): Each working seed lot from previously approved master seed lot where the procedure of working seed lot preparation is different from the approved procedure S 4.5. Justification of Specifications S 7 Stability (Stability tests on the active substances: results from monovalent bulks where they are used for more than	Applicant Company/Manufacturer (For the whole Part II: Quality Document)

Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients (new strains) P 3 Manufacture P 3.1. Batch Formula P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities P 8 Product Stability	
Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Product Development Rationale 2. Overview of Biopharmaceutics 3. Overview of Clinical Pharmacology 4. Overview of Efficacy 5. Overview of Safety 6. Benefits and Risks Conclusions Sec. D Tabular Listing of All Clinical Studies Sec. E Clinical Study Reports (if applicable)	Applicant Company/Manufacturer (For the whole Part IV: Clinical Document) Applicant Company/ Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer
Additional Requirements: Representative Samples (w/COA) may be submitted at a later date, e.g. when the application has already been decked as indicated in the Document Tracking System. Risk Management Plan Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) List of Countries where the product is already licensed and the date of approval Information on the number system of the lots or batches Summary Lot Protocol Lot to Lot Consistency from three (3) consecutive batches Copy of valid CPR	 Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company

Notarized Letter of Request for Major Variation – Strain Clearance (refer to Appendix 2) indicating the affected product, as well as declaration that there is/are no other change/s except from the update on the annual strain. This shall be signed by the Head of Regulatory Office. Adverse event following immunization report (summary of annual reports)	Applicant Company Applicant Company
CHECKLIST OF REQUIREMENTS FOR MINOR VARIATION – STRAIN CLEARANCE (MiV-SC) OF HUMAN INFLUENZA VACCINES	
Notarized Integrated Application Form (in excel and pdf format) (with proof of payment) Certifications	Applicant Company Applicant Company
For contract manufacturing: License of pharmaceutical industries and contract manufacturer Contract manufacturing agreement GMP certificate of contract manufacturer	 Applicant Company/ Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer
For manufacturing “under-license” License of pharmaceutical industries GMP certificate of the manufacturer Copy of “under-license” agreement	 Applicant Company/ Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer
For locally manufactured products: a.License of pharmaceutical industries b.GMP certificate (country specific)	 Applicant Company/ Manufacturer Applicant Company/Manufacturer
For imported products a.Foreign GMP Clearance b. License of pharmaceutical industries/importer/wholesaler (country specific)	 Applicant Company/ Manufacturer

3.Labeling (new strains)	
4.Product Information	Applicant Company/Manufacturer
a. Package Insert	Applicant Company/Manufacturer
b. Summary of Product Characteristics (Product Data Sheet)	
4. Representative Samples (w/COA)	Applicant Company/Manufacturer
5. Risk Management Plan	Applicant Company/Manufacturer
6. Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report **(PBRER)**	Applicant Company/Manufacturer
7. List of Countries where the product is already licensed and the date of approval	
8. Information on the number system of the lots or batches	Applicant Company/Manufacturer
10. Summary Lot Protocol	Applicant Company/Manufacturer
11. Copy of valid CPR	Applicant Company/Manufacturer
12. Notarized Letter of Request for Minor Variation – Strain Clearance (refer to Appendix	Applicant Company/Manufacturer
3) indicating the affected product, as well as declaration that there is/are no other change/s. This shall be signed by the Head of Regulatory Office.	Applicant Company/Manufacturer
13. Adverse event following immunization report (summary of annual reports)	Applicant Company/Manufacturer

*Where the seed virus is tested for extraneous agents using Polymerase Chain Reaction (PCR), these data should be included in this application

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1.Secures a schedule of appointment / submission to FDAC E-mail submission:	1.Sends the scheduled date of submission for pre-assessment	None	0	FDAC Personnel

2.Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2.Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None	0	CDRR Personnel
3.For accepted applications, pays the required fee through any of the following: FDA Cashier BANCNET Landbank OnColl Landbank Link.BizPortal Sends proof of payment to the FDAC. Remarks: If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1.Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/ Landbank FDAC Personnel
	3.2.Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	3.3.Queuing time of the application before decking to evaluators	None	5 working days	CDRR-CRR Unit Personnel
	3.4.Decks/Assigns the application to the assigned evaluator	None	1 working day	LRD Chief

	3.5.Evaluates the application according to requirements and prescribed standards	None	23 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
	3.6.Prepares a worksheet and drafts certification when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic	None	1 working day	FDRO I/II/III
	3.7.Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	16 working days	FDRO III
	3.8.Prepares the final output document (Certification/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III)	None	1 working day	FDRO I/II
	3.9.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III

	3.10.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	3 working days	FDRO IV (Supervisor)
	3.11.Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	3 working days (per batch of applications)	LRD Chief
	3.12.Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	3.13.Encodes/Updates the Database and endorses the final output document (Certification/LOD/Letter) to the FDA-Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	3.14.Scans and emails the scanned copy of the final output document (Certification/LOD/ Letter) to the client; and endorses the final output document to the AFS- Releasing Section	None	2 working days (per batch of applications)	FDA-Records Personnel
4. Receives the Certification /LOD/letter	4.Releases the Certification /LOD to the client	None	1 working day	AFS-Releasing Section Personnel
TOTAL: Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13, and Republic Act No. 7394 Article 31, wherein 60 working days was proposed instead of 180 working days.			60 working days^	

Additional processing time shall be applied if consequential changes that are related to the strain change are filed together with the MaV-SC.

8.ISSUANCE OF CERTIFICATE FOR PHARMACEUTICAL PRODUCTS (MAJOR AND MINOR VARIATION-PRIOR APPROVAL) VIA FACILITATED REGISTRATION PATHWAY (FRP)

This Certificate is granted to Marketing Authorization Holders once the proposed post-approval changes on the quality (e.g. manufacture, controls and container closure system), safety, efficacy, and administrative information of pharmaceutical products has been substantiated.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Post-Approval Change/s: Regular PACs, including change of capsule color: Php500.00 + LRF With FDA Clinical Review for revision/update of PI, PIL, Prescribing Information, Core Data Sheet and Basic Succinct statement: Php500.00 + LRF With FDA Clinical Review for additional indication: Php2,500.00 + LRF With Subsequent Labeling Amendment per product strength: Php 500.00+LRF Change or addition of brand name: Php2,500.00 + LRF + 510.00 (for each brand name proposed) Shelf-life extension/reduction: Php1,000.00 + LRF Equivalent to Initial Registration, including Additional Route of Administration Branded: Php 15,000.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF Monitored Release Status: Php 33,333.33/5 years + 1% LRF Reclassification: Php 3,000.00 + LRF

ELIGIBILITY CRITERIA **(provided under Sec. IV.B. of Administrative-Order-2020-0045 , reiterated with necessary clarifications under Sec. V.A of FDA-Circular-No.2022-004)**
The applicant shall be a holder of a valid License to Operate (LTO) issued by the FDA;

The applicant may avail of the following submission pathways under FRP, subject to certain conditions.
Abridged review may be availed when the drug product, vaccine, or biological has been approved by a Reference Drug Regulatory Authority (RDRA) and the product application is within three (3) years from the date of approval of the RDRA.
Verification review may be availed when the drug product, vaccine, or biological has been approved by at least two (2) RDRAs and the product application is within three (3) years from the date of approval of the RDRA/s.
The applicant may choose to avail of only one (1) type of FRP per application based on compliance with the requirements. If the requirements of any of the FRP cannot be complied with, the application shall be processed following the regular review pathway.
The eligible product shall be the same as the product duly approved or registered in the RDRA/s identified by the applicant.
All aspects of the drug product's quality, including but not limited to the formulation, manufacturing site/s, release and shelf-life specifications, and primary packaging, must be the same as those currently approved by the identified RDRA/s at the time of submission.
The proposed indication/s, dosing regimen/s, patient group/s, and/or direction/s for use should be the same as those approved by the identified RDRA/s.
The product and its intended use have not been rejected, withdrawn, suspended, revoked, or has pending deferral by any RDRA due to quality, safety, or efficacy reasons.
The information on the proposed Package Insert/Patient Information Leaflet shall be identical to that of the approved by the RDRA with the addition of country-specific information stipulated in the current FDA labeling requirements.
All documents to be submitted shall be written/translated into the English language.

DOCUMENTARY REQUIREMENTS

Applications for RDRA/s post-approval changes
A formal, written request from the applicant drug distributor notifying the FDA of its intent to avail of the abridged or verification review, identifying the RDRA/s that approved the post approval changes.
Note: The date of RDRA approval to be reflected in Annex B shall be the date the post-approval change/s was/were approved by the RDRA.
Official approval letter or notification of the post-approval change/s from the identified RDRA/s.
For changes and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product (categorized as major variation [MaV]-1 based on the ASEAN Variation Guideline for Pharmaceutical Products and as adopted through FDA-Circular-No.-2014-008 or any amendment or latest issuance thereafter), Assessment Report from each of the identified RDRA/s shall be required.

In addition to the foregoing requirements for applications for new drugs, vaccines, and biologicals and post-approval changes, all applications should be accompanied by a Sworn Assurance and (Annex B) signed exclusively by the Head of Regulatory Office of the product owner stating

the following: (1) the product being applied is the same in all respects as the product approved by the RDRA, (2) the product and its intended use has not been rejected, withdrawn, suspended, revoked, or has pending deferral by any RDRA due to quality, safety, or efficacy reasons, and (3) that there is full compliance with the eligibility requirements provided under this Circular. The applications shall comply with rules on filing and receiving pursuant to the latest issuances until such time that an automated system has been developed and launched. See checklist of requirements below for additional requirements.

CHECKLIST OF REQUIREMENTS FOR POST-APPROVAL CHANGES FDA-Circular-No.-2014-008 Application Process and Requirements for Post-Approval Changes of Pharmaceutical Products ASEAN Variation Guidelines A.O. No. 47-a s.2001 Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products Annex A (A maximum of 3 proposed variations shall be made per application, consistent with those reflected on the Integrated Application Form.) Complete List of Documentary Requirements based on Annex C of FDA-Circular-No.-2014-008 and ASEAN Variation Guidelines (attached as annexure to this document) 3. Proof of Payment based on Annex D of FDA-Circular-No.-2014-008 4. Additional requirement for Biologics/Vaccines: Stringent Regulatory Authority (SRA)/National Regulatory Authority (NRA) approval for the proposed variation (where applicable)	Applicant Company Applicant Company ASEAN Variation Guidelines Link: https://www.fda.gov.ph/wp-content/uploads/2021/03/ASEAN-Variation-Guideline-for-Pharmaceutical-Products-R1.pdf FDA Circular No. 2014-008 Link: https://www.fda.gov.ph/wp-content/uploads/2021/04/FDA-Circular-No.-2014-008.pdf

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	Sends the scheduled date of submission for pre-assessment	None	0	FDAC Personnel
	Pre-assesses the completeness of the application and verifies the application if indeed for the abridged/verification review pathway for post-approval changes. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None	0	CDRR Pre-assessor

2. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.bizPortal Sends proof of payment to the FDAC.	2.1. Endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/ Landbank FDAC Personnel
	Receives the application from FDAC and encodes/updates the database.	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	Decks/Assigns the application to the assigned evaluator of the Registration Section.	None	1 working day	CDRR Director
	Evaluates the application according to requirements and prescribed standards	None	16 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/III (Senior Evaluator)

3. If an electronic notice of deficiencies0 (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) or Certificate issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation. *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication.	None		FDRO I/II/III
	3.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	5 working days	FDRO III
	Prepares the final output document (CPR/ Certification/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR.	None	1 working day	FDRO I/II/III
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None		FDRO III
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	1 working day	FDRO IV (Supervisor)

	Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	1 working day	LRD Chief
	Signs and approves the final decision	None	1 working day	CDRR Director
	Encodes/Updates the Database and endorses the final output document (CPR/Certification/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	Scans, barcodes the final output document (CPR/Certification/ LOD/Letter); and endorses the final output document to the FDAC Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel
4. Receives the CPR/Certification /LOD/Letter	4. Releases the CPR/ Certification /LOD/Letter to the client	None	1 working day	AFS - Releasing Section Personnel
(Service is covered under FDA-Circular-No.2022-004).		TOTAL:	30 working days	

9.ISSUANCE OF CERTIFICATE OF PRODUCT REGUSTRATION FOR PHARMACEUTICAL PRODUCTS (VARIATION-TURNED-INITIAL APPLICATIONS)

This Certificate of Product Registration is granted to Marketing Authorization Holders once the proposed post-approval changes on the quality (e.g. manufacture, controls and container closure system), safety, efficacy, and administrative information of pharmaceutical products has been substantiated.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Drug Products
Fees to be Paid		Refer to FDA-Circular-No.-2014-008, Annex D Payment shall be on a per product, per change basis Variation-turned-Initial: Branded: Php 15,000.00 + LRF Unbranded: Php 10,000.00 + LRF Monitored Release Status: New application: Php 33,333.33 + LRF (5-year validity); Pending application: Php 13,333.33 + LRF (paid for 3-years and will avail 5-year validity) (according to FDA Advisory No. 2021-2904) The Legal Research Fund (LRF) fee is the amount equivalent to one percent (1%) of the fee imposed

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
LIST OF VARIATION-TURNED-INITIAL APPLICATIONS Mav-1: Change and/or additional indication/dosing regimen/patient population/inclusion of clinical indication extending the usage of the product MaV-4: Addition or replacement of the manufacturing site of the drugs product MaV-10: Qualitative or quantitative change of excipient For immediate release oral dosage forms (as per Level 2 and 3, Part III Components and Composition, SUPAC guideline)	Applicant Company Applicant Company ASEAN Variation Guidelines Link: https://www.fda.gov.ph/wp-content/uploads/2021/03/ASEAN-Variation-Guideline-for-Pharmaceutical-Products-R1.pdf

For modified release oral dosage forms For other critical dosage forms such as sterile preparations MaV-11: Quantitative change in the coating weight of tablets or weight and/or size of the capsule shell for modified release dosage form MaV-12: Change in the primary packaging material for sterile drug product Qualitative and quantitative composition and/or Type of container and/or nclusion of primary packaging material MaV-13: Change or addition of pack size/fill volume and/or change of shape or dimension of container or closure for a sterile solid and liquid drug product (unless the change is dimension, i.e. wide-mouth bottles vs. narrow-mouth bottles) MiV-PA15: Qualitative or quantitative change of excipient For immediate release oral dosage forms (as per Level 1, Part III Components and Composition, SUPAC guideline) For other non-critical dosage forms (e.g. oral liquid, external preparation) MiV-PA16: Quantitative change in coating weight of tablets or weight and/or size of capsule shell for immediate release oral dosage form MiV-PA17: Change of the colouring/flavouring agent of the product [addition, deletion or replacement of colourant(s)/flavour(s)] MiV-PA28: Change in primary packaging for non-sterile drug product Qualitative and quantitative composition and/or Type of container and/or Inclusion of the primary packaging material Additional route of administration Change of manufacturing site (same subsidiary) of the drug product	FDA Circular No. 2014-008 Link: https://www.fda.gov.ph/wp-content/uploads/2021/04/FDA-Circular-No.-2014-008.pdf

CHECKLIST OF REQUIREMENTS FOR VARIATION-TURNED INITIAL APPLICATIONS FDA-Circular-No.-2014-008 Application Process and Requirements for Post-Approval Changes of Pharmaceutical Products ASEAN Variation Guidelines A.O. No. 47-a s.2001 Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products Annex A (A maximum of 3 proposed variations shall be made per application, consistent with those reflected on the Integrated Application Form.) Complete List of Documentary Requirements based on Annex C of FDA-Circular-No.-2014-008 and ASEAN Variation Guidelines (attached as annexure to this document) Proof of Payment based on Annex D of FDA-Circular-No.-2014-008 Additional requirement for Biologics/Vaccines: Stringent Regulatory Authority (SRA)/National Regulatory Authority (NRA) approval for the proposed variation (where applicable) No.-2014-008 Annex D	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC	1 Sends the scheduled date of submission for pre-assessment	None	0	FDAC Personnel

E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2.1 Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None	0	CDRR Personnel
3. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.BizPortal Sends proof of payment to the FDAC.	3.1.Endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/ Landbank FDAC Personnel
	3.2.Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit

	3.3.Queuing time of the application before decking to evaluators of Registration Section and/or Clinical Research Section	None	20 working days	CDRR-CRR Unit Personnel
	3.4.Decks/Assigns the application to the assigned evaluators of Registration Section and/or Clinical Research Section	None	1 working day	CDRR Director
	3.5.Evaluates the application according to requirements and prescribed standards	None	50 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
4. If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) (from safety and efficacy evaluation, if applicable) when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS) Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS)			

	4.2 For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None		FDRO I/II/III
	4.3.Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	40 working days	FDRO III
	4.4.Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the Certificate	None	1 working day	FDRO I/II
	4.5.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III
	4.6.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day (per batch of applications)	FDRO IV (Supervisor)

	4.7.Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	1 working day (per batch of applications)	LRD Chief
	4.8.Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	4.9.Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	4.10.Scans and barcodes the final output document (CPR/LOD/Letter); emails scanned copy of the final output document to the client; and endorses the final output document (hard copy) to the AFS Releasing Section.	None	1 working day (per batch of applications)	FDA Records *Personnel*
5. Receives the CPR/ LOD letter	5.Releases the CPR/LOD/letter to the client	None	1 working day	AFS Releasing Section *Personnel*
TOTAL: (Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13 and Republic Act No. 7394 Article 31).			120 working days	

10.ISSUANCE OF CERTIFICATE FOR PHARMACEUTICAL PRODUCTS (MAJOR AND MINOR VARIATION-PRIOR APPROVAL) VIA FACILITATED REGISTRATION PATHWAY (FRP)

This Certificate is granted to Marketing Authorization Holders once the proposed post-approval changes on the quality (e.g. manufacture, controls and container closure system), safety, efficacy, and administrative information of pharmaceutical products has been substantiated.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Post-Approval Change/s: Regular PACs, including change of capsule color: Php500.00 + LRF With FDA Clinical Review for revision/update of PI, PIL, Prescribing Information, Core Data Sheet and Basic Succinct statement: Php500.00 + LRF With FDA Clinical Review for additional indication: Php2,500.00 + LRF With Subsequent Labeling Amendment per product strength: Php 500.00+LRF Change or addition of brand name: Php2,500.00 + LRF + 510.00 (for each brand name proposed) Shelf-life extension/reduction: Php1,000.00 + LRF Equivalent to Initial Registration, including Additional Route of Administration Branded: Php 15,000.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF Monitored Release Status: Php 33,333.33/5 years + 1% LRF Reclassification: Php 3,000.00 + LRF

ELIGIBILITY CRITERIA
(provided under Sec. IV.B. of Administrative-Order-2020-0045 , reiterated with necessary clarifications under Sec. V.A of FDA-Circular-No.2022-004)

The applicant shall be a holder of a valid License to Operate (LTO) issued by the FDA;
The applicant may avail of the following submission pathways under FRP, subject to certain conditions.
Abridged review may be availed when the drug product, vaccine, or biological has been approved by a Reference Drug Regulatory Authority (RDRA) and the product application is within three (3) years from the date of approval of the RDRA.
Verification review may be availed when the drug product, vaccine, or biological has been approved by at least two (2) RDRAs and the product

application is within three (3) years from the date of approval of the RDRA/s.
The applicant may choose to avail of only one (1) type of FRP per application based on compliance with the requirements. If the requirements of any of the FRP cannot be complied with, the application shall be processed following the regular review pathway.
The eligible product shall be the same as the product duly approved or registered in the RDRA/s identified by the applicant.
All aspects of the drug product's quality, including but not limited to the formulation, manufacturing site/s, release and shelf-life specifications, and primary packaging, must be the same as those currently approved by the identified RDRA/s at the time of submission.
The proposed indication/s, dosing regimen/s, patient group/s, and/or direction/s for use should be the same as those approved by the identified RDRA/s.
The product and its intended use have not been rejected, withdrawn, suspended, revoked, or has pending deferral by any RDRA due to quality, safety, or efficacy reasons.
The information on the proposed Package Insert/Patient Information Leaflet shall be identical to that of the approved by the RDRA with the addition of country-specific information stipulated in the current FDA labeling requirements.
All documents to be submitted shall be written/translated into the English language.

DOCUMENTARY REQUIREMENTS

Applications for RDRA/s post-approval changes
A formal, written request from the applicant drug distributor notifying the FDA of its intent to avail of the abridged or verification review, identifying the RDRA/s that approved the post approval changes.
Note: The date of RDRA approval to be reflected in Annex B shall be the date the post-approval change/s was/were approved by the RDRA.
Official approval letter or notification of the post-approval change/s from the identified RDRA/s.
For changes and/or additional indication/dosing regimen/patient population/inclusion of clinical information extending the usage of the product (categorized as major variation [MaV]-1 based on the ASEAN Variation Guideline for Pharmaceutical Products and as adopted through FDA-Circular-No.-2014-008 or any amendment or latest issuance thereafter), Assessment Report from each of the identified RDRA/s shall be required.

In addition to the foregoing requirements for applications for new drugs, vaccines, and biologicals and post-approval changes, all applications should be accompanied by a Sworn Assurance and (Annex B) signed exclusively by the Head of Regulatory Office of the product owner stating the following: (1) the product being applied is the same in all respects as the product approved by the RDRA, (2) the product and its intended use has not been rejected, withdrawn, suspended, revoked, or has pending deferral by any RDRA due to quality, safety, or efficacy reasons, and (3) that there is full compliance with the eligibility requirements provided under this Circular.

The applications shall comply with rules on filing and receiving pursuant to the latest issuances until such time that an automated system has been developed and launched.

See checklist of requirements below for additional requirements.

CHECKLIST OF REQUIREMENTS FOR POST-APPROVAL CHANGES FDA-Circular-No.-2014-008 Application Process and Requirements for Post-Approval Changes of Pharmaceutical Products ASEAN Variation Guidelines A.O. No. 47-a s.2001 Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products Annex A (A maximum of 3 proposed variations shall be made per application, consistent with those reflected on the Integrated Application Form.) Complete List of Documentary Requirements based on Annex C of FDA-Circular-No.-2014-008 and ASEAN Variation Guidelines (attached as annexure to this document) roof of Payment based on Annex D of FDA-Circular-No.-2014-008 4. Additional requirement for Biologics/Vaccines: Stringent Regulatory Authority (SRA)/National Regulatory Authority (NRA) approval for the proposed variation (where applicable)	Applicant Company Applicant Company ASEAN Variation Guidelines Link: https://www.fda.gov.ph/wp-content/uploads/2021/03/ASEAN-Variation-Guideline-for-Pharmaceutical-Products-R1.pdf FDA Circular No. 2014-008 Link: https://www.fda.gov.ph/wp-content/uploads/2021/04/FDA-Circular-No.-2014-008.pdf

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1.1 Sends the scheduled date of submission for pre-assessment	None	0	FDAC Personnel
	1.2 Pre-assesses the completeness of the application and verifies the application if indeed for the abridged/verification review pathway for post-approval changes. If the application is acceptable,	None	0	CDRR Pre-assessor

	informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).			
2. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.bizPortal Sends proof of payment to the FDAC.	2.2 Endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/ Landbank FDAC Personnel
	2.3 Receives the application from FDAC and encodes/updates the database.	None	Day 1 1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.4 Decks/Assigns the application to the assigned evaluator of the Registration Section.	None	Day 2 1 working day	CDRR Director

	2.5 Evaluates the application according to requirements and prescribed standards	None	Day 3-18 16 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/III (Senior Evaluator)
3. f an electronic notice of deficiencies0 (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) or Certificate issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation. *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None		FDRO I/II/III
	Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	Day 19-23 5 working days	FDRO III

	3.3 repares the final output document (CPR/ Certification/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR.	None	Day 24 1 working day	FDRO I/II/III
	3.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None		FDRO III
	3.5 eviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	Day 25 1 working day	FDRO IV (Supervisor)
	3.6 Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	Day 26 1 working day	LRD Chief
	3.7 Signs and approves the final decision	None	Day 27 1 working day	CDRR Director
	3.8 Encodes/Updates the Database and endorses the final output document (CPR/Certification/LOD/Letter) to the FDA Records Section	None	Day 28 1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	3.9 Scans, barcodes the final output document (CPR/Certification/ LOD/Letter); and endorses the final output document to the FDAC Releasing Section	None	Day 29 1 working day (per batch of applications)	FDA Records Personnel

4. Receives the CPR/Certification /LOD/Letter	4.Releases the CPR/ Certification /LOD/Letter to the client	None	Day 30 1 working day	AFS - Releasing Section Personnel
(Service is covered under FDA-Circular-No.2022-004).		**TOTAL:**	**30 working days**	

11.ISSUANCE OF CERTIFICATE FOR POST-APPROVAL CHANGES OF PHARMACEUTICAL PRODUCTS FOR HUMAN USE INCLUDING VACCINES AND BIOLOGICALS THROUGH THE WHO COLLABORATIVE REGISTRATION PROCEDURE (CRP)

This Certificate is granted to Marketing Authorization Holders once the proposed post-approval changes on the quality (e.g. manufacture, controls and container closure system), safety, efficacy, and administrative information of pharmaceutical products has been substantiated.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of WHO Pre-qualified Pharmaceutical Products
Fees to be Paid	:	Post-Approval Change/s: Regular PACs, including change of capsule color: Php500.00 + LRF With FDA Clinical Review for revision/update of PI, PIL, Prescribing Information, Core Data Sheet and Basic Succinct statement: Php500.00 + LRF With FDA Clinical Review for additional indication: Php2,500.00 + LRF With Subsequent Labeling Amendment per product strength: Php 500.00+LRF Change or addition of brand name: Php2,500.00 + LRF + 510.00 (for each brand name proposed) Shelf-life extension/reduction: Php1,000.00 + LRF Equivalent to Initial Registration, including Additional Route of Administration Branded: Php 15,000.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF Monitored Release Status: Php 33,333.33/5 years + 1% LRF Reclassification: Php 3,000.00 + LRF

ELIGIBILITY CRITERIA **(provided under Sec. V.B. of FDA-Circular-No.-2022-009)**
1. Only FDA-licensed drug manufacturers, traders, and distributors with WHO-prequalified pharmaceutic products and vaccines may apply for registration through this procedure. 2. Prior to the submission of the registration application with the FDA, the applicant shall ensure that the form provided under Appendix 2 of WHO TRS 996 Annex 8, Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the Procedure (Annex A), has been duly accomplished and submitted by the Manufacturer or Prequalification Holder to the World Health Organization Prequalification Team (WHO/PQT). 3. The eligible product shall be the same as the product prequalified by the WHO/PQT. a. All aspects of the drug product's quality, including but not limited to the formulation, manufacturing site/s, release and shelf-life specifications, primary packaging, and commercial presentation must be the same as those currently approved by the WHO/PQT at the time of submission. b. The proposed indication/s, dosing regimen/s, patient group/s, and/or direction/s for use should be the same as those approved by the WHO/PQT. 4. For post-approval change/s, only applications submitted to FDA not later than thirty (30) calendar days after approval of the change/s by WHO/PQT may be applied through CRP of WHO-prequalified pharmaceutical products and vaccines. Applications for post approval change/s which have not undergone WHO prequalification shall be evaluated through the regular FDA registration pathway following FDA-Circular-No.-2014-008, its amendment FDA-Circular-No.-2014-008-A, supplement FDA-Circular-No.-2016-017, and succeeding issuances for the same purposes. 5. The applicant may choose to avail of the CRP of WHO-prequalified pharmaceutical products and vaccines only if the application has not been applied through other types of facilitated review pathway (i.e. abridged review and verification review). If any of the requirements of CRP of WHO-prequalified pharmaceutical products and vaccines cannot be complied with, the application shall not be accepted and the applicant shall be advised to submit their application following the regular review pathway.
GENERAL REQUIREMENTS
Documentary requirements: Accomplished application form as per FDA-Circular-No.-2014-003, as prescribed in FDA-Advisory-No.2022-0001, subject to any future issuance providing for its amendment, repeal, or modification; Letter of Request for Post-Approval Changes (Annex E); The official post-prequalification variation approval document issued by the WHO/PQT; and Documentary requirements following FDA-Circular-No.-2014-008 (Application Process and Requirements for Post-approval Changes of Pharmaceutical Products) and its amendment, FDA-Circular-No.-2014-008-A, or any future issuance providing for its repeal, further amendment, or modification.

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. 1.Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1.1.Sends the scheduled date of submission for pre-assessment	None	0	FDAC Personnel
	1.2.Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None	0	CDRR Pre-assessor
2. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.bizPortal Sends proof of payment to the FDAC.	2.1.Endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/ Landbank FDAC Personnel

	2.2.Receives the application from FDAC and encodes/updates the database.	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3.Decks/Assigns the application to the assigned evaluators of Registration Section and/or Clinical Research Section.	None	1 working day	CDRR Director
	2.4.Evaluator verifies the registration pathway of the application if indeed for Collaborative Review/Registration Procedure (CRP). The evaluator shall inform the WHO/PQT and the applicant of its consent to apply the procedure through Appendix 3, Part B of WHO TRS 996 Annex 8, Decision on acceptance by the NRA to apply the Procedure to a specified WHO-prequalified product and request for access to product-specific information and documentation (Annex C). The regulatory time is stopped (stop clock) until the WHO/PQT has provided the FDA with the requested product-related information and documentation, through the restricted-access website.	None	5 working days	FDRO I/II/III
	2.5.Evaluates the application according to requirements and prescribed standards	None	8 working days	FDRO I/II/III

3. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR)/Certificate issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None		FDRO I/II/III
	3.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	7 working days	FDRO III
	3.3.Prepares the final output document (CPR/Certificate LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR or Certificate	None	1 working day	FDRO I/II/III
	3.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III
	3.5 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	1 working day	FDRO IV (Supervisor)
	3.6 Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	1 working day	LRD Chief

	3.7 Signs and approves the final decision	None	1 working day	CDRR Director
	3.8 Encodes/Updates the Database and endorses the final output document (CPR/Certificate/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	3.9 Scans, barcodes the final output document (CPR/Certificate/LOD/Letter); and endorses the final output document to the FDAC Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel
4. Receives the CPR/Certificate/LOD/Letter	4.1 Releases the CPR/Certificate/LOD/Letter to the client	None	1 working day	AFS - Releasing Section Personnel
	4.2 Notifies the WHO/PQT of the regulatory decision (CPR/Certificate/LOD/Letter)	None		FDRO I/II/III
(Service is covered under FDA-Circular-No.-2022-009).		TOTAL:	25 working days	

12.ISSUANCE OF CERTIFICATE OF PHARMACEUTICAL PRODUCTS (COPP), CERTIFICATE OF FREE SALE (CFS), EXPORT CERTIFICATE (EC), AND GENERIC LABELING EXEMPTION (GLE)

These certificates are issued to indicate that the product is registered and marketed in the country; or for export; or exempted from the generic labeling guidelines.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders
Fees to be Paid	:	COPP - Php 500.00 each/per product/per country + 1% LRF CFS - Php 500.00 each/per product/per country + 1% LRF EC - Php 500.00 each/per product/per country + 1% LRF GLE - Php 500.00 each/per product/per year for low volume of importation + 1% LRF Php 500.00/product for special handling + 1% LRF as per A.O. No. 50 s. 2001 (Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Certificate of Pharmaceutical Product	
Application Form	Applicant Company Applicant
Valid Certificate of Product Registration	Company Applicant Company
Valid License to Operate (LTO) of manufacturer/exporter	Applicant Company Applicant
Valid cGMP of manufacturer	Company Applicant Company
Immediate and secondary labeling materials	Applicant Company
Unit Dose Formulation	
Proof of Payment (per product/per country)	

Certificate of Free Sale	
Application Form	Applicant Company Applicant
Valid Certificate of Product Registration	Company Applicant Company
Valid License to Operate (LTO) of Manufacturer/exporter	Applicant Company
Proof of Payment (per product/per country)	
Export Certificate	Applicant Company Applicant
Application Form	Company Applicant Company
Valid Certificate of Product Registration	Applicant Company
Valid License to Operate (LTO)	Applicant Company
Quantity, batch number, manufacturing and expiry dates of the drug product/s to be exported	
Proof of Payment (per product/per country)	Applicant Company Applicant
Generic Labeling Exemption	Company Applicant Company
Completely filled and signed Integrated Application Form (in excel and pdf format)	Applicant Company Applicant
Signed Letter of Request (stating the basis of exemption)	Company Applicant Company
Copy of valid CPR with attachments, if applicable	
License to Operate as Drug Importer (for low volume of importation)	
Facsimile of the labeling materials (primary and secondary packaging materials)	Applicant Company
Copy of previously approved certificate of generic labeling exemption (for renewal applications)	
Market forecast for the period applying for, in case of low volume of importation	Applicant Company
(must be specified monthly and separated with the letter of request)	
Proof of Payment	
References:	
A.O. No. 2016-0008 - Revised Rules and Regulations Governing the Generic Labeling Requirements of Drug Products for Human Use	
DOH Administrative Order (AO) No. 105, s. 1991 - Requirement for Labelling Materials of Veterinary Drugs and Products	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC	1.1 Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
2. E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2.1 Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment.	None		CDRR *Personnel*
	If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre- assessment and new Document Tracking Number (DTN).			
For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.bizPortal Sends proof of payment to the FDAC.	3.1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC *Personnel*
	3.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR)
				– Central Receiving and Releasing (CRR) Unit

	3.3 Decks/Assigns the application to the assigned evaluator	None	1 working day	LRD Chief/ CRR Unit *Personnel*
	3.4 Evaluates the application according to requirements and prescribed standards	None	11 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior)*
If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares a worksheet and drafts Certification issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an Approval recommendation *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	3 working days	*FDRO I/II*
	4.2 Prepares the final output document (Certification /LOD), affixes initial, and forwards it to the Section Supervisor	None	1 working day	*FDRO I/II*
	4.3 Reviews the final output document, signs and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	*FDRO IV (Supervisor)*
	4.4 Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	1 working day (per batch of applications)	*LRD Chief*

	4.5 Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	4.6 Encodes/Updates the Database and endorses the final output document to the AFS Releasing Section	None	2 working days (per batch of applications)	*CDRR-CRR Unit Personnel*
5. Receives the Certification /LOD	5.1 Releases the Certification /LOD to the client	None	1 working day	*AFS Releasing Section Personnel*
TOTAL:			**20 working days**	

13.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR BIOLOGICALS AND VACCINES (NEW CHEMICAL ENTITIES/MONITORED RELEASE AND INITIAL)

The issuance of a Certificate of Product Registration is granted to Marketing Authorization Holder of Biologics and Vaccines which meets the standards for Quality, Safety and Efficacy of their product based on the provided documentation. It is a marketing approval that the FDA grants for the sale and distribution of such product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Vaccines, Biologicals, stem cell, and blood and blood products
Fees to be Paid	:	New Chemical Entities/Monitored Release Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + Php 2,500.00* [Post-Marketing Surveillance (i.e., Local Phase IV Clinical Trial) Protocol Review] + 1% LRF Initial Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2/5-year CPR validity. 2 year-validity: Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF 5 year-validity: Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF Variation-turned-Initial:

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE AND INITIAL REGISTRATION OF VACCINES AND BIOLOGICALS	
A.O. No. 47-a s.2011 Rules and Regulations on the Registration, including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biological Products	Applicant Company
ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information	Applicant Company
Sec. A Introduction	Applicant Company
Sec. B Overall ASEAN Common Technical Dossier Table of Contents	Applicant Company
Sec. C Guidance on the Administrative Data and Product Information	Applicant Company
Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) Letter of Authorization (where applicable)	FDA Website Applicant Company/ Manufacturer
Certifications For contract manufacturing:	
. License of pharmaceutical industries and contract manufacturer . Contract manufacturing agreement . GMP certificate of contract manufacturer	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For manufacturing “under-license” . License of pharmaceutical industries . GMP certificate of the manufacturer . Copy of “under-license” agreement	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer

For locally manufactured products: . License of pharmaceutical industries . GMP certificate (country specific)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Risk Management Plan (RMP) which shall include the following: RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems RMP Philippine-Specific Annex (as applicable) RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report . List of Countries where the product is already licensed and the date of approval (for vaccines) . Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA . Person/s responsible for production and control of the product (Name/s Position, Department, and sample of signature) . Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer

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P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control Information on the number system of the lots or batches System for the re-processing of the product in the event of rejection of the lot or batch by the manufacturer's QA/QC P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses	

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2. Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials	

2.1. Plasma Protein Binding Study Reports 2.2. Reports of Hepatic Metabolism and Drug Interaction Studies 2.3. Reports of Studies Using Other Human Biomaterials 3. Reports of Human Pharmacokinetic (PK) Studies 3.1. Healthy Subject PK and Initial Tolerability Study Reports 3.2. Patient PK and Initial Tolerability Study Reports 3.3. Population PK Study Reports 4. Reports of Human Pharmacodynamic (PD) Studies 4.1. Healthy Subject PD and PK/PD Study Reports 4.2. Patient PD and PK/PD Study Reports 5. Reports of Efficacy and Safety Studies 5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2. Study Reports of Uncontrolled Clinical Studies 5.3. Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses 5.4. Other Clinical Study Reports 6. Reports of Post-Marketing Experience 7. Case Report Forms and Individual Patient Listing Sec. F List of Key Literature References Additional Requirements: For MRE/MR to Initial applications, proof of approval/clearance/extension of Post- Marketing Surveillance (PMS) Report and Post Approval Commitments as specified in the provided RMP. 2. For MR, Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020]	Applicant Company/Manufacture Applicant Company/Manufacturer
CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE AND INITIAL APPLICATION FOR SIMILAR BIOTHERAPEUTIC PRODUCTS	
Part I: Administrative Data and Product Information Sec. A Introduction	Applicant Company/Manufacturer

Sec. B Overall ASEAN Common Technical Dossier	Applicant
Table of Contents	Company/Manufacturer
Sec. C Guidance on the Administrative Data and	Applicant
Product Information	Company/Manufacturer
1. Integrated Application Form (with proof of payment)	
2. Letter of Authorization (where applicable)	Applicant
3. Certifications	Company/Manufacturer
For contract manufacturing:	(For the whole Section C)
a. License of pharmaceutical industries and contract manufacturer	FDA Website & Cashier
b. Contract manufacturing agreement	
c. GMP certificate of contract manufacturer	
For manufacturing “under-license”	
a. License of pharmaceutical industries	
b. GMP certificate of the manufacturer	
c. Copy of “under-license” agreement	
For locally manufactured products:	
a. License of pharmaceutical industries	
b. GMP certificate (country specific)	
For imported products	
License of pharmaceutical industries/importer/wholesaler (country specific)	
Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format	
Foreign GMP Clearance	
4. Site Master File	
5. Labeling	
6. Representative Sample with corresponding Certificate of Analysis	
7. Product Information	
Package Insert	
Summary of Product Characteristics (Product Data Sheet)	
8. Risk Management Plan (RMP)	
9. Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report	

10. List of Countries where the product is already licensed and the date of approval 11. Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA 12. Person/s responsible for production and control of the product (Name/s Position, Department, and sample of signature) 13. Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)	
Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures	Applicant Company/Manufacturer (For whole Part II: Quality)

S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability	
Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control Information on the number system of the lots or batches System for the re-processing of the product in the event of rejection of the lot or batch by the manufacturer's QA/QC P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications	

P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses Lot to Lot Consistency from three (3) consecutive batches P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Quality Comparability P 9.1. Reference Biotherapeutic Product P 9.2. Manufacturing Process P 9.3. Characterization P 9.3.1. Physicochemical Properties P 9.3.2. Biological Activity P 9.3.3. Immunochemical Properties P 9.3.4. Impurities P 9.4. Specifications P 9.5. Analytical Techniques P 9.6. Stability	
Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1. General Consideration 2. Special Consideration	Applicant Company/Manufacturer (For Whole Part III: Nonclinical Document)

2.1. In Vitro Studies 2.2. In Vivo Studies	
Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Pharmacokinetic Studies 2. Pharmacodynamic Studies 3. Confirmatory Pharmacokinetic/ Pharmacodynamic Studies 4. Efficacy Studies 5. Safety Studies 6. Immunogenicity 7. Extrapolation of Efficacy and Safety Data Additional Requirements: 1. For MRE/MR to Initial applications, proof of approval/clearance/extension of Post- Marketing Surveillance (PMS) Report and Post Approval Commitments as specified in the provided RMP 2. For MR, Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020]	Applicant Company/Manufacturer (For Whole Part IV: Clinical Document) Applicant Company Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1.Sends the scheduled date of submission for pre-assessment	None	0	FDAC *Personnel*
	1.1.Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None	0	CDRR *Personnel*

2.For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.BizPortal Sends proof of payment to the FDAC. Remarks: If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	2.1.Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/Landbank FDAC *Personnel*
	2.2.Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR)
	2.3.Queuing time of the application before decking to evaluators of Registration Section and Clinical Research Section.	None	20 working days	CDRR-CRR Unit *Personnel*
	2.4.Decks/Assigns the application to the assigned evaluator of Registration Section and/or Clinical Research Section.	None	1 working day	CDRR *Director*

	2.5.Evaluates the application according to requirements and prescribed standards The registration evaluator determines if the application should be reviewed as a standalone biotherapeutic product or biosimilar then refers the RMP and PMS Protocol (for MR only), safety and efficacy to CRS for evaluation. If the product is classified as a vaccine, toxoid, or immunoglobulin, review of the Summary Lot Protocol is referred to the Common Services Laboratory- Vaccines and Biologics Unit (CSL-VBU).	None	50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator) / Medical Specialist II*

	a. Clinical Research Section (Safety and Efficacy evaluator) Prepares a worksheet with Recommendations on the evaluated safety and efficacy dossier, RMP and PMS protocol (if any), then forwards this to the Quality evaluator of the Registration Section. b. Registration Section (Quality evaluator) Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS).	None		*FDRO I/II/III/ Medical Specialist II*

	Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS) For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication			
	2.6.Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	40 working days	*FDRO III*
	2.7.Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR.	None	1 working day	*FDRO II*

	2.8.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor.	None	1 working day	*FDRO III*
	2.9.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	*FDRO IV (Supervisor)*
	2.10.Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	1 working day (per batch of applications)	*LRD Chief*
	2.11.Signs and approves the final decision	None	1 working day	*CDRR Director*
	2.12.Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA-Records Section	None	1 working day	*CDRR-CRR Unit Personnel*
	2.13.Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section.	None	1 working day (per batch of applications)	*FDA-Records Personnel*
3.Receives the CPR/LOD/letter	3.Releases the CPR/LOD/letter to the client.	None	1 working day	*AFS - Releasing Section Personnel*
TOTAL: (Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13, Republic Act No. 7394 Article 31, and Republic Act No. 11215 Article VI Section 23).			120 working days	

14.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR CANCER DRUGS (NEW CHEMICAL ENTITIES/MONITORED-RELEASE)

This Certificate of Product Registration is granted to Marketing Authorization Holders of cancer drugs upon compliance to Quality, Safety, Efficacy standards. It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Cancer Drugs
Fees to be Paid	:	FDA-Advisory-No.2021-2904 New Drug/Monitored Release (for all types of products): Php Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + Php 2,500.00* [Post-Marketing Surveillance (i.e., Local Phase IV Clinical Trial) Protocol Review] + 1% LRF *If additional PV activity(ies) are necessary based on FDA Circular No. 2021-020

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR NEW CHEMICAL ENTITIES/MONITORED-RELEASE REGISTRATION	

ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information Sec. A Introduction Sec. B Overall ASEAN Common Technical Dossier Table of Contents Sec. C Guidance on the Administrative Data and Product Information	Applicant Company/Manufacturer (For the whole Part I)
Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) Letter of Authorization (where applicable) Certifications	FDA Website & Cashier
For contract manufacturing: . License of pharmaceutical industries and contract manufacturer . Contract manufacturing agreement . GMP certificate of contract manufacturer	
For manufacturing “under-license” . License of pharmaceutical industries . GMP certificate of the manufacturer . Copy of “under-license” agreement	
For locally manufactured products: . License of pharmaceutical industries . GMP certificate (country specific)	
For imported products . License of pharmaceutical industries/importer/wholesaler (country specific) . Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format . Foreign GMP Clearance	
Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information	

Package Insert Summary of Product Characteristics (Product Data Sheet) Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability Drug Product (P) P 1 Description and Composition	Applicant Company/Manufacturer (For the whole Part II: Quality)

P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Product Interchangeability/Equivalence Evidence (if applicable)	

Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1. General Aspect 2. Content and Structural Format Sec. C Nonclinical Written and Tabulated Summaries 1. Nonclinical Written Summaries 1.1. Introduction 1.2. General Presentation Issues 2. Content of Nonclinical Written and Tabulated Summaries 2.1. Pharmacology 2.1.1. Written Summary 2.1.1.1. Primary Pharmacodynamics 2.1.1.2. Secondary Pharmacodynamics 2.1.1.3. Safety Pharmacology 2.1.1.4. Pharmacodynamic Drug Interactions 2.1.2. Tabulated Summary 2.2. Pharmacokinetics 2.2.1. Written Summary 2.2.1.1. Absorption 2.2.1.2. Distribution 2.2.1.3. Metabolism 2.2.1.4. Excretion 2.2.1.5. Pharmacokinetic Drug Interaction (Nonclinical) 2.2.2. Tabulated Summary 2.3. Toxicology 2.3.1. Written Summary 2.3.1.1. Single-Dose Toxicity 2.3.1.2. Repeat-Dose Toxicity 2.3.1.3. Genotoxicity 2.3.1.4. Carcinogenicity 2.3.1.5. Reproductive and Developmental Toxicity 2.3.1.5.1. Fertility and Early Embryonic Development 2.3.1.5.2. Embryo-Foetal Development 2.3.1.5.3. Prenatal and Postnatal Development	Applicant Company/Manufacturer (For the whole Part III: Nonclinical Document)

2.3.1.6. Local Tolerance 2.3.1.7. Other Toxicity Studies (if available) 2.3.2. Tabulated Summary 3. Nonclinical Tabulated Summaries Sec. D Nonclinical Study Reports 1. Table of Contents 2. Pharmacology 2.1. Written Study Reports 2.1.1. Primary Pharmacodynamics 2.1.2. Secondary Pharmacodynamics 2.1.3. Safety Pharmacology 2.1.4. Pharmacodynamic Drug Interactions 3. Pharmacokinetics 3.1. Written Study Reports 3.1.1. Analytical Methods and Validation Reports 3.1.2. Absorption 3.1.3. Distribution 3.1.4. Metabolism 3.1.5. Excretion 3.1.6. Pharmacokinetic Drug Interaction (Nonclinical) 3.1.7. Other Pharmacokinetic Studies 4. Toxicology 4.1. Written Study Reports 4.1.1. Single-Dose Toxicity 4.1.2. Repeat-Dose Toxicity 4.1.3. Genotoxicity 4.1.3.1. In vitro Reports 4.1.3.2. In vivo Reports 4.1.4. Carcinogenicity 4.1.4.1. Long Term Studies 4.1.4.2. Short- or Medium-Term Studies 4.1.4.3. Other Studies 4.1.5. Reproductive and Developmental Toxicity 4.1.5.1. Fertility and Early Embryonic Development	Applicant Company/Manufacturer (For the whole Part IV: Clinical Document)

4.1.5.2. Embryo-Fetal Development 4.1.5.3. Prenatal and Postnatal Development 4.1.5.4. Studies in which the Offspring are Dosed and/or further Evaluated 4.1.6. Local Tolerance 4.1.7. Other Toxicity Studies (if available) 4.1.7.1. Antigenicity 4.1.7.2. Immunotoxicity 4.1.7.3. Dependence 4.1.7.4. Metabolites 4.1.7.5. Impurities 4.1.7.6. Other Sec. E List of Key Literature References Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Product Development Rationale 2. Overview of Biopharmaceutics 3. Overview of Clinical Pharmacology 4. Overview of Efficacy 5. Overview of Safety 6. Benefits and Risks Conclusions Sec. C Clinical Summary 1. Summary of Biopharmaceutic Studies and Associated Analytical Methods 1.1. Background and Overview 1.2. Summary of Results of Individual Studies 1.3. Comparison and Analyses of Results across Studies Appendix 1 2. Summary of Clinical Pharmacology Studies 2.1. Background and Overview 2.2. Summary of Results of Individual Studies 2.3. Comparison and Analyses of Results across Studies 2.4. Special Studies Appendix 2	

3. Summary of Clinical Efficacy 3.1. Background and Overview of Clinical Efficacy 3.2. Summary of Results of Individual Studies 3.3. Comparison and Analyses of Results across Studies 3.3.1. Study Populations 3.3.2. Comparison of Efficacy Results of all Studies 3.3.3. Comparison of Results in Sub-populations 3.4. Analysis of Clinical Information Relevant to Dosing Recommendations 3.5. Persistence of Efficacy and/or Tolerance Effects Appendix 3 4. Summary of Clinical Safety 4.1. Exposure to the Drug 4.1.1. Overall Safety Evaluation Plan and Narratives of Safety Studies 4.1.2. Overall extent of Exposure 4.1.3. Demographic and Other Characteristics of Study Population 4.2. Adverse Events 4.2.1. Analysis of Adverse Events 4.2.1.1. Common Adverse Events 4.2.1.2. Deaths 4.2.1.3. Other Serious Adverse Events 4.2.1.4. Other Significant Adverse Events 4.2.1.5. Analysis of Adverse Events by Organ System or Syndrome 4.2.2. Narratives 4.3. Clinical Laboratory Evaluations 4.4. Vital Signs, Physical Findings, and Other Observations Related to Safety 4.5. Safety in Special Groups and Situations 4.5.1. Patient Groups 4.5.2. Drug Interactions 4.5.3. Use in Pregnancy and Lactation 4.5.4. Overdose 4.5.5. Drug Abuse 4.5.6. Withdrawal and Rebound 4.5.7. Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability 4.6. Post-Marketing Data	

Appendix 4 5. Synopses of Individual Studies Sec. D Tabular Listing of All Clinical Studies Sec. E Clinical Study Reports (if applicable) 1. Reports of Biopharmaceutic Studies 1.1. Bioavailability (BA) Study Reports 1.2. Comparative BA or Bioequivalence (BE) Study Reports 1.3. In vitro-In vivo Correlation Study Reports 1.4. Reports of Bioanalytical and Analytical Methods for Human Studies 2. Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials 2.1. Plasma Protein Binding Study Reports 2.2. Reports of Hepatic Metabolism and Drug Interaction Studies 2.3. Reports of Studies Using Other Human Biomaterials 3. Reports of Human Pharmacokinetic (PK) Studies 3.1. Healthy Subject PK and Initial Tolerability Study Reports 3.2. Patient PK and Initial Tolerability Study Reports 3.3. Population PK Study Reports 4. Reports of Human Pharmacodynamic (PD) Studies 4.1. Healthy Subject PD and PK/PD Study Reports 4.2. Patient PD and PK/PD Study Reports 5. Reports of Efficacy and Safety Studies 5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2. Study Reports of Uncontrolled Clinical Studies 5.3. Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses 5.4. Other Clinical Study Reports 6. Reports of Post-Marketing Experience 7. Case Report Forms and Individual Patient Listing Sec. F List of Key Literature References Additional Requirements: 1. Risk Management Plan – which shall include the following: RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems RMP Philippine-Specific Annex (as applicable)	

RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted 2. Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020] Note: • ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1.1.Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
	1.2.Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*

2. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.bizPortal Sends proof of payment to the FDAC.	2.1.Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above	1 working day	FDA Cashier/ Landbank FDAC *Personnel*
	2.2.Receives the application from FDAC and encodes/updates the database.	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3.Queuing time of the application before decking to evaluators of Registration Section and Clinical Research Section.	None	21 working days	CDRR-CRR Unit *Personnel*
	2.4.Decks/Assigns the application to the assigned evaluators of Registration Section and Clinical Research Section.	None	1 working day	CDRR *Director*
	2.5.Evaluates the application according to requirements and prescribed standards	None	130 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)/ Medical Specialist II*
If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	.a. Clinical Research Section (Safety and Efficacy evaluator) 2.6. Prepares a worksheet with Recommendations on the evaluated safety and efficacy dossier, RMP,	None		*FDRO I/II/III/ Medical Specialist II/III*

	and PMS protocol (if any), then forwards this to the Quality evaluator of the Registration Section. b. Registration Section (Quality evaluator) Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS) Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS) *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication			
	2.7.Reviews the evaluated application bearing the recommendation of the Junior Evaluator (for Quality evaluation).	None	78 working days	FDRO III
	2.8.Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR For Dangerous Drugs, prepares a letter/notification to PDEA for the approval of the application	None	1 working day	FDRO I/II
	2.9.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III

	2.10.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	1 working day (per batch of applications)	FDRO IV (Supervisor)
	2.11.Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	1 working day (per batch of applications)	LRD Chief
	2.12.Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	2.13.Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	2.14.Scans, barcodes the final output document (CPR/LOD/Letter); and endorses the final output document to the FDAC Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel
3. Receives the CPR/LOD/letter	3.Releases the CPR/LOD/letter to the client	None	1 working day	AFS - Releasing Section Personnel
(Service is covered under Republic Act No. 11215 Article VI, Section 23)		TOTAL:	240 working days	

15.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR CANCER VACCINES AND BIOLOGICALS (NEW CHEMICAL ENTITIES/MONITORED-RELEASE AND INITIAL)

The issuance of a Certificate of Product Registration is granted to Marketing Authorization Holder of Biologics and Vaccines which meets the standards for Quality, Safety and Efficacy of their product based on the provided documentation. It is a marketing approval that the FDA grants for the sale and distribution of such product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Anti-Cancer Vaccines, Biologicals, stem cell, and blood and blood products
Fees to be Paid	:	**New Chemical Entities/Monitored Release** Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + Php 2,500.00* [Post-Marketing Surveillance (i.e., Local Phase IV Clinical Trial) Protocol Review] + 1% LRF **Initial** Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2/5-year CPR validity. 2 year-validity: Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF 5 year-validity: Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE AND INITIAL REGISTRATION OF VACCINES AND BIOLOGICALS	
A.O. No. 47-a s.2011 Rules and Regulations on the Registration, including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biological Products	Applicant Company
ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information	Applicant Company
Sec. A Introduction	Applicant Company
Sec. B Overall ASEAN Common Technical Dossier able of Contents	Applicant Company
Sec. C Guidance on the Administrative Data and Product Information	Applicant Company
1. Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) 2. Letter of Authorization (where applicable)	FDA Website Applicant Company/ Manufacturer
3. Certifications For contract manufacturing:	
a. License of pharmaceutical industries and contract manufacturer b. Contract manufacturing agreement c. GMP certificate of contract manufacturer	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For manufacturing “under-license” a. License of pharmaceutical industries b. GMP certificate of the manufacturer c. Copy of “under-license” agreement	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For locally manufactured products: a. License of pharmaceutical industries b. GMP certificate (country specific)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer

For imported products a. License of pharmaceutical industries/importer/wholesaler (country specific) b. Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format c. Foreign GMP Clearance	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
4. Site Master File 5. Labeling 6. Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) 7. Product Information a. Package Insert b. Summary of Product Characteristics (Product Data Sheet) 8. Risk Management Plan (RMP) which shall include the following: a. RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems b. RMP Philippine-Specific Annex (as applicable) c. RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted 9. Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report 10. List of Countries where the product is already licensed and the date of approval (for vaccines) 11. Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA 12. Person/s responsible for production and control of the product (Name/s Position, Departmen t, and sample of signature) 13. Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties	Applicant Company/ Manufacturer (For whole Part II: Quality)

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Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1. General Aspect 2. Content and Structural Format Sec. C Nonclinical Written and Tabulated Summaries 1. Nonclinical Written Summaries 1.1. Introduction	Applicant Company/Manufacturer (For whole Part III: Nonclinical Document)

1.2. General Presentation Issues 2.Content of Nonclinical Written and Tabulated Summaries 2.1.Pharmacology 2.1.1.Written Summary 2.1.1.1.Primary Pharmacodynamics 2.1.1.2.Secondary Pharmacodynamics 2.1.1.3.Safety Pharmacology 2.1.1.4.Pharmacodynamic Drug Interactions 2.1.2. Tabulated Summary 2.2.Pharmacokinetics 2.2.1.Written Summary 2.2.1.1.Absorption 2.2.1.2.Distribution 2.2.1.3.Metabolism 2.2.1.4.Excretion 2.2.1.5.Pharmacokinetic Drug Interaction (Nonclinical) 2.2.2. Tabulated Summary 2.3.Toxicology 2.3.1.Written Summary 2.3.1.1.Single-Dose Toxicity 2.3.1.2.Repeat-Dose Toxicity 2.3.1.3.Genotoxicity 2.3.1.4.Carcinogenicity 2.3.1.5.Reproductive and Developmental Toxicity 2.3.1.5.1.Fertility and Early Embryonic Development 2.3.1.5.2.Embryo-Foetal Development 2.3.1.5.3.Prenatal and Postnatal Development 2.3.1.6.Local Tolerance 2.3.1.7.Other Toxicity Studies (if available) 2.3.2. Tabulated Summary	

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1.4. Reports of Bioanalytical and Analytical Methods for Human Studies	
2. Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials	
2.1. Plasma Protein Binding Study Reports	
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2.3. Reports of Studies Using Other Human Biomaterials	
3. Reports of Human Pharmacokinetic (PK) Studies	
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3.2. Patient PK and Initial Tolerability Study Reports	
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4. Reports of Human Pharmacodynamic (PD) Studies	Applicant Company/Manufacture
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4.2. Patient PD and PK/PD Study Reports	
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b. GMP certificate of the manufacturer c. Copy of “under-license” agreement For locally manufactured products: a. License of pharmaceutical industries b. GMP certificate (country specific) For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance 4. Site Master File 5. Labeling 6. Representative Sample with corresponding Certificate of Analysis 7. Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) 8. Risk Management Plan (RMP) 9. Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report 10. List of Countries where the product is already licensed and the date of approval 11. Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA 12. Person/s responsible for production and control of the product (Name/s Position, Department, and sample of signature) 13. Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)	
Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S)	Applicant Company/Manufacturer (For whole Part II: Quality)

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Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Pharmacokinetic Studies 2. Pharmacodynamic Studies 3. Confirmatory Pharmacokinetic/ Pharmacodynamic Studies 4. Efficacy Studies 5. Safety Studies 6. Immunogenicity 7. Extrapolation of Efficacy and Safety Data Additional Requirements:	Applicant Company/Manufacturer (For Whole Part IV: Clinical Document) Applicant Company Applicant Company

1. For MRE/MR to Initial applications, proof of approval/clearance/extension of Post- Marketing Surveillance (PMS) Report and Post Approval Commitments as specified in the provided RMP 2. For MR, Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020]	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC :-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1.1 Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
	1.2 Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*
2. For accepted applications, pays the required fee through any of the following: • BANCNET	2.1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/Landbank FDAC *Personnel*

• Landbank OnColl • Landbank Link.BizPortal Sends proof of payment to the FDAC. Remarks: If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	2.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3 Queuing time of the application before decking to evaluators of Registration Section and Clinical Research Section.	None	21 working days	CDRR-CRR Unit *Personnel*
	2.4 Decks/Assigns the application to the assigned evaluator of Registration Section and/or Clinical Research Section.	None	1 working day	CDRR *Director*
	2.5 Evaluates the application according to requirements and prescribed standards The registration evaluator determines if the application should be reviewed as a standalone biotherapeutic product or biosimilar then refers the RMP and PMS Protocol (for MR only), safety and efficacy to CRS for evaluation. If the product is classified as a vaccine, toxoid, or immunoglobulin, review of the Summary Lot Protocol is referred to the Common Services Laboratory- Vaccines and Biologics Unit (CSL-VBU).	None	130 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator) / Medical Specialist II*

	Clinical Research Section (Safety and Efficacy evaluator) Prepares a worksheet with Recommendations on the evaluated safety and efficacy dossier, RMP and PMS protocol (if any), then forwards this to the Quality evaluator of the Registration Section. Registration Section (Quality evaluator) Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS).	None		*FDRO I/II/III/ Medical Specialist II*

	Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS) For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication			
	2.6 Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	78 working days	*FDRO III*
	2.7 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR.	None	1 working day	*FDRO II*
	2.8 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor.	None	1 working day	*FDRO III*
	2.9 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	*FDRO IV (Supervisor)*
	2.10 Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	1 working day (per batch of applications)	*LRD Chief*
	2.11 Signs and approves the final decision	None	1 working day	*CDRR Director*

	2.12 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA-Records Section	None	1 working day	*CDRR-CRR Unit Personnel*
	2.13 Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section.	None	1 working day (per batch of applications)	*FDA-Records Personnel*
3. Receives the CPR/LOD/letter	3. Releases the CPR/LOD/letter to the client.	None	1 working day	*AFS - Releasing Section Personnel*
(Service is covered under Republic Act No. 11215 Article VI, Section 23)	**TOTAL:**		**240 working days**	

16.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR HERBAL MEDICINE/TRADITIONALLY-USED HERBAL PRODUCTS (INITIAL)

The issuance of a Certificate of Product Registration is granted to Marketing Authorization Holder of Herbal Medicines and Traditionally Used Herbal Product which meets the standards for Quality, Safety and Efficacy/Claimed Benefit of their product based on the provided documentation. It is a marketing approval that the FDA grants for the sale and distribution of such product in the country.

Center/Office/Division	**:**	Center for Drug Regulation and Research
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B – Government-to-Businesses
Who May Avail	**:**	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products (Herbal and Traditionally-Used Herbal Medicines)
Fees to be Paid	**:**	**Initial** Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2/5-year CPR validity. 2 year-validity: Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF **5 year-validity:** Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF HERBAL MEDICINES Administrative-Order-No.-172-s.-2004 Guidelines on the Registration of Herbal Medicines	
Notarized Integrated Application Form (in excel and in pdf format)	
Proof of Payment	Applicant Company
Valid agreements between the manufacturer, trader, importer, distributor, where applicable	Applicant Company
Unit Dose and Batch Formulation	Applicant Company/Manufacturer
Technical Specifications of all Raw Materials	
Certificate of Analysis of active Raw Material(s)	Applicant Company/Manufacturer
From supplier of Active Raw Material	Applicant Company/Manufacturer
From manufacturer of finished product	Applicant Company (API Supplier & Manufacturer)
Certification of Authenticity of Plant Specimen from the National Museum or any FDA-recognized Taxonomist	
Technical Specifications of Finished Product	National Museum or any FDA-recognized Taxonomist
Certificate of Analysis (CA) of Finished Product from the same batch of representative sample)	
Manufacturing Procedure, Production Equipment, Sampling, In-process controls, and Master Packaging Procedure (including specification for container closure system)	Applicant Company/Manufacturer
Assay and Other Test Procedures including Identity, Purity Tests, with Data Analysis, where applicable	Applicant Company/Manufacturer
Stability Studies	Applicant Company/Manufacturer
Labeling Materials (facsimile)	
Evidence of Safety and Efficacy	
Representative Sample (upon request of the evaluator	NIRPROMP & Applicant Company
Additional Requirements: For herbal medicines validated by the National Integrated Research Program on Medicinal Plants (NIRPROMP), Copy of the Memorandum of Agreement between NIRPROMP and the applicant; otherwise, a copy of approval of FDA Committee on the registration of the said herbal medicine.	

For products in plastic container: Certificate of Analysis for Test of Migratable Substances/ Leachability	Applicant Company/ Manufacturer
For imported products:	
Certificate of Pharmaceutical Product (CPP)	Applicant Company/ Manufacturer
Foreign GMP Clearance	
Valid LTO (Importer/Manufacturer/Distributor/Trader)	FDA CDRR
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF TRADITIONALLY-USED HERBAL PRODUCTS	
Administrative-Order-No.-184-s.-2004	
Guidelines on the Registration of Traditionally-Used Herbal Products	
	Applicant Company
Notarized Integrated Application Form (in excel and in pdf format)	Applicant Company
Proof of Payment	Applicant Company/Manufacturer
Valid agreements between the manufacturer, trader, importer, distributor, where applicable	
Unit Dose and Batch Formulation	Applicant Company/Manufacturer
Technical Specifications of all Raw Materials	Applicant Company/Manufacturer
Certificate of Analysis of active Raw Material(s)	Applicant Company (API Supplier &
From supplier of Active Raw Material	Finished Product Manufacturer)
From manufacturer of finished product	
Certification of Authenticity of Plant Specimen from the National Museum or any FDA -recognized Taxonomist	National Museum or any FDA-recognized Taxonomist
Technical Specifications of Finished Product	
Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)	Applicant Company/ Manufacturer
Manufacturing Procedure, Production Equipment, Sampling, In-process controls, and Master Packaging	
Procedure (including specification for container closure system)	Applicant Company/ Manufacturer
Assay and Other Test Procedures including Identity, Purity Tests, with Data Analysis, where applicable	
Stability Studies	Applicant Company/ Manufacturer

Labeling Materials (facsimile labels)	Applicant Company/ Manufacturer
Evidence of Safety	Applicant Company/ Manufacturer
Evidence of Claimed Application	Applicant Company/ Manufacturer
Representative Sample	Applicant Company/ Manufacturer
Additional Requirements:	
For products in plastic container:	Applicant Company/ Manufacturer
Certificate of Analysis for Test of Migratable Substances/ Leachability	Applicant Company/ Manufacturer
For imported products:	Applicant Company/ Manufacturer
Certificate of Traditionally –Used Herbal Product	
Foreign GMP Clearance	Applicant Company/ Manufacturer
Valid LTO (Importer/Manufacturer/Distributor/Trader)	FDA CDRR

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Secure a schedule of appointment /submission to FDAC	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
2. E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2.1 Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*

3.For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.BizPortal Sends proof of payment to the FDAC.	3.1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC *Personnel*
	3.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	3.3 Queuing time of the application before decking to evaluators of Registration Section and/or Clinical Research Section	None	20 working days	CDRR-CRR Unit *Personnel*
	3.4 Decks/Assigns the application to the assigned evaluator of Registration Section and/or Clinical Research Section	None	1 working day	*CDRR Director*
	3.5 Evaluates the application according to requirements and prescribed standards	None	50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator) / Medical Specialist II*

If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	**a. Clinical Research Section (Evidence of Safety and Efficacy evaluator)** Prepares a worksheet with Recommendations on the evaluated evidence of safety and efficacy, and PMS protocol (if any), then forwards this to the Quality evaluator of the Registration Section. **b. Registration Section (Quality evaluator)** Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and Evidence of Safety & Efficacy received from the CRS).	None	1 working day	*FDRO I/II/III/ Medical Specialist II*
	3.6 Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	40 working days	*FDRO III*
	3.7 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None	1 working day	*FDRO II*
	3.8 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	*FDRO III*

	3.9 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	*FDRO IV (Supervisor)*
	3.10 Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	1 working day (per batch of applications)	LRD *Chief*
	3.11 Signs and approves the final decision	None	1 working day	CDRR Director
	3.12 Encodes/Updates the Database and Endorses the final output document to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	3.13 Scans, barcodes, and emails the scanned copy of the document to the client; and endorses the final output document to the AFS - Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel
4. Receives the CPR/LOD/letter	4. Releases the CPR/LOD/letter to the client	None	1 working day	AFS Releasing Section Personnel
TOTAL: (Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13 and Republic Act No. 7394 Article 31.			**120 working days**	

17.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR MEDICAL GRADE OXYGEN (INITIAL)

The issuance of a Certificate of Product Registration is granted to Marketing Authorization Holder of Medical Gases which meets the standards for Quality, Safety and Efficacy of their product based on the provided documentation. It is a marketing approval that the FDA grants for the sale and distribution of such product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Medical Grade Oxygen
Fees to be Paid	:	**nitial Branded:** Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2 or 5-year CPR validity (Based on Bureau Circular No. 5 s. 1997). Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF **5 year-validity:** Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF MEDICAL GRADE OXYGEN	
1. Notarized Integrated Application Form (in excel and in pdf format)	FDA Website
2. Proof of payment	FDA Cashier
3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable	Applicant Company/ Manufacturer
4. Technical Specifications of Finished Product	Applicant Company/ Manufacturer
5. Certificate of Analysis (CA) of Finished Product	Applicant Company/ Manufacturer
6. Certificate of Analysis issued by CIGI for the product	CIGI
7. Manufacturing Procedure, Production, Equipment, Sampling, In-process controls	Applicant Company/ Manufacturer

8. Complete quality control procedures for the finished product.	Applicant Company/ Manufacturer
9. Philippine Standard Quality Certification Mark issued by the Bureau of Product Standards, Department of Trade and Industry	Bureau of Product Standards, Department of Trade and Industry
10. Labeling Materials (facsimile)	Applicant Company/Manufacturer
11. For imported products: Foreign GMP Clearance	FDA CDRR
12. Copy of valid License to Operate	FDA CDRR

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Secures a schedule of appointment / submission to FDAC.	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
2. E-mail submission: Submits the application for pre- assessment through fdac.pacd.cdrr@fda.gov.ph	2. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*

3. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.BizPortal Sends proof of payment to the FDAC.	L Endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/Landbank FDAC *Personnel*
	3.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	3.3 Queuing time of the application before decking to evaluators	None	9 working days	
	3.4 Decks/Assigns the application to the assigned evaluator	None	1 working day	LRD *Chief*
	3.5 Evaluates the application according to requirements and prescribed standards	None	23 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*

4. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended	None	1 working day	*FDRO I/II/III*
	Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E- NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication			
	4.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	12 working days	*FDRO III*

	4.3 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None	1 working day	*FDRO I/II*
	4.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None		*FDRO III*
	4.5 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	3 working days (per batch of applications)	*FDRO IV (Supervisor)*
	4.6 Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	3 working days (per batch of applications)	*LRD Chief*
	4.7 Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	4.8 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*

	4.9 Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section.	None	2 working days (per batch of applications)	*FDA Records Personnel*
5. Receives the CPR/LOD/letter	5. Releases the CPR/LOD/letter to the client	None	1 working day	*AFS Releasing Section Personnel*
(Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13, and Republic Act No. 7394 Article 31 wherein a timeline of 60 working days was proposed instead of 180 working days).		**TOTAL:**	60. **working days**	

18.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR OVER-THE-COUNTER DRUGS AND HOUSEHOLD REMEDY DRUG PRODUCTS (INITIAL)

The issuance of a Certificate of Product Registration is granted to Marketing Authorization Holder of Over -the-Counter Drugs and Household Remedy preparations which meets the standards for Quality, Safety and Efficacy/Claimed Benefit of their product based on the provided documentation. It is a marketing approval that the FDA grants for the sale and distribution of such product in the country.

Center/Office/Division	**:**	Center for Drug Regulation and Research
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B – Government-to-Businesses
Who May Avail	**:**	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	**:**	**Initial** Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2/5-year CPR validity (Based on Bureau Circular No. 5 s.1997). **2 year-validity:** Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF **5 year-validity:** Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF OVER-THE-COUNTER DRUGS AND HOUSEHOLD REMEDIES	
1. Notarized Integrated Application Form (in excel and in pdf format)	
2. Proof of payment	FDA Website
3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable	FDA Cashier

4. Unit Dose and Batch Formulation	Applicant Company /Manufacturer
5. Technical Specifications of all Raw Materials	
6. Certificate of Analysis of Active Raw Material(s)	Applicant Company /Manufacturer
a. From supplier of API	Applicant Company/ Manufacturer
b. From manufacturer of finished product	Applicant Company /Manufacturer
7. Technical Specifications of Finished Product	(Supplier of API & Manufacturer)
8. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)	
9. Manufacturing Procedure, Production, Equipment, Sampling, In-process controls, and Master Packaging	Applicant Company/ Manufacturer
Procedure (including specification for container closure system)	Applicant Company /Manufacturer
10. Assay and Other Test Procedures including Identity, Purity Tests, with Data Analysis, where applicable	
11. Stability Studies	Applicant Company /Manufacturer
12. Labeling Materials (facsimile labels)	FDA CDRR (Applicant Company)
13. Representative Samples (w/ COA) may be submitted at a later date, e.g. when the application has already been decked as indicated in the Document Tracking System (upon request of the evaluator).	
Additional Requirements:	
14. For products in plastic container: Certificate of Analysis for Test of Migratable Substances/ Leachability	
15. For imported products:	
a. Certificate of Pharmaceutical Product (CPP) or Certificate of Free Sale	
b. Foreign GMP Clearance	
16. Valid LTO (Importer/Manufacturer/Distributor/Trader)	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Secure a schedule of appointment / submission to FDAC	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*

2. E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	L Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*
3. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.BizPortal Sends proof of payment to the FDAC.	L Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC *Personnel*
	3.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	3.3 Queuing time of application before decking to evaluators	None	20 working days	CDRR-CRR Unit *Personnel*
	3.4 Decks/Assigns the application to the assigned evaluator	None	1 working day	LRD *Chief*
	3.5 Evaluates the application according to requirements and prescribed standards	None	50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*

4. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD)when the application does not merit an Approval recommendation For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	1 working day	*FDRO I/II/III*
	4.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	40 working days	*FDRO III*
	4.3 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None	1 working day	*FDRO I/II*
	4.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	*FDRO III*

	4.5 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day (per batch of applications)	*FDRO IV (Supervisor)*
	4.6 Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	1 working day (per batch of applications)	*LRD Chief*
	4.7 Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	4.8 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*
	4.9 Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	*FDA Records Personnel*
5. Receives the CPR/LOD/letter	5. Releases the CPR/LOD/letter to the client	None	1 working day	*AFS Releasing Section Personnel*
(Serviced is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13, and Republic Act No. 7394 Article 31 wherein a timeline of 120 working days was proposed instead of 180 working days).		**TOTAL:**	**120 working days**	

19.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF NEW DRUG PRODUCTS FOR HUMAN AND VETERINARY USE INCLUDING VACCINES AND BIOLOGICALS THROUGH THE VERIFICATION REVIEW PATHWAY

This Certificate of Product Registration or Certification is granted to Marketing Authorization Holders of drug products classified under Monitored Release either as a New Drug/New Chemical Entity or a pharmaceutical/therapeutic innovation of a Tried and Tested/Established Drug (i.e., involving use for a new indication, a new mode of administration, a new dosage form, a new dosage strength, and/or a new fixed-dose combination of two or more active ingredients) upon compliance to the agency-prescribed Quality, Safety, Efficacy standards through the **Verification Review Pathway** based on F FDA-Circular-No.2022-004.
It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products • Monitored Release (MR) for human and veterinary drug products • MR for human and animal vaccines and biologicals
Fees to be Paid	:	Administrative-Order-No.-50-2001 FDA-Advisory-No.2021-2904 New Drug/Monitored Release (for all types of products): Php Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + Php 2,500.00* [Post-Marketing Surveillance (i.e., Local Phase IV Clinical Trial) Protocol Review] + 1% LRF *If additional PV activity(ies) are necessary based on FDA Circular No. 2021-020

ELIGIBILITY CRITERIA **(Provided under Sec. IV.B. of Administrative-Order-2020-0045 , reiterated with necessary clarifications under Sec. V.A of FDA-Circular-No.2022-004)**
1. The applicant shall be a holder of a valid License to Operate (LTO) issued by the FDA; 2. The applicant may avail of the following submission pathways, subject to certain conditions.

a. Abridged review may be availed when the drug product, vaccine, or biological has been approved by a Reference Drug Regulatory Authority (RDRA) and the product application is within three (3) years from the date of approval of the RDRA.
b. Verification review may be availed when the drug product, vaccine, or biological has been approved by at least two (2) RDRAs and the product application is within three (3) years from the date of approval of the RDRA/s.
c. The applicant may choose to avail of only one (1) type of FRP per application based on compliance with the requirements. If the requirements of any of the FRP cannot be complied with, the application shall be processed following the regular review pathway.
3. The eligible product shall be the same as the product duly approved or registered in the RDRA/s identified by the applicant.
a. All aspects of the drug product's quality, including but not limited to the formulation, manufacturing site/s, release and shelf-life specifications, and primary packaging, must be the same as those currently approved by the identified RDRA/s at the time of submission.
b. The proposed indication/s, dosing regimen/s, patient group/s, and/or direction/s for use should be the same as those approved by the identified RDRA/s.
4. The product and its intended use have not been rejected, withdrawn, suspended, revoked, or has pending deferral by any RDRA due to quality, safety, or efficacy reasons.
5. The information on the proposed Package Insert/Patient Information Leaflet shall be identical to that of the approved by the RDRA with the addition of country-specific information stipulated in the current FDA labeling requirements.
6. All documents to be submitted shall be written/translated into the English language.

DOCUMENTARY REQUIREMENTS

1. Applications for new drugs, vaccines, and biologicals
a. A formal, written request from the applicant drug distributor notifying the FDA of its intent to avail of the abridged or verification review, identifying the RDRA/s.
b. Assessment Report from each of the identified RDRA/s.
c. A valid Certificate of Pharmaceutical Product (CPP) following the WHO Certification Scheme or its equivalent from the identified RDRA/s. If the product is not marketed in the jurisdiction of the identified RDRA/s, then a valid CPP or its equivalent from any of the RDRA/s as listed in Annex A may be provided.
d. Complete International Council for Harmonization of Technical Requirements for Pharmaceutical for Human Use (ICH) Common Technical Document (CTD) or ASEAN Common Technical Dossier (ACTD) data requirements following existing guidelines. (See detailed checklist of requirements below).
e. Complete documentary requirements submitted to the RDRA's following the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).
f. A report of stability studies conducted under climatic Zone IVB (hot and very humid), with the required minimum time period covered by data at submission, the minimum number of batches, and storage conditions for accelerated and long-term conditions shall be provided unless otherwise justified.

g. Proposed Package Insert/Patient Information Leaflet identical to that approved by the RDRA with the addition of country-specific information stipulated in the current FDA labeling requirements.

In addition to the foregoing requirements for applications for new drugs, vaccines, and biologicals and post-approval changes, all applications should be accompanied by a Sworn Assurance and (Annex B) signed exclusively by the Head of Regulatory Office of the product owner stating the following: (1) the product being applied is the same in all respects as the product approved by the RDRA, (2) the product and its intended use has not been rejected, withdrawn, suspended, revoked, or has pending deferral by any RDRA due to quality, safety, or efficacy reasons, and (3) that there is full compliance with the eligibility requirements provided under this Circular.

The applications shall comply with rules on filing and receiving pursuant to the latest issuances until such time that an automated system has been developed and launched.

CHECKLIST OF REQUIREMENTS FOR NEW CHEMICAL ENTITIES/MONITORED-RELEASE REGISTRATION OF PHARMACEUTICAL PRODUCTS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information	Applicant
Sec. A Introduction	Company/Manufacturer
Sec. B Overall ASEAN Common Technical Dossier	(For the whole Part I)
Table of Contents	
Sec. C Guidance on the Administrative Data and Product Information	
Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment)	FDA Website & Cashier
Letter of Authorization (where applicable)	
Certifications	
For contract manufacturing:	
License of pharmaceutical industries and contract manufacturer	
Contract manufacturing agreement	
GMP certificate of contract manufacturer	
For manufacturing “under-license”	
License of pharmaceutical industries	
GMP certificate of the manufacturer	
Copy of “under-license” agreement	

For locally manufactured products: License of pharmaceutical industries GMP certificate (country specific) For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures	Applicant Company/Manufacturer (For the whole Part II: Quality)

S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities	

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2.3.1.5.3. Prenatal and Postnatal Development	
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4.1.2. Repeat-Dose Toxicity	
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4.1.3.1. In vitro Reports	
4.1.3.2. In vivo Reports	
4.1.4. Carcinogenicity	
4.1.4.1. Long Term Studies	Applicant Company /Manufacturer
4.1.4.2. Short- or Medium-Term Studies	Applicant Company /Manufacturer
4.1.4.3. Other Studies	FDA (Applicant Company)
4.1.5. Reproductive and Developmental Toxicity	
4.1.5.1. Fertility and Early Embryonic Development	
4.1.5.2. Embryo-Foetal Development	
4.1.5.3. Prenatal and Postnatal Development	

4.1.5.4. Studies in which the Offspring are Dosed and/or further Evaluated 4.1.6. Local Tolerance 4.1.7. Other Toxicity Studies (if available) 4.1.7.1. Antigenicity 4.1.7.2. Immunotoxicity 4.1.7.3. Dependence 4.1.7.4. Metabolites 4.1.7.5. Impurities 4.1.7.6. Other Sec. E List of Key Literature References Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Product Development Rationale 2. Overview of Biopharmaceutics 3. Overview of Clinical Pharmacology 4. Overview of Efficacy 5. Overview of Safety 6. Benefits and Risks Conclusions Sec. C Clinical Summary 1. Summary of Biopharmaceutic Studies and Associated Analytical Methods 1.1. Background and Overview 1.2. Summary of Results of Individual Studies 1.3. Comparison and Analyses of Results across Studies Appendix 1 2. Summary of Clinical Pharmacology Studies 2.1. Background and Overview 2.2. Summary of Results of Individual Studies 2.3. Comparison and Analyses of Results across Studies 2.4. Special Studies Appendix 2 3. Summary of Clinical Efficacy 3.1. Background and Overview of Clinical Efficacy 3.2. Summary of Results of Individual Studies 3.3. Comparison and Analyses of Results across Studies 3.3.1. Study Populations	

3.3.2. Comparison of Efficacy Results of all Studies 3.3.3. Comparison of Results in Sub-populations 3.4. Analysis of Clinical Information Relevant to Dosing Recommendations 3.5. Persistence of Efficacy and/or Tolerance Effects Appendix 3 4. Summary of Clinical Safety 4.1. Exposure to the Drug 4.1.1. Overall Safety Evaluation Plan and Narratives of Safety Studies 4.1.2. Overall extent of Exposure 4.1.3. Demographic and Other Characteristics of Study Population 4.2. Adverse Events 4.2.1. Analysis of Adverse Events 4.2.1.1. Common Adverse Events 4.2.1.2. Deaths 4.2.1.3. Other Serious Adverse Events 4.2.1.4. Other Significant Adverse Events 4.2.1.5. Analysis of Adverse Events by Organ System or Syndrome 4.2.2. Narratives 4.3. Clinical Laboratory Evaluations 4.4. Vital Signs, Physical Findings, and Other Observations Related to Safety 4.5. Safety in Special Groups and Situations 4.5.1. Patient Groups 4.5.2. Drug Interactions 4.5.3. Use in Pregnancy and Lactation 4.5.4. Overdose 4.5.5. Drug Abuse 4.5.6. Withdrawal and Rebound 4.5.7. Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability 4.6. Post-Marketing Data Appendix 4 5. Synopses of Individual Studies Sec. D Tabular Listing of All Clinical Studies Sec. E Clinical Study Reports (if applicable) 1. Reports of Biopharmaceutic Studies 1.1. Bioavailability (BA) Study Reports 1.2. Comparative BA or Bioequivalence (BE) Study Reports 1.3. In vitro-In vivo Correlation Study Reports 1.4. Reports of Bioanalytical and Analytical Methods for Human Studies 2. Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials	

2.1. Plasma Protein Binding Study Reports 2.2. Reports of Hepatic Metabolism and Drug Interaction Studies 2.3. Reports of Studies Using Other Human Biomaterials 3. Reports of Human Pharmacokinetic (PK) Studies 3.1. Healthy Subject PK and Initial Tolerability Study Reports 3.2. Patient PK and Initial Tolerability Study Reports 3.3. Population PK Study Reports 4. Reports of Human Pharmacodynamic (PD) Studies 4.1. Healthy Subject PD and PK/PD Study Reports 4.2. Patient PD and PK/PD Study Reports 5. Reports of Efficacy and Safety Studies 5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2. Study Reports of Uncontrolled Clinical Studies 5.3. Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses 5.4. Other Clinical Study Reports 6. Reports of Post-Marketing Experience 7. Case Report Forms and Individual Patient Listing Sec. F List of Key Literature References Additional Requirements: 1. Risk Management Plan – which shall include the following: RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems RMP Philippine-Specific Annex (as applicable) RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted 2. Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020] Note: • ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions.	

CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE REGISTRATION OF VACCINES AND BIOLOGICALS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
A.O. No. 47-a s.2001 Rules and Regulations on the Registration, including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biological Products	Applicant Company
ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information	Applicant Company
Sec. A Introduction	Applicant Company
Sec. B Overall ASEAN Common Technical Dossier Table of Contents	Applicant Company
Sec. C Guidance on the Administrative Data and Product Information	Applicant Company
Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) Letter of Authorization (where applicable)	FDA Website Applicant Company/ Manufacturer
Certifications For contract manufacturing:	
License of pharmaceutical industries and contract manufacturer Contract manufacturing agreement GMP certificate of contract manufacturer	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For manufacturing “under-license” License of pharmaceutical industries GMP certificate of the manufacturer Copy of “under-license” agreement	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For locally manufactured products: License of pharmaceutical industries GMP certificate (country specific)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format	Applicant Company/ Manufacturer Applicant Company/ Manufacturer

Foreign GMP Clearance	Applicant Company/ Manufacturer
Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Risk Management Plan (RMP) which shall include the following: RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems RMP Philippine-Specific Annex (as applicable) RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report List of Countries where the product is already licensed and the date of approval (for vaccines) Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA Person/s responsible for production and control of the product (Name/s Position, Department, and sample of signature) Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization S 3.1. Elucidation of Structure and Characteristics	Applicant Company/ Manufacturer (For whole Part II: Quality)

S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability	
Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control Information on the number system of the lots or batches System for the re-processing of the product in the event of rejection of the lot or batch by the manufacturer's QA/QC P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications	

P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses Summary Lot Protocol (for vaccines, toxoids and immunoglobulins) Lot to Lot Consistency from three (3) consecutive batches P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability	
Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1. General Aspect 2. Content and Structural Format Sec. C Nonclinical Written and Tabulated Summaries 1. Nonclinical Written Summaries 1.1. Introduction 1.2. General Presentation Issues 2.Content of Nonclinical Written and Tabulated Summaries 2.1.Pharmacology 2.1.1.Written Summary 2.1.1.1.Primary Pharmacodynamics 2.1.1.2.Secondary Pharmacodynamics 2.1.1.3.Safety Pharmacology 2.1.1.4.Pharmacodynamic Drug Interactions 2.1.2. Tabulated Summary 2.2.Pharmacokinetics 2.2.1.Written Summary 2.2.1.1.Absorption 2.2.1.2.Distribution 2.2.1.3.Metabolism 2.2.1.4.Excretion 2.2.1.5.Pharmacokinetic Drug Interaction (Nonclinical) 2.2.2. Tabulated Summary 2.3.Toxicology 2.3.1.Written Summary 2.3.1.1.Single-Dose Toxicity	Applicant Company/Manufacturer (For whole Part III: Nonclinical Document)

2.3.1.2.Repeat-Dose Toxicity 2.3.1.3.Genotoxicity 2.3.1.4.Carcinogenicity 2.3.1.5.Reproductive and Developmental Toxicity 2.3.1.5.1.Fertility and Early Embryonic Development 2.3.1.5.2.Embryo-Foetal Development 2.3.1.5.3.Prenatal and Postnatal Development 2.3.1.6.Local Tolerance 2.3.1.7.Other Toxicity Studies (if available) 2.3.2. Tabulated Summary 3.Nonclinical Tabulated Summaries Sec. D Nonclinical Study Reports 1. Table of Contents 2. Pharmacology 2.1. Written Study Reports 2.1.1. Primary Pharmacodynamics 2.1.2. Secondary Pharmacodynamics 2.1.3. Safety Pharmacology 2.1.4. Pharmacodynamic Drug Interactions 3. Pharmacokinetics 3.1. Written Study Reports 3.1.1. Analytical Methods and Validation Reports 3.1.2. Absorption 3.1.3. Distribution 3.1.4. Metabolism 3.1.5. Excretion 3.1.6. Pharmacokinetic Drug Interaction (Nonclinical) 3.1.7. Other Pharmacokinetic Studies 4. Toxicology 4.1. Written Study Reports 4.1.1. Single-Dose Toxicity 4.1.2. Repeat-Dose Toxicity 4.1.3. Genotoxicity 4.1.3.1. In vitro Reports 4.1.3.2. In vivo Reports 4.1.4. Carcinogenicity 4.1.4.1. Long Term Studies 4.1.4.2. Short- or Medium-Term Studies	

4.1.4.3. Other Studies 4.1.5. Reproductive and Developmental Toxicity 4.1.5.1. Fertility and Early Embryonic Development 4.1.5.2. Embryo-Foetal Development 4.1.5.3. Prenatal and Postnatal Development 4.1.5.4. Studies in which the Offspring are Dosed and/or further Evaluated 4.1.6. Local Tolerance 4.1.7. Other Toxicity Studies (if available) 4.1.7.1. Antigenicity 4.1.7.2. Immunotoxicity 4.1.7.3. Dependence 4.1.7.4. Metabolites 4.1.7.5. Impurities 4.1.7.6. Other	
Sec. E List of Key Literature References Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Product Development Rationale 2. Overview of Biopharmaceutics 3. Overview of Clinical Pharmacology 4. Overview of Efficacy 5. Overview of Safety 6. Benefits and Risks Conclusions Sec. C Clinical Summary 1. Summary of Biopharmaceutic Studies and Associated Analytical Methods 1.1. Background and Overview 1.2. Summary of Results of Individual Studies 1.3. Comparison and Analyses of Results across Studies Appendix 1 2. Summary of Clinical Pharmacology Studies 2.1. Background and Overview 2.2. Summary of Results of Individual Studies 2.3. Comparison and Analyses of Results across Studies 2.4. Special Studies Appendix 2 3. Summary of Clinical Efficacy 3.1. Background and Overview of Clinical Efficacy 3.2. Summary of Results of Individual Studies	Applicant Company/Manufacturer (For whole Part IV: Clinical Document)

3.3. Comparison and Analyses of Results across Studies 3.3.1. Study Populations 3.3.2. Comparison of Efficacy Results of all Studies 3.3.3. Comparison of Results in Sub-populations 3.4. Analysis of Clinical Information Relevant to Dosing Recommendations 3.5. Persistence of Efficacy and/or Tolerance Effects Appendix 3 4. Summary of Clinical Safety 4.1. Exposure to the Drug 4.1.1. Overall Safety Evaluation Plan and Narratives of Safety Studies 4.1.2. Overall extent of Exposure 4.1.3. Demographic and Other Characteristics of Study Population 4.2. Adverse Events 4.2.1. Analysis of Adverse Events 4.2.1.1. Common Adverse Events 4.2.1.2. Deaths 4.2.1.3. Other Serious Adverse Events 4.2.1.4. Other Significant Adverse Events 4.2.1.5. Analysis of Adverse Events by Organ System or Syndrome 4.2.2. Narratives 4.3. Clinical Laboratory Evaluations 4.4. Vital Signs, Physical Findings, and Other Observations Related to Safety 4.5. Safety in Special Groups and Situations 4.5.1. Patient Groups 4.5.2. Drug Interactions 4.5.3. Use in Pregnancy and Lactation 4.5.4. Overdose 4.5.5. Drug Abuse 4.5.6. Withdrawal and Rebound 4.5.7. Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability 4.6. Post-Marketing Data Appendix 4 5. Synopses of Individual Studies Sec. D Tabular Listing of All Clinical Studies Sec. E Clinical Study Reports (if applicable) 1. Reports of Biopharmaceutic Studies 1.3. In vitro-In vivo Correlation Study Reports 1.4. Reports of Bioanalytical and Analytical Methods for Human Studies 2. Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials	

2.1. Plasma Protein Binding Study Reports 2.2. Reports of Hepatic Metabolism and Drug Interaction Studies 2.3. Reports of Studies Using Other Human Biomaterials 3. Reports of Human Pharmacokinetic (PK) Studies 3.1. Healthy Subject PK and Initial Tolerability Study Reports 3.2. Patient PK and Initial Tolerability Study Reports 3.3. Population PK Study Reports 4. Reports of Human Pharmacodynamic (PD) Studies 4.1. Healthy Subject PD and PK/PD Study Reports 4.2. Patient PD and PK/PD Study Reports 5. Reports of Efficacy and Safety Studies 5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2. Study Reports of Uncontrolled Clinical Studies 5.3. Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses 5.4. Other Clinical Study Reports 6. Reports of Post-Marketing Experience 7. Case Report Forms and Individual Patient Listing Sec. F List of Key Literature References Additional Requirements: 1. For MR, Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020]	Applicant Company/Manufacturer

CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE REGISTRATION OF SIMILAR BIOTHERAPEUTIC PRODUCTS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
AO No. 47-a s.2001 Rules and Regulations on the Registration, including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biological Products A.O. No.-2014-0016 Adoption of the World Health Organization “Guidelines on Evaluation of Similar Biotherapeutic Products (SBPs)” for the Registration of Biosimilar Products	Applicant Company
ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information	Applicant Company
Sec. A Introduction	Applicant Company

Sec. B Overall ASEAN Common Technical Dossier Table of Contents	Applicant Company
Sec. C Guidance on the Administrative Data and Product Information	Applicant Company
Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) Letter of Authorization (where applicable)	FDA Website Applicant Company/ Manufacturer
Certifications For contract manufacturing:	
License of pharmaceutical industries and contract manufacturer Contract manufacturing agreement GMP certificate of contract manufacturer	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For manufacturing “under-license” License of pharmaceutical industries GMP certificate of the manufacturer Copy of “under-license” agreement	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For locally manufactured products: License of pharmaceutical industries GMP certificate (country specific)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information	Applicant Company /Manufacturer Applicant Company/ Manufacturer

Package Insert Summary of Product Characteristics (Product Data Sheet) Risk Management Plan (RMP) which shall include the following: RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems RMP Philippine-Specific Annex (as applicable) RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA Person/s responsible for production and control of the product (Name/s Position, Department, and sample of signature) Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities	Applicant Company/ Manufacturer (For whole Part II: Quality)

S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability	
Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control Information on the number system of the lots or batches System for the re-processing of the product in the event of rejection of the lot or batch by the manufacturer's QA/QC P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures	

P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses Lot to Lot Consistency from three (3) consecutive batches P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Head to Head Comparability	
Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1. General Consideration 2. Special Consideration	Applicant Company/Manufacturer (For whole Part III: Nonclinical Document)
Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Pharmacokinetic Studies 2. Pharmacodynamic Studies 3. Confirmatory Pharmacokinetic/Pharmacodynamic Studies 4. Efficacy Studies 5. Safety Studies 6. Immunogenicity 7. Extrapolation of Efficacy and Safety Data Additional Requirements: 1. For MRE/MR to Initial applications, proof of approval/clearance/extension of Post- Marketing Surveillance (PMS) Report and Post Approval Commitments as specified in the provided RMP. 2. For MR, Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020]	Applicant Company/Manufacturer (For whole Part IV: Clinical Document)

CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE REGISTRATION OF VETERINARY DRUGS, VACCINES AND BIOLOGICALS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Integrated Application Form	FDA Website
2. Proof of Payment	FDA Cashier
3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable	Applicant Company/Manufacturer
4. Unit Dose and Batch Formulation	Applicant Company/Manufacturer
5. Technical Specifications of all Raw Materials	Applicant Company/Manufacturer
6. Certificate of Analysis of active Raw Material(s)	Applicant Company/
a. From supplier of API	Manufacturer
b. From manufacturer of finished product	(Supplier of API & Manufacturer)
7. Technical Specifications of Finished Product	Applicant Company/ Manufacturer
8. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)	Applicant Company/ Manufacturer
9. Manufacturing Procedure, Production, Equipment, Sampling, In-process controls, and Master Packaging Procedure (including specification for container closure system)	Applicant Company/ Manufacturer
10. Assay and Other Test Procedures including Identity, Purity Tests, with Data Analysis, where applicable	Applicant Company/
11. Stability Studies	Manufacturer
12. Labeling Materials (facsimile labels)	Applicant Company/
13. Representative Sample (upon request of the evaluator)	Manufacturer
	Applicant Company/
Additional Requirements:	Manufacturer
1. For products in plastic container: Certificate of Analysis for Test of Migratable Substances/Leachability	
2. For imported products:	Applicant Company/
a. Certificate of Pharmaceutical Product (CPP)	Manufacturer
b. Foreign GMP Clearance	Applicant Company/
3. For new veterinary drugs:	Manufacturer
a. Pre-clinical studies	
b. Protocol for monitored release	

4. For fixed-dose combination: Rationale of the Combination	Applicant Company/ Manufacturer
5. Valid LTO (Importer/Manufacturer/Distributor/Trader)	Applicant Company/ Manufacturer FDA CDRR

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
. Secure a schedule of appointment / submission to FDAC -mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1.1 Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
	1.2 Pre-assesses the completeness of the application and verifies the registration pathway of the application if indeed for verification review. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR Pre-assessor

2. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.bizPortal Sends proof of payment to the FDAC.	2.1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC *Personnel*
	2.2 Receives the application from FDAC and encodes/updates the database.	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3 Decks/Assigns the application to the assigned evaluator of the Registration Section. For human vaccines and biologicals, determines if the application is MR and refers the RMP and PMS Protocol (if any) to the Clinical Research Section (CRS) for evaluation. For human drug products, simultaneously decks the RMP and PMS Protocol (if any) to CRS for evaluation.	None	1 working day	CDRR *Director* CDRR-CRR
	2.4 Evaluates the application according to requirements and prescribed standards For human vaccines, toxoids and immunoglobulins, Summary Lot Protocol shall be referred to CSL.	None	16 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/III (Senior Evaluator)*

3. If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation. *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None		*FDRO I/II/III*
	2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	5 working days	FDRO III
	3 Prepares the final output document (CPR /LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR For Dangerous Drugs, prepares a letter/notification to PDEA for its recommendation on the application particularly on the formulation and labeling	None	1 working day	FDRO I/II/III
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None		FDRO III
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	1 working day	FDRO IV (Supervisor)

	Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	1 working day	LRD Chief
	3.7 Signs and approves the final decision	None	1 working day	CDRR Director
	3.8 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	3.9 Scans, barcodes the final output document (CPR/LOD/Letter); and endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel
4. Receives the CPR/LOD/Letter	4. Releases the CPR/LOD/Letter to the client	None	1 working day	AFS - Releasing Section Personnel
(Service is covered under FDA-Circular-No.2022-004).		**TOTAL:**	**30 working days**	

20.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR OVER-THE-COUNTER DRUGS AND HOUSEHOLD REMEDY DRUG PRODUCTS (INITIAL)

The issuance of a Certificate of Product Registration is granted to Marketing Authorization Holder of Over -the-Counter Drugs and Household Remedy preparations which meets the standards for Quality, Safety and Efficacy/Claimed Benefit of their product based on the provided documentation. It is a marketing approval that the FDA grants for the sale and distribution of such product in the country.

Center/Office/Division	**:**	Center for Drug Regulation and Research
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B – Government-to-Businesses
Who May Avail	**:**	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	**:**	**Initial** Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2/5-year CPR validity (Based on Bureau Circular No. 5 s.1997). **2 year-validity:** Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF **5 year-validity:** Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF OVER-THE-COUNTER DRUGS AND HOUSEHOLD REMEDIES	
1. Notarized Integrated Application Form (in excel and in pdf format)	FDA Website
2. Proof of payment	FDA Cashier
3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable	Applicant Company /Manufacturer
4. Unit Dose and Batch Formulation	Applicant Company /Manufacturer
5. Technical Specifications of all Raw Materials	Applicant Company/ Manufacturer

6. Certificate of Analysis of Active Raw Material(s)	Applicant Company /Manufacturer
a. From supplier of API	(Supplier of API & Manufacturer)
b. From manufacturer of finished product	Applicant Company/ Manufacturer
7. Technical Specifications of Finished Product	Applicant Company /Manufacturer
8. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)	Applicant Company /Manufacturer
9. Manufacturing Procedure, Production, Equipment, Sampling, In-process controls, and Master Packaging Procedure (including specification for container closure system)	
10. Assay and Other Test Procedures including Identity, Purity Tests, with Data Analysis, where applicable	
11. Stability Studies	
12. Labeling Materials (facsimile labels)	
13. Representative Samples (w/ COA) may be submitted at a later date, e.g. when the application has already been decked as indicated in the Document Tracking System (upon request of the evaluator).	
Additional Requirements:	
14. For products in plastic container: Certificate of Analysis for Test of Migratable Substances/ Leachability	
15. For imported products:	
a. Certificate of Pharmaceutical Product (CPP) or Certificate of Free Sale	
b. Foreign GMP Clearance	
16. Valid LTO (Importer/Manufacturer/Distributor/Trader)	FDA CDRR (Applicant Company)

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Secure a schedule of appointment / submission to FDAC	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*

2. E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*
3. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.BizPortal Sends proof of payment to the FDAC.	1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC *Personnel*
	3.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	3.3 Queuing time of application before decking to evaluators	None	20 working days	CDRR-CRR Unit *Personnel*
	3.4 Decks/Assigns the application to the assigned evaluator	None	1 working day	LRD *Chief*
	3.5 Evaluates the application according to requirements and prescribed standards	None	50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior*

				Evaluator)/ FDRO III (Senior Evaluator)
4. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD)when the application does not merit an Approval recommendation For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	1 working day	*FDRO I/II/III*
	4.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	40 working days	*FDRO III*
	4.3 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None	1 working day	*FDRO I/II*
	4.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	*FDRO III*

	4.5 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day (per batch of applications)	*FDRO IV (Supervisor)*
	4.6 Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	1 working day (per batch of applications)	*LRD Chief*
	4.7 Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	4.8 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*
	4.9 Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	*FDA Records Personnel*
5. Receives the CPR/LOD/letter	5. Releases the CPR/LOD/letter to the client	None	1 working day	*AFS Releasing Section Personnel*
(Serviced is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13, and Republic Act No. 7394 Article 31 wherein a timeline of 120 working days was proposed instead of 180 working days).		**TOTAL:**	**120 working days**	

21.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR PHARMACEUTICAL PRODUCTS (ELECTRONIC AUTOMATIC RENEWAL) [e-AR]

This Certificate of Product Registration is granted by the FDA to the Marketing Authorization Holder in order to continue marketing a specific product in the country provided that the conditions for Automatic Renewal stipulated in Book II Article 1 Section 3.B (2) of the IRR of RA 9711 have been fulfilled.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Drug Products for Human and Veterinary Use
Fees to be Paid	:	Administrative-Order-No.-50-2001 Branded: Php 10,000.00 + 1% LRF Unbranded: Php 7,500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Checklist of Requirements for Eligibility to Automatic Renewal Registration Implementing Rules and Regulations (IRR) of Republic Act No. 9711 There shall be automatic renewal of the Certificate of Product Registration (CPR) when the following conditions are satisfied: The application is filed before the expiration date of the registration; The prescribed renewal fee is paid upon filing of the application; and A sworn statement indicating no change or variation whatsoever in the product is attached to the application.	Applicant Company

References: Republic Act 9711 – Food and Drug Administration Act of 2009 The Rules and Regulations Implementing Republic Act No. 9711 – The Food and Drug Administration Act of 2009 FDA-Advisory-No.2021-0999 - Implementation of The Food and Drug Administration (FDA) eServices Portal System for Automatic Renewal (AR) Applications for Drug Products.	

APPLICANT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1.1.Access the online application portal through (http://eservices.fda.gov.ph) “Applications“		None	0	Applicant
1.2.Select “Certificate of Product Registration” and select “Drug”. Select the classification of the product to be renewed then select “Automatic Renewal Registration for Regular CPR & PCPR” or “Automatic Renewal Registration for CLIDP” whichever is applicable.		None	0	Applicant
1.3.Click “I have read and accepted the terms and conditions stated on this form”. Declining the declaration shall mean forfeiture of the opportunity to proceed with the application		None	0	Applicant
1.4.Fill-out all the information needed and upload the required documents as indicated on the Checklist of Requirements		None	0	Applicant

1.5.After providing the required information, applicants can review the duly filled out form in the Self-Assessment Review. By agreeing to the Terms and Conditions, the applicants confirm the correctness of information given. (Pre-assessment)	1.Assess the completeness and veracity of documents submitted. If complete, Order of Payment will be generated and will be given to the applicant thru the eService and email notification. If incomplete, the application will not be accepted. A pre-assessment result indicating the grounds for non-acceptance shall be sent by the eServices to the email address of the applicant.	None	0	CDRR Pre-assessor
2.1.Print the Order of Payment form with Reference Number sent through the declared e-mail address		None	0	Applicant
2.2.Pay the assessed fee as per the system generated Order of Payment Form through payment channels prescribed by FDA (e.g. BANCNET, LANDBANK ONCOLL, Landbank Link.bizPortal).	2.1.FDA Cashier receives the payment for FDAC Cashier payments/ receives notification of payment for bank payments;	Branded: Php 10,000.00 + 1% LRF Unbranded: Php 7,500.00 + 1% LRF	0	FDA Cashier

	2.2 Post payment in eServices for confirmed payments. This will prompt automatic decking of application to respective Center Note: Acknowledgement receipt will automatically be sent to the applicant once payment is posted and will signify the start of processing time of the application.	None	1 working day	FDA Cashier
3.Receives acknowledgement receipt through email	3.1 The assigned Evaluator reviews for the correctness of the information and documents provided and recommends approval / disapproval of the application which will be forwarded to QA.	None	9 working days	CDRR Evaluator
	3.2 QA reviews the recommendation and forwards the application to the CDRR Director for final decision.	None	5 working days	FDRO IV (Supervisor)

	3.3 Final Decision Once the CDRR Director approves/disapproves the application, the system automatically generates the CPR/ Letter of Disapproval and sends it to the applicant's registered e-mail address for printing.	None	5 working days	CDRR Director
4. Receive notification and link of CPR/Letter of Disapproval for printing.		None	0	Applicant
	TOTAL:		20. **Working days**	

22.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR PHARMACEUTICAL PRODUCTS (NEW CHEMICAL ENTITIES/MONITORED RELEASE)

This Certificate of Product Registration is granted to Marketing Authorization Holders of chemical or synthetic drug products classified under Monitored Release either as a New Drug/New Chemical Entity or a pharmaceutical/therapeutic innovation of a Tried and Tested/Established Drug (i.e., involving use for a new indication, a new mode of administration, a new dosage form, and/or a new fixed-dose combination of two or more active ingredients) upon compliance to the agency-prescribed Quality, Safety, Efficacy standards. It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Administrative-Order-No.-50-2001 FDA-Advisory-No.2021-2904 New Drug/Monitored Release (for all types of products): Php Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + Php 2,500.00* [Post-Marketing Surveillance (i.e., Local Phase IV Clinical Trial) Protocol Review] + 1% LRF *If additional PV activity(ies) are necessary based on FDA Circular No. 2021-020

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR NEW CHEMICAL ENTITIES/MONITORED-RELEASE REGISTRATION	
ASEAN Common Technical Dossier Part I: Administrative Data and Product Information Sec. A Introduction Sec. B Overall ASEAN Common Technical Dossier	 Applicant Company/Manufacturer (For the whole Part I)

Table of Contents Sec. C Guidance on the Administrative Data and Product Information Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) Letter of Authorization (where applicable) Certifications For contract manufacturing: License of pharmaceutical industries and contract manufacturer Contract manufacturing agreement GMP certificate of contract manufacturer For manufacturing “under-license” License of pharmaceutical industries GMP certificate of the manufacturer Copy of “under-license” agreement For locally manufactured products: License of pharmaceutical industries GMP certificate (country specific) For imported products License of pharmaceutical industries/importer/wholesaler (country specific) Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format Foreign GMP Clearance Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information Package Insert Summary of Product Characteristics (Product Data Sheet) Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary	FDA Website & Cashier

Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product	Applicant Company/Manufacturer (For the whole Part II: Quality)

P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Product Interchangeability/Equivalence Evidence (if applicable) Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1. General Aspect 2. Content and Structural Format Sec. C Nonclinical Written and Tabulated Summaries	

1. Nonclinical Written Summaries 1.1. Introduction 1.2. General Presentation Issues 2. Content of Nonclinical Written and Tabulated Summaries 2.1. Pharmacology 2.1.1. Written Summary 2.1.1.1. Primary Pharmacodynamics 2.1.1.2. Secondary Pharmacodynamics 2.1.1.3. Safety Pharmacology 2.1.1.4. Pharmacodynamic Drug Interactions 2.1.2. Tabulated Summary 2.2. Pharmacokinetics 2.2.1. Written Summary 2.2.1.1. Absorption 2.2.1.2. Distribution 2.2.1.3. Metabolism 2.2.1.4. Excretion 2.2.1.5. Pharmacokinetic Drug Interaction (Nonclinical) 2.2.2. Tabulated Summary 2.3. Toxicology 2.3.1. Written Summary 2.3.1.1. Single-Dose Toxicity 2.3.1.2. Repeat-Dose Toxicity 2.3.1.3. Genotoxicity 2.3.1.4. Carcinogenicity 2.3.1.5. Reproductive and Developmental Toxicity 2.3.1.5.1. Fertility and Early Embryonic Development 2.3.1.5.2. Embryo-Foetal Development 2.3.1.5.3. Prenatal and Postnatal Development 2.3.1.6. Local Tolerance 2.3.1.7. Other Toxicity Studies (if available) 2.3.2. Tabulated Summary 3. Nonclinical Tabulated Summaries Sec. D Nonclinical Study Reports	Applicant Company/Manufacturer (For the whole Part III: Nonclinical Document)

1. Table of Contents 2. Pharmacology 2.1. Written Study Reports 2.1.1. Primary Pharmacodynamics 2.1.2. Secondary Pharmacodynamics 2.1.3. Safety Pharmacology 2.1.4. Pharmacodynamic Drug Interactions 3. Pharmacokinetics 3.1. Written Study Reports 3.1.1. Analytical Methods and Validation Reports 3.1.2. Absorption 3.1.3. Distribution 3.1.4. Metabolism 3.1.5. Excretion 3.1.6. Pharmacokinetic Drug Interaction (Nonclinical) 3.1.7. Other Pharmacokinetic Studies 4. Toxicology 4.1. Written Study Reports 4.1.1. Single-Dose Toxicity 4.1.2. Repeat-Dose Toxicity 4.1.3. Genotoxicity 4.1.3.1. In vitro Reports 4.1.3.2. In vivo Reports 4.1.4. Carcinogenicity 4.1.4.1. Long Term Studies 4.1.4.2. Short- or Medium-Term Studies 4.1.4.3. Other Studies 4.1.5. Reproductive and Developmental Toxicity 4.1.5.1. Fertility and Early Embryonic Development 4.1.5.2. Embryo-Fetal Development 4.1.5.3. Prenatal and Postnatal Development 4.1.5.4. Studies in which the Offspring are Dosed and/or further Evaluated 4.1.6. Local Tolerance 4.1.7. Other Toxicity Studies (if available) 4.1.7.1. Antigenicity	Applicant Company/Manufacturer (For the whole Part IV: Clinical Document)

4.1.7.2. Immunotoxicity 4.1.7.3. Dependence 4.1.7.4. Metabolites 4.1.7.5. Impurities 4.1.7.6. Other Sec. E List of Key Literature References Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Product Development Rationale 2. Overview of Biopharmaceutics 3. Overview of Clinical Pharmacology 4. Overview of Efficacy 5. Overview of Safety 6. Benefits and Risks Conclusions Sec. C Clinical Summary 1. Summary of Biopharmaceutic Studies and Associated Analytical Methods 1.1. Background and Overview 1.2. Summary of Results of Individual Studies 1.3. Comparison and Analyses of Results across Studies Appendix 1 2. Summary of Clinical Pharmacology Studies 2.1. Background and Overview 2.2. Summary of Results of Individual Studies 2.3. Comparison and Analyses of Results across Studies 2.4. Special Studies Appendix 2 3. Summary of Clinical Efficacy 3.1. Background and Overview of Clinical Efficacy 3.2. Summary of Results of Individual Studies 3.3. Comparison and Analyses of Results across Studies 3.3.1. Study Populations	

3.3.2. Comparison of Efficacy Results of all Studies 3.3.3. Comparison of Results in Sub-populations 3.4. Analysis of Clinical Information Relevant to Dosing Recommendations 3.5. Persistence of Efficacy and/or Tolerance Effects Appendix 3 4. Summary of Clinical Safety 4.1. Exposure to the Drug 4.1.1. Overall Safety Evaluation Plan and Narratives of Safety Studies 4.1.2. Overall extent of Exposure 4.1.3. Demographic and Other Characteristics of Study Population 4.2. Adverse Events 4.2.1. Analysis of Adverse Events 4.2.1.1. Common Adverse Events 4.2.1.2. Deaths 4.2.1.3. Other Serious Adverse Events 4.2.1.4. Other Significant Adverse Events 4.2.1.5. Analysis of Adverse Events by Organ System or Syndrome 4.2.2. Narratives 4.3. Clinical Laboratory Evaluations 4.4. Vital Signs, Physical Findings, and Other Observations Related to Safety 4.5. Safety in Special Groups and Situations 4.5.1. Patient Groups 4.5.2. Drug Interactions 4.5.3. Use in Pregnancy and Lactation 4.5.4. Overdose 4.5.5. Drug Abuse 4.5.6. Withdrawal and Rebound 4.5.7. Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability 4.6. Post-Marketing Data Appendix 4 5. Synopses of Individual Studies Sec. D Tabular Listing of All Clinical Studies Sec. E Clinical Study Reports (if applicable) 1. Reports of Biopharmaceutic Studies 1.1. Bioavailability (BA) Study Reports	

1.2. Comparative BA or Bioequivalence (BE) Study Reports 1.3. In vitro-In vivo Correlation Study Reports 1.4. Reports of Bioanalytical and Analytical Methods for Human Studies 2. Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials 2.1. Plasma Protein Binding Study Reports 2.2. Reports of Hepatic Metabolism and Drug Interaction Studies 2.3. Reports of Studies Using Other Human Biomaterials 3. Reports of Human Pharmacokinetic (PK) Studies 3.1. Healthy Subject PK and Initial Tolerability Study Reports 3.2. Patient PK and Initial Tolerability Study Reports 3.3. Population PK Study Reports 4. Reports of Human Pharmacodynamic (PD) Studies 4.1. Healthy Subject PD and PK/PD Study Reports 4.2. Patient PD and PK/PD Study Reports 5. Reports of Efficacy and Safety Studies 5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2. Study Reports of Uncontrolled Clinical Studies 5.3. Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses 5.4. Other Clinical Study Reports 6. Reports of Post-Marketing Experience 7. Case Report Forms and Individual Patient Listing Sec. F List of Key Literature References Additional Requirements: 1. Risk Management Plan – which shall include the following: RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems RMP Philippine-Specific Annex (as applicable) RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted 2. Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020]	

Note: • ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1.1 Sends the scheduled date of submission for pre-assessment	None	0	FDAC Personnel
	1.2 Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None	0	CDRR Pre-assessor

2. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.bizPortal Sends proof of payment to the FDAC.	2.1 Endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/ Landbank FDAC Personnel
	2.2 Receives the application from FDAC and encodes/updates the database.	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3 Queuing time of the application before decking to evaluators of Registration Section and Clinical Research Section.	None	20 working days	CDRR-CRR Unit Personnel
	2.4 Decks/Assigns the application to the assigned evaluators of Registration Section and Clinical Research Section.	None	1 working day	CDRR Director
	2.5 Evaluates the application according to requirements and prescribed standards	None	51 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)/ Medical Specialist II

3. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	a. Clinical Research Section (Safety and Efficacy evaluator) 3.1 Prepares a worksheet with Recommendations on the evaluated safety and efficacy dossier, RMP, and PMS protocol (if any), then forwards this to the Quality evaluator of the Registration Section. b. Registration Section (Quality evaluator) 3.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS) Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS) *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None		FDRO I/II/III/ Medical Specialist II/III
	3.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator (for Quality evaluation).	None	40 working days	FDRO III

	3.3 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR For Dangerous Drugs, prepares a letter/notification to PDEA for the approval of the application	None	1 working day	FDRO I/II
	3.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III
	3.5 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	1 working day (per batch of applications)	FDRO IV (Supervisor)
	3.6 Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	1 working day (per batch of applications)	LRD Chief
	3.7 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	3.8 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	3.9 Scans, barcodes the final output document (CPR/LOD/Letter); and endorses the final output document to the FDAC Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel

4. Receives the CPR/LOD/letter	4. Releases the CPR/LOD/letter to the client	None	1 working day	AFS - Releasing Section Personnel
(Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13 and Republic Act No. 7394 Article 31).		TOTAL:	120 working days	

RENEWAL & POST-APPROVAL CHANGES (PAC)

23.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF REPRODUCTIVE HEALTH (RH) PRODUCTS (AUTOMATIC RENEWAL) [MANUAL SUBMISSION]

This Certificate of Product Registration is granted by the FDA to the Marketing Authorization Holder in order to continue marketing a specific product in the country provided that the conditions for Automatic Renewal stipulated in Book II Article 1 Section 3.B (2) of the IRR of RA 9711 have been fulfilled.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Reproductive Health Products
Fees to be Paid	:	Administrative-Order-No.-50-2001 and AO No.-2005-0031 Branded: Php 10,000.00 + 1% LRF Unbranded: Php 7,500.00 + 1% LRF

CKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR ELIGIBILITY TO AUTOMATIC RENEWAL REGISTRATION Implementing Rules and Regulations (IRR) of Republic Act No. 9711 There shall be automatic renewal of the CPR when the following conditions are satisfied: 1.The application is filed before the expiration date of the registration; 2.The prescribed renewal fee is paid upon filing of the application; and 3. A sworn statement indicating no change or variation whatsoever in the product is attached to the application.	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secures 14-digit Document Tracking Number (DTN) and schedule of appointment/submission to FDAC.	1. Sends the Document Tracking Log (DTL) bearing the DTN and schedule of submission for pre-assessment	None		FDAC *Personnel*
2. E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*

3. For accepted applications, pays the required fee through any of the following: • BANCNET •Landbank OnColl •Landbank Link.BizPortal Sends proof of payment to the FDAC.	3.1 Endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC *Personnel*
	3.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit *Personnel*
	3.3 Decks/Assigns the application to the assigned evaluator	None	1 working day	LRD *Chief*/ CRR *Personnel*

	3.4 Evaluates the application according to requirements and prescribed standards	None	9 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*
	3.5 Prepares draft Certificate of Product Registration (CPR) issuance when the approval of the application is recommended Prepares draft Letter of Disapproval (LOD) when the application does not merit an Approval recommendation	None	1 working day	*FDRO I/II*
	3.6 Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	3 working days	*FDRO III*
	3.7 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None		*FDRO II*
	3.8 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None		*FDRO III*
	3.9 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day (per batch of applications)	*FDRO IV (Supervisor)*

	3.10 Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	1 working day (per batch of applications)	*LRD Chief*
	3.11 Recommends the final decision by affixing signature when approval of the application is recommended.	None	1 working day (per batch of applications)	*CDRR Director*
	3.12 Signs and approves the final decision	None	1 working day (per batch of applications)	FDA *Director General*
	3.13 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*
	3.14 Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	*FDA Records Personnel*
4. Receives the CPR/LOD/letter	4. Releases the CPR/LOD/letter to the client	None	1 working day	*AFS Releasing Section Personnel*
	TOTAL:		**20 WORKING DAYS**	

24.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR REPRODUCTIVE HEALTH PRODUCTS (NEW CHEMICAL ENTITIES AND INITIAL)

This Certificate of Product Registration is granted to Marketing Authorization Holders of reproductive health products upon compliance to Quality, Safety, Efficacy standards. It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Administrative-Order-No.-50-2001 **Initial Branded:** Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF **Unbranded:** Php 2,000.00/year + 1% LRF The applicant may apply for 2 or 5-year CPR validity (Based on Bureau Circular No. 5 s. 1997). **2 year-validity:** Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF **5 year-validity:** Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF **New Drug/Monitored Release:** Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + Php 2,500.00* [Post-Marketing Surveillance (i.e., Local Phase IV Clinical Trial) Protocol Review] + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
ASEAN Common Technical Dossier	
Part I: Administrative Data and Product Information	Applicant Company
Sec. A Introduction	Applicant Company
Sec. B Overall ASEAN Common Technical Dossier Table of Contents	Applicant Company
Sec. C Guidance on the Administrative Data and Product Information	Applicant Company
Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) Letter of Authorization (where applicable)	FDA Website Applicant Company/ Manufacturer
Certifications For contract manufacturing:	
a. License of pharmaceutical industries and contract manufacturer b. Contract manufacturing agreement c. GMP certificate of contract manufacturer	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For manufacturing “under-license” a. License of pharmaceutical industries b. GMP certificate of the manufacturer c. Copy of “under-license” agreement	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer

For locally manufactured products: a. License of pharmaceutical industries b. GMP certificate (country specific)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For imported products a. License of pharmaceutical industries/importer/wholesaler (country specific) b. Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format c. Foreign GMP Clearance	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Site Master File Labeling Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) Product Information a. Package Insert b. Summary of Product Characteristics (Product Data Sheet)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula	Applicant Company/Manufacturer (For whole Part II: Quality)

S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability	
Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility	

P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Product Interchangeability/Equivalence Evidence (if applicable)	
ADDITIONAL REQUIREMENTS FOR NEW CHEMICAL ENTITIES/MONITORED RELEASE REGISTRATION:	
Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1. General Aspect 2. Content and Structural Format Sec. C Nonclinical Written and Tabulated Summaries 1. Nonclinical Written Summaries 1.1. Introduction 1.2. General Presentation Issues 2.Content of Nonclinical Written and Tabulated Summaries 2.1.Pharmacology 2.1.1.Written Summary	Applicant Company/Manufacturer (For whole Part III: Nonclinical Document)

2.1.1.1.Primary Pharmacodynamics 2.1.1.2.Secondary Pharmacodynamics 2.1.1.3.Safety Pharmacology 2.1.1.4.Pharmacodynamic Drug Interactions 2.1.2. Tabulated Summary 2.2.Pharmacokinetics 2.2.1.Written Summary 2.2.1.1.Absorption 2.2.1.2.Distribution 2.2.1.3.Metabolism 2.2.1.4.Excretion 2.2.1.5.Pharmacokinetic Drug Interaction (Nonclinical) 2.2.2. Tabulated Summary 2.3.Toxicology 2.3.1.Written Summary 2.3.1.1.Single-Dose Toxicity 2.3.1.2.Repeat-Dose Toxicity 2.3.1.3.Genotoxicity 2.3.1.4.Carcinogenicity 2.3.1.5.Reproductive and Developmental Toxicity 2.3.1.5.1.Fertility and Early Embryonic Development 2.3.1.5.2.Embryo-Foetal Development 2.3.1.5.3.Prenatal and Postnatal Development76 2.3.1.6.Local Tolerance 2.3.1.7.Other Toxicity Studies (if available) 2.3.2. Tabulated Summary 3.Nonclinical Tabulated Summaries Sec. D Nonclinical Study Reports 1. Table of Contents 2. Pharmacology 2.1. Written Study Reports 2.1.1. Primary Pharmacodynamics 2.1.2. Secondary Pharmacodynamics 2.1.3. Safety Pharmacology 2.1.4. Pharmacodynamic Drug Interactions	

3. Pharmacokinetics 3.1. Written Study Reports 3.1.1. Analytical Methods and Validation Reports 3.1.2. Absorption 3.1.3. Distribution 3.1.4. Metabolism 3.1.5. Excretion 3.1.6. Pharmacokinetic Drug Interaction (Nonclinical) 3.1.7. Other Pharmacokinetic Studies 4. Toxicology 4.1. Written Study Reports 4.1.1. Single-Dose Toxicity 4.1.2. Repeat-Dose Toxicity 4.1.3. Genotoxicity 4.1.4.3. Other Studies 4.1.5. Reproductive and Developmental Toxicity 4.1.5.1. Fertility and Early Embryonic Development 4.1.5.2. Embryo-Foetal Development 4.1.5.3. Prenatal and Postnatal Development 4.1.5.4. Studies in which the Offspring are Dosed and/or further Evaluated77 4.1.6. Local Tolerance 4.1.7. Other Toxicity Studies (if available) 4.1.7.1. Antigenicity 4.1.7.2. Immunotoxicity 4.1.7.3. Dependence 4.1.7.4. Metabolites 4.1.7.5. Impurities 4.1.7.6. Other Sec. E List of Key Literature References	
Part IV: Clinical Document Sec. A Table of Contents Sec. B Clinical Overview 1. Product Development Rationale 2. Overview of Biopharmaceutics 3. Overview of Clinical Pharmacology 4. Overview of Efficacy 5. Overview of Safety	Applicant Company/Manufacturer (For whole Part IV: Clinical Document)

6. Benefits and Risks Conclusions Sec. C Clinical Summary 1. Summary of Biopharmaceutic Studies and Associated Analytical Methods 1.1. Background and Overview 1.2. Summary of Results of Individual Studies 1.3. Comparison and Analyses of Results across Studies Appendix 1 2. Summary of Clinical Pharmacology Studies 2.1. Background and Overview 2.2. Summary of Results of Individual Studies 2.3. Comparison and Analyses of Results across Studies 2.4. Special Studies Appendix 2 3. Summary of Clinical Efficacy 3.1. Background and Overview of Clinical Efficacy 3.2. Summary of Results of Individual Studies 3.3. Comparison and Analyses of Results across Studies 3.3.1. Study Populations 3.3.2. Comparison of Efficacy Results of all Studies 3.3.3. Comparison of Results in Sub-populations 3.4. Analysis of Clinical Information Relevant to Dosing Recommendations 3.5. Persistence of Efficacy and/or Tolerance Effects 2.3. Reports of Studies Using Other Human Biomaterials 3. Reports of Human Pharmacokinetic (PK) Studies 3.1. Healthy Subject PK and Initial Tolerability Study Reports 3.2. Patient PK and Initial Tolerability Study Reports 3.3. Population PK Study Reports 4. Reports of Human Pharmacodynamic (PD) Studies 4.1. Healthy Subject PD and PK/PD Study Reports 4.2. Patient PD and PK/PD Study Reports 5. Reports of Efficacy and Safety Studies 5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2. Study Reports of Uncontrolled Clinical Studies 5.3. Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses	

5.4. Other Clinical Study Reports 6. Reports of Post-Marketing Experience 7. Case Report Forms and Individual Patient Listing Sec. F List of Key Literature References	
Additional Requirements: 1. Risk Management Plan – which shall include the following: a. RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems b. RMP Philippine-Specific Annex (as applicable) c. RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) 2. MRE to Initial: Periodic Safety Update Report (PSUR), or proof of prior submission 3. For MR, Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA-Circular-No.2021-020] 4. Scientific Evidence/s (*including but not limited to meta analyses, systematic reviews, national clinical practice guidelines where available, and recommendations of international organizations*) on the Non-Abortifacient Property based on the indication/use, at the dose/usage of the product*** Note: • ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions • Petitions, Position papers and/or Scientific Evidence on the Non-Abortifacient Property of the drug product from interested parties (if available) ***As per Revised Implementing Rules and Regulations of Republic Act No. 10354, Rule 7, Sec. 7.04 (C).	Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer (FDA) Applicant Company/ Manufacturer

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1.1 Sends the scheduled date of submission for pre-assessment	None	0	FDAC Personnel

	1.2 Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN)	None	0	CDRR Personnel
2. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.bizPortal Sends proof of payment to the FDAC.	.1 Endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/ Landbank /FDAC *Personnel*
	2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3 Queuing time of the application before decking to evaluators	None	20 working days	CDRR-CRR Unit Personnel

	2.4 Decks/Assigns the application to the assigned evaluator *For MR applications, simultaneous decking to registration evaluator and CRS evaluator *For Initial applications, the registration evaluator shall endorse the submitted non-abortifacient evidence to the CRS.	None	1 working day	LRD Chief
	2.5 Evaluates the application according to the requirements and prescribed standards	None	21 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
3. If an electronic notice of deficiencies (ENOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 For MR applications: a. Clinical Research Section (Safety and Efficacy evaluator) Prepares a worksheet with Recommendations on the evaluated safety and efficacy dossier, RMP, and PMS protocol (if any), then forwards this to the Quality evaluator of the Registration Section. b. Registration Section (Quality evaluator) Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS) Prepares a worksheet and Letter of	None		FDRO I/II/III/ Medical Specialist II/III

	Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS)			
	3.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator (for Quality evaluation).	None	10 working days	FDRO III
	3.3 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None	1 working day	FDRO I/II
	3.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III
	3.5 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	1 working day	FDRO IV (Supervisor)
	3.6 Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	1 working day	LRD Chief
	3.7 The assigned evaluator shall notify the TWG on RH product secretariat for applications which passed the QSE evaluation.	None	1 working day	FDRO I/II/TWG RH product secretariat

	3.8 Preparation of the FDA Advisory for the publication of submitted non-abortifacient evidence by the MAH/applicant as a notice for the start of submission of petitions, position papers and corresponding evidence of interested parties.		10 working days	TWG RH product secretariat
	3.9 Issues FDA Advisory on the publication of notice for the submission of petitions, position papers and corresponding evidence of interested parties.	None	10 working days	CDRR Director/Information and Communication Technology Management Division (ICTMD) Staff
4. Submits petitions, position papers and corresponding evidence from interested parties.	4.1 Receives documents related to the petitions, position papers and corresponding evidence of interested parties and forwards the aforementioned documents to the CRS and Registration Section.	None	1 working day	CRR personnel
	4.2 For new non-abortifacient evidence, forwards the endorsement letter and corresponding documents on the non-abortifacient property to the Independent Evidence Review Group (ERG) for review. For non-abortifacient evidence previously reviewed, proceed to item no. 4.4.	None	1 working day	FDRO I/II (CRS evaluator)/ Medical Specialist II/III

	4.3 Reviews and provides recommendation on whether the drug product is abortifacient or non-abortifacient, based on the submitted evidence for non-abortifacient from the applicant; petitions and/or comments from interested parties and available scientific evidence.	None	20 working days	External consultants
	4.4 Consolidates the assessment review of the ERG and prepares a summary of findings based on the submitted evidence for non-abortifacient from the applicant; petitions or comments from interested parties; and recommendations from external experts and forwards to the FDA TWG. In case of regulatory action/s with other National Regulatory Agency/ies (NRAs), conflicting evidence on non-abortifacient evidence, safety concern from the country of origin where the RH product is available or from Stringent Regulatory Agency (SRA), a Communication Letter shall be issued to the applicant company.	None	10 working days	FDRO I/II (CRS evaluator)/ Medical Specialist II/III
	4.5 Deliberates on the drug product based on the summary of findings forwarded by the CRS and makes the final recommendation and determines if the drug product is abortifacient or non-abortifacient.	None	1 working day	FDA TWG on RH products

	4.6 Drafts the resolution in accordance with the final recommendation of the TWG and forwards for review and comments of the TWG on RH Product Chairperson, Vice-Chairperson and Members.	None	1 working day	TWG RH product secretariat/ TWG RH Product Chairperson, Vice-Chairperson and Members
	4.7 Forwards the resolution to the Office of the Director General.	None	1 working day	CRR personnel
	4.8 Signs and approves the resolution. Forwards the signed copy of resolution to CDRR.	None	1 working day	Director General
	4.9 Prints the final output document (CPR) in accordance with the resolution (found that the product is non-abortifacient), affixes initial, and forwards it to the senior evaluator (FDRO III). If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR If non-compliant, prints the final output document (LOD).	None	1 working day	FDRO I/II/FDRO III
	4.10 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III
	4.11 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	FDRO IV (Supervisor)

	4.12 Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	1 working day	LRD Chief
	4.13 Recommends the final decision by affixing signature.	None	1 working day	CDRR Director
	4.14 Signs and approves the final decision (CPR/LOD).	None	1 working day	Director General
	4.15 Forwards the signed CPR or LOD to the CDRR-CRR	None	1 working day	ODG personnel
	4.16 Encodes/Updates the database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	4.17 Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel
5. Received the CPR/LOD/Letter	5 Releases the CPR/LOD/letter to the client	None	1 working day	AFS Releasing Section Personnel
(Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13		**TOTAL:**		**120 WORKING DAYS**

25.ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) FOR VETERINARY DRUGS AND PRODUCTS [INITIAL/MONITORED RELEASE (NEW CHEMICAL ENTITIES)]

This Certificate of Product Registration is granted to Marketing Authorization Holders of veterinary drugs and products upon compliance to Quality, Safety, Efficacy standards. It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	**:**	Center for Drug Regulation and Research
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B – Government-to-Businesses
Who May Avail	**:**	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Veterinary Drug and Products
Fees to be Paid	**:**	**Initial** Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF The applicant may apply for 2/5-year CPR validity. **2 year-validity:** Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF **5 year-validity:** Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF Monitored Release (New Chemical Entities): Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF VETERINARY DRUGS AND PRODUCTS 1. Notarized Integrated Application Form (in excel and in pdf format) 2. Proof of Payment	FDA Website FDA Cashier

3. Valid agreements between the manufacturer, trader, importer, distributor, where applicable	Applicant Company/ Manufacturer
4. Unit Dose and Batch Formulation	Applicant Company/ Manufacturer
5. Technical Specifications of all Raw Materials	Applicant Company/
6. Certificate of Analysis of active Raw Material(s)	Manufacturer
a. From supplier of API	Applicant Company/
b. From manufacturer of finished product	Manufacturer
7. Technical Specifications of Finished Product	(Supplier of API & Manufacture
8. Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample)	Applicant Company/
9. Manufacturing Procedure, Production, Equipment, Sampling, In-process controls, and Master Packaging Procedure (including specification for container closure system)	Manufacturer
10. Assay and Other Test Procedures including Identity, Purity Tests, with Data Analysis, where applicable	Applicant Company/ Manufacturer
11. Stability Studies	Applicant Company/
12. Labeling Materials (facsimile labels)	Manufacturer
13. Representative Sample (upon request of the evaluator)	Applicant Company/ Manufacturer
Additional Requirements:	Applicant Company/
1. For products in plastic container: Certificate of Analysis for Test of Migratable Substances/Leachability	Manufacturer
2. For imported products:	Applicant Company/
a. Certificate of Pharmaceutical Product (CPP)	Manufacturer
b. Foreign GMP Clearance	Applicant Company/
3. For new veterinary drugs:	Manufacturer
a. Pre-clinical studies	Applicant Company/
b. Protocol for monitored release	Manufacturer
4. For fixed-dose combination: Rationale of the Combination	Applicant Company/
5. Valid LTO (Importer/Manufacturer/Distributor/Trader)	Manufacturer
	FDA CDRR (Applicant Compan
	Applicant Company/ Manufacturer

	Applicant Company/ Manufacturer Applicant Company/ Manufacturer FDA CDRR
References: 1. DOH AO No. 67 s. 1989 - Revised Rules and Regulations on Registration of Pharmaceutical Products 2. DOH AO No. 111-A s. 1991 – Rules and Regulations on Registration of Veterinary Drugs and Products 3. BC No. 5 s. 1997 – Revised Checklist of Requirements and the 1997 Guidelines for the Registration of Pharmaceutical Products	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC	1. Sends the scheduled date of submission for pre-assessment	None	0	FDAC *Personnel*
E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None	0	CDRR *Personnel*

For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.BizPortal Sends proof of payment to the FDAC.	3.1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/Landbank FDAC *Personnel*
	3.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	3.3 Queuing time of the application before decking to evaluators	None	20 working days	CDRR-CRR Unit *Personnel*
	3.4 Decks/Assigns the application to the assigned evaluator	None	1 working day	LRD *Chief*
	3.5 Evaluates the application according to requirements and prescribed standards (Quality)	None	50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*
	3.6 Evaluates the application according to requirements and prescribed standards (Pre-clinical studies)	None		*FDRO III (Senior Evaluator)*

If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an Approval recommendation For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	1 working day	FDRO I/II/III
	4.2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	40 working days	FDRO III
	4.3 Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None	1 working day	FDRO I/II/III
	4.4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III
	4.5 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	FDRO IV (Supervisor)
	4.6 Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	1 working day (per batch of applications)	LRD Chief
	4.7 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director

	4.8 Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	4.9 Scans, barcodes, and emails the scanned copy of the final output document (CPR/LOD/Letter) to the client; and endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel
Receives the CPR/LOD/letter	5. Releases the CPR/LOD/letter to the client	None	1 working day	AFS Releasing Section Personnel
TOTAL: (Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13, and Republic Act No. 7394 Article 31.			working days	

26. ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF PHARMACEUTICAL PRODUCTS (REGULAR RENEWAL)

This Certificate of Product Registration is granted to Marketing Authorization Holders to continue the manufacture, distribution and sale of pharmaceutical products based on compliance with quality, safety and efficacy standards.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Administrative-Order-No.-50-2001 and AO No.-2005-0031 Branded: Php 10,000.00 + 1% LRF Unbranded: Php 7,500.00 + 1% LRF Additional (if with variation/s) Payment shall be based on FDA-Circular-No.-2014-008 , Annex D on a per product, per change basis. Surcharge (based on FDA-Circular-No.2011-004) Computation: 2 x (renewal registration fee) + 10%* (renewal registration fee) *If the renewal application is submitted on the: First month: 10% First day of the second month: 20% First day of the third month: 30% First day of the fourth month: 40% Any renewal application filed after the 4th month (120th day) shall be treated as an initial application.

CHECKLIST OF REQUIREMENTS	ERE TO SECURE
Documentary Requirements	
a. Copy of previously issued CPR	Applicant
b. Copy of LTO of manufacturer, importer, trader, and/or distributor (and renewal case number with proof of payment)	Company Applicant
Copy of Certificate of GMP Clearance for imported product (and/or initial or renewal application, whichever is applicable)	Company Applicant Company
CHECKLIST OF REQUIREMENTS FOR REGULAR RENEWAL REGISTRATION **FOR PRESCRIPTION PRODUCTS/ OVER-THE-COUNTER PREPARATIONS/ HOUSEHOLD REMEDIES** 1. Notarized Integrated Application Form (in excel and pdf format) 2. Proof of Payment . Unit Dose and Batch Formulation . Technical Specifications of Finished Product Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample) 6. Assay and Other Test Procedures including Assay with Data Analysis 7. Stability Studies . Labeling Materials (actual/commercial label) 9. Actual commercial samples (w/Certificate of Analysis) (upon request of the evaluator) If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.) Additional Requirements: 1. Post-marketing commitments (if any) 2 . For imported products: Foreign GMP Clearance For oral solid dosage forms, proof of interchangeability (Bioequivalence study or Biowaiver, whichever is applicable)	Applicant Company/FDA Website Applicant Company Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant

FOR BIOLOGICALS/SIMILAR BIOTHERAPEUTIC PRODUCTS 1. Integrated Application Form 2. Proof of Payment 3. Periodic Safety Update Report (PSUR) and Risk Management Plan (RMP) Certification that there were no changes during the 5-year period. If there were any, the summary changes made by the manufacturer for the 5-year period shall be incorporated 5.Labeling Materials (actual/commercial labels) 6.Actual commercial sample (w/Certificate of Analysis) (upon request of the evaluator) 7.If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.)	Applicant Company/FDA Website Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant
Additional Requirements: 1. Post-marketing commitments (if any) 2. For products qualifying for Generic Labeling Exemption (GLE): Request for GLE 3. For imported products: Foreign GMP Clearance 4. Summary Lot Protocol (for vaccines, toxoids and immunoglobulins) 5. List of Countries where the vaccine is already licensed and date of approval (for vaccines) 6. Adverse event following immunization report (Summary of Annual Reports) (for vaccines)	Applicant Company/Manufacturer Applicant Company/Manufacturer pplicant Company/Manufactur
FOR HERBAL MEDICINES/TRADITIONALLY USED HERBAL PRODUCTS 1. Notarized Integrated Application Form (in excel and pdf format) 2. Proof of Payment 3. Unit Dose and Batch Formulation 4. Technical Specifications of Finished Product Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample) 6. Stability Studies	Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufactur

7. Labeling Materials (actual/commercial label) 8. Actual commercial sample (w/Certificate of Analysis) (upon request of the evaluator) If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application)	Applicant Company/Manufacturer Applicant Company/Manufacturer
Additional Requirements: Post-marketing commitments (if any) For imported products: Foreign GMP Clearance	Applicant Company/Manufacturer
EDICAL GAS (OXYGEN) otarized Integrated Application Form (in excel and pdf format) oof of Payment Valid agreements between the manufacturer, trader, importer, distributor, where applicable Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample) Certificate of Analysis issued by CIGI for the product Manufacturing Procedure, Production Equipment, Sampling, In-process controls Labeling Materials (actual/commercial label) If with previously approved/acknowledged variation applications filed prior to CPR renewal: Copy of the approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.)	 Applicant Company/Manufacturer Applicant Company/Manufacturer pplicant Company/Manufacturer Applicant Company/Manufacturer Applicant
Additional Requirements: Post-marketing commitments (if any) For imported products: Foreign GMP Clearance	Applicant Company/Manufactu Applicant Company/Manufactu
TERINARY DRUG PRODUCTS 1. Notarized Integrated Application Form (in excel and pdf format)	

2. Proof of Payment 3.Unit Dose and Batch Formulation 4.Technical Specifications of Finished Product Certificate of Analysis (CA) of Finished Product (from the same batch of representative sample) Assay and Other Test Procedures including Assay with Data Analysis Stability Studies Labeling Materials (actual/commercial label) Actual commercial sample (w/Certificate of Analysis) (upon request of the evaluator) If with previously approved/acknowledged variation applications filed prior to CPR renewal:	Applicant Company Applicant Company Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer Applicant Company/Manufacturer
he approved/acknowledged Certification and/or Notification (Note that request/s for variation shall be filed separately from the renewal application.) l Requirements: Post-marketing commitments (if any)	Applicant Company/ Manufacturer

For imported products: Foreign GMP Clearance	FDA CDRR
onitored-Release Extension (MRE)	
Notarized Integrated Application Form (in excel and pdf format)	Applicant
Proof of payment	Company/ Manufacturer
Copy of Latest Certificate of Product Registration (CPR)	Applicant
Unit Dose and Batch Formulation	Company/ Manufacturer
Actual/Commercial Labeling Materials	Applicant
l Requirements:	
For MRE/MR to Initial applications, proof of approval/clearance/extension of Post-Marketing Surveillance (PMS) Report	Company/ Manufacturer
MRE to Initial: Periodic Safety Update Report (PSUR), or proof of submission	Applicant
Risk Management Plan (RMP)	Company/ Manufacturer
Periodic Safety Update Report (PSUR)	Applicant
For imported products:	Company/ Manufacturer
Certificate of Pharmaceutical Product (CPP) Foreign GMP Clearance	Applicant
	Company/ Manufacturer
	Applicant
	Company/ Manufacturer
	Applicant
	Company/ Manufacturer
	Applicant
	Company/ Manufacturer
	Applicant
	Company/ Manufacturer
	FDA CDRR

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
2. E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*
3.For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.bizPortal Sends proof of payment to the FDAC.	3.1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/Landbank FDAC *Personnel*
	Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit

	Queuing time of the application before decking to evaluators of Registration Section and/or Clinical Research Section		20 working days	CDRR-CRR Unit Personnel
	Decks/Assigns the application to the assigned evaluators of Registration Section and/or Clinical Research Section	None	1 working day	LRD Chief
	Evaluates the application according to requirements and prescribed standards	None	51 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
4. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and/or Safety & Efficacy received from the CRS) For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator.		1 working day	FDRO I/II/III
	4.2 If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic			

	4.3.Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	40 working days	FDRO III
	4.4.Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR	None	1 working day	FDRO I/II
	4.5.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	FDRO III
	4.6.Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day (per batch of applications)	FDRO IV (Supervisor)
	4.7.Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	1 working day (per batch of applications)	LRD Chief
	4.8.Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	4.9.Encodes/Updates the Database and Endorses the final output document (CPR/Certificate/Letter/LOD) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel

	4.10.Scans, barcodes, and emails the scanned copy of the final output document (CPR/Certificate/LOD/Letter) to the client, updates the database and website, and endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel
5.Receives the CPR/LOD/letter	5. Releases the CPR/LOD/letter to the client	None	1 working day	AFS Releasing Section Personnel
TOTAL: (Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13 and Republic Act No. 7394 Article 31).			120 working days	

27. ISSUANCE OF CERTIFICATE OF PRODUCT REGUSTRATION FOR PHARMACEUTICAL PRODUCTS (VARIATION-TURNED-INITIAL APPLICATIONS)

This Certificate of Product Registration is granted to Marketing Authorization Holders once the proposed post-approval changes on the quality (e.g. manufacture, controls and container closure system), safety, efficacy, and administrative information of pharmaceutical products has been substantiated.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Drug Products
Fees to be Paid		Refer to FDA-Circular-No.-2014-008, Annex D Payment shall be on a per product, per change basis Variation-turned-Initial: Branded: Php 15,000.00 + LRF Unbranded: Php 10,000.00 + LRF Monitored Release Status: New application: Php 33,333.33 + LRF (5-year validity); Pending application: Php 13,333.33 + LRF (paid for 3-years and will avail 5-year validity) (according to FDA Advisory No. 2021-2904) The Legal Research Fund (LRF) fee is the amount equivalent to one percent (1%) of the fee imposed but in no case lower than ten (10) pesos.

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
LIST OF VARIATION-TURNED-INITIAL APPLICATIONS Mav-1: Change and/or additional indication/dosing regimen/patient population/inclusion of clinical indication extending the usage of the product MaV-4: Addition or replacement of the manufacturing site of the drugs product MaV-10: Qualitative or quantitative change of excipient For immediate release oral dosage forms (as per Level 2 and 3, Part III Components and Composition, SUPAC guideline)	Applicant Company Applicant Company ASEAN Variation Guidelines Link: https://www.fda.gov.ph/wp-content/uploads/2021/03/ASEAN-

For modified release oral dosage forms For other critical dosage forms such as sterile preparations MaV-11: Quantitative change in the coating weight of tablets or weight and/or size of the capsule shell for modified release dosage form MaV-12: Change in the primary packaging material for sterile drug product Qualitative and quantitative composition and/or Type of container and/or nclusion of primary packaging material MaV-13: Change or addition of pack size/fill volume and/or change of shape or dimension of container or closure for a sterile solid and liquid drug product (unless the change is dimension, i.e. wide-mouth bottles vs. narrow-mouth bottles) MiV-PA15: Qualitative or quantitative change of excipient For immediate release oral dosage forms (as per Level 1, Part III Components and Composition, SUPAC guideline) For other non-critical dosage forms (e.g. oral liquid, external preparation) MiV-PA16: Quantitative change in coating weight of tablets or weight and/or size of capsule shell for immediate release oral dosage form MiV-PA17: Change of the colouring/flavouring agent of the product [addition, deletion or replacement of colourant(s)/flavour(s)] MiV-PA28: Change in primary packaging for non-sterile drug product Qualitative and quantitative composition and/or Type of container and/or Inclusion of the primary packaging material Additional route of administration Change of manufacturing site (same subsidiary) of the drug product	Variation-Guideline-for-Pharmaceutical-Products-R1.pdf FDA Circular No. 2014-008 Link: https://www.fda.gov.ph/wp-content/uploads/2021/04/FDA-Circular-No.-2014-008.pdf

CHECKLIST OF REQUIREMENTS FOR VARIATION-TURNED INITIAL APPLICATIONS FDA-Circular-No.-2014-008 Application Process and Requirements for Post-Approval Changes of Pharmaceutical Products ASEAN Variation Guidelines A.O. No. 47-a s.2001 Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products 1. Annex A (A maximum of 3 proposed variations shall be made per application, consistent with those reflected on the Integrated Application Form.) 2. Complete List of Documentary Requirements based on Annex C of FDA-Circular-No.-2014-008 and ASEAN Variation Guidelines (attached as annexure to this document) 3. Proof of Payment based on Annex D of FDA-Circular-No.-2014-008 4. Additional requirement for Biologics/Vaccines: Stringent Regulatory Authority (SRA)/National Regulatory Authority (NRA) approval for the proposed variation (where applicable) No.-2014-008 Annex D	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC	Sends the scheduled date of submission for pre-assessment	None	0	FDAC *Personnel*

E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	2. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for	None	0	CDRR *Personnel*
3. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.BizPortal Sends proof of payment to the FDAC.	Endorses the application to CDRR for evaluation.	See Table Above	0	FDA Cashier/ Landbank FDAC *Personnel*

	Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR)
	Queuing time of the application before decking to evaluators of Registration Section and/or Clinical Research Section	None	20 working days	CDRR-CRR Unit *Personnel*
	Decks/Assigns the application to the assigned evaluators of Registration Section and/or Clinical Research Section	None	1 working day	CDRR *Director*
	Evaluates the application according to requirements and prescribed standards	None	50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/*
4. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares a worksheet and drafts Certificate of Product Registration (CPR) (from safety and efficacy evaluation, if applicable) when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS) Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS)			

	4.2 For applications with proposed brand names, requests clearance from the Brand Name Clearance evaluator. If the proposed brand name is disapproved, this shall be cited in the electronic deficiencies (E-NOD) or Letter of Disapproval (LOD) to be issued *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None		*FDRO I/II/III*
	Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	40 working days	*FDRO III*
	Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the Certificate	None	1 working day	*FDRO I/II*
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	*FDRO III*
	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day (per batch of applications)	*FDRO IV (Supervisor)*

	Checks and recommends the decision of the evaluators and supervisor by affixing signature	None	1 working day (per batch of applications)	*LRD Chief*
	Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit *Personnel*
	Scans and barcodes the final output document (CPR/LOD/Letter); emails scanned copy of the final output document to the client; and endorses the final output document (hard copy) to the AFS Releasing Section.	None	1 working day (per batch of applications)	FDA Records *Personnel*
5. Receives the CPR/ LOD letter	5. Releases the CPR/LOD/letter to the client	None	1 working day	AFS Releasing Section *Personnel*
TOTAL: (Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13 and Republic Act No. 7394 Article 31).			120 working days	

28. ISSUANCE OF CLEARANCE AND CERTIFICATE FOR FOREIGN DONATIONS

This certificate and clearance are issued for foreign drug donations in support of the service and programs of the health sector.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	Php 500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Administrative Order No. 2020-0001: Revised Guidelines in the Facilitation and Management of Foreign Donations involving Health and Health-Related Products I. Criteria for Acceptable Foreign Drug Donations Listed in the Latest Edition of the Philippine National Formulary For pharmaceuticals which are not included in the Latest Edition of the Philippine National Formulary (PNF), must satisfy at least one of the following conditions: Must contain the same active ingredients, dosage form and strength as those products already approved by and registered at FDA Philippines; or Orphan drugs and drugs for compassionate use; or Critically needed drugs (Note: Subject to approval by the Secretary of Health) Must NOT be classified under the following: Experimental/investigational drugs and MR registration of FDA Philippines Regulated, prohibited and/or dangerous drugs of PDEA Must have a shelf-life of at least 12 months (or 1 year) at the expected date of arrival For pharmaceuticals with shelf life below 12 months, must satisfy at least one of the following conditions:	Applicant Company Applicant Company

The product has a total shelf-life of less than 2 years AND has a remaining of at least one-third (1/3) of its shelf-life. Recommended as suitable for distribution as per case assessment by the DOH/TWG and approved by the Secretary of Health despite the limited product shelf-life remaining	
II. Requirements	
II-A. Administrative Data	
Endorsement Letter from the Bureau of International Health Cooperation (BIHC) – DOH	BIHC – DOH
Letter of intent to donate	Applicant Company
Authenticated Deed of Donation (Philippine Embassy/Philippine Consulate)	Philippine Embassy/Philippine Consulate
Letter of Concurrence or Acceptance	Applicant Company
List of all drug products to be donated with the following information: International Nonproprietary Name (INN) or Generic name Brand name (if any) Dosage Form and Strength Batch/Lot Number Expiration Date Total quantity of batch/lot of products to be donated	Applicant Company
Certificate of no commercial use and given for free or Notarized Affidavit of Undertaking indicating “not for commercial distribution or sale” duly signed by the recipient/consignee	Applicant Company
Distribution plan/ Allocation list of intended beneficiaries	
Photocopy of shipping documents such as bill of lading airway bill, commercial invoice, and packing list	
8. Copy of Post donation report (where applicable)	
9. Proof of payment (PHP 510.00)]	Applicant Company
II-B. Quality	Applicant Company
Certificate of Pharmaceutical Product (CPP)	Applicant Company
For countries not issuing CPP, the following shall be submitted: Current Good Manufacturing Practice (CGMP) Certificate issued by the drug regulatory authority of the product’s country of origin	Applicant Company
Certificate of Free Sale (CFS) authenticated by the territorial Philippine Consulate	Applicant Company

Certificate of Analysis (CoA) per batch/lot of products Complete labelling materials, i.e., primary and secondary packaging, and package insert, which must contain texts in English/English translation of ALL of the following mandatory information: International Nonproprietary Name (INN) or Generic name Brand name (if any) Dosage Form and Strength Mode of Administration Batch/Lot Number Expiration Date Formulation Storage conditions	Applicant Company Applicant Company

CLIENT STEPS	**AGENCY ACTION**	**FEES TO BE PAID**	**CESSING TIME**	**PERSON RESPONSIBLE**
Secure a schedule of appointment / submission to FDAC	Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
2.E-mail submission: Submits the application for pre- assessment through fdac.letters.cdrr@fda.gov.ph	Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre- assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		Center for Drug Regulation and Research Personnel/ FDAC personnel

For accepted applications, pays the required fee through any of the following:BANCNET Landbank OnColl Landbank Link.bizPortal Sends proof of payment to the FDAC.	Verifies and posts the payment through updating the FDA FIS. FDA personnel forwards the application with proof of payment to CDRR.	ee Table Above		Administrative Finance Service (AFS) Staff/Cashier
	. Receives the application from FDAC and encodes/updates the database	None	1 working day	CDRR- Central Receiving and Releasing (CRR) unit
	2 Decks/Assigns the application to the assigned evaluator	None	1 working day	*LRD Chief/ CRR Unit Personnel*
	3 Evaluates the application according to requirements and prescribed standards	None	1 working day	*Food-Drug Regulation Officer (FDRO) I/II*

4. If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Prepares the worksheet and draft Clearance Letter/Certificate of Foreign Donated Product Registration issuance upon approval of the recommendation Prepares the worksheet and Letter of Disapproval (LOD) when the application does not merit an Approval recommendation *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	1-11 working days varies depending on the value of the received requests and the total number of batches/lots of products to be donated)	*FDRO I/II*
	2 Reviews the evaluated application bearing the recommendation of the Junior Evaluator	None	1 working day	*FDRO III*
	3 Prepares the final output document (Clearance Letter, Certificate(s) of Foreign Donated Product Registration, and/or Letter of Disapproval), affixes initial, and forwards it to the senior evaluator (FDRO III)	None	depending on the value of the received requests and the total number of batches/lots of products to be donated)	*FDRO II*
	4 Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor	None	1 working day	*FDRO III*

	Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief	None		*FDRO IV (Supervisor)*
	Checks and recommends the decision of the evaluators and supervisor by affixing initial/signature	None	1 working day (per batch of applications)	*LRD Chief*
	4.7 Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	Encodes/Updates the Database and Endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*
Receives the Clearance Letter, Certificate(s) of Foreign Donated Product Registration, and/or Letter of Disapproval	eleases the Clearance Letter, Certificate(s) of Foreign Donated Product Registration, and/or Letter of Disapproval to the client	None	1 working day	*AFS Releasing Section Personnel*
	TOTAL:	**PHP510.00**	**20 working days**	

29. ISSUANCE OF CLINICAL TRIAL AMENDMENT APPROVAL UNDER REGULATORY RELIANCE

The CTA Amendment is granted to Sponsor, Clinical Research Organization and/or Principal Investigator once the proposed changes to the protocol and other related documents on the conduct of clinical trial has been approved.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Sponsors, Contract Research Organizations (CROs), Principal Investigators and Importers of Pharmaceutical Products
Fees to be Paid	:	AO No.-50-2001 Php 1,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
AO -2020-0010: Regulations on the Conduct of Clinical Trials for Investigational Products Initial Clinical Trial & Import License Application Requirements 1. Cover Letter (FDA-CRS Form 2.0) 2. Application Form (Appendix D1) 3. Original Version, corresponding amendments/s and rationale in a tabulated format 4. Supporting Data 5. Proof of Payment	Applicant Company
References: 1. Administrative Order 2020-0010 - Regulations on the Conduct of Clinical Trials for Investigational Products 2. FDA Circular No.2023-004 - Guidelines on Regulatory Reliance on the Conduct of Clinical Trials	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
E-mail submission: Submits the application for preassessment through clinicalresearch@fda.gov.ph.	Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the preassessment, issue the Document Tracking Number (DTN), and instructs the client to proceed with the payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule, inform the client of the deficiency/ies.	None	1 working day	CRS Administrative Staff
. For accepted applications, pays the required fee through any of the following: • FDA Cashier • BANCNET • Landbank OnColl Sends proof of payment to Clinical Research Section through clinicalresearch@fda.gov.ph	2.1 Upon receipt of the proof of payment, the application will be encoded/update in the database.	AO 50 s. 2001 Php 1,000.00 + 1% LRF	1 working day ***Timeline starts after posting of payment**	CRS Administrative Staff
	2 Decks/Assigns the application to an evaluator.	None	1 working day	CRS Administrative Staff

3. If an electronic notice of deficiencies (ENOD) was issued by the evaluator, submits complete compliance documents to the evaluator	1 Evaluates the application according to requirements and prescribed standards *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	10 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
	2 Assignment of Scientific Advisory Committee (SAC) **The decision to assign to SAC is based upon the complexity of the amendments.*	None	1 working day	FDRO I/II/III
	3.3 SAC Review	None	9 working days	Scientific Advisory Committee (SAC)
	3.4 Reviews the evaluated application bearing the recommendation of the evaluator.	None	2 working days	Clinical Research Section Supervisor
	3.5 Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD)	None	1 working day	PRSDD Chief
	3.6 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director

	3.7 Encodes/Updates the Database and Endorses the final output document to the FDAC Releasing Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
. Receives the letter	4. Releases the letter to the client	None	1 working day (per batch of applications)	FDAC Releasing Section Personnel
	TOTAL:	**PHP 1,010.00**	**15 Working Days**	

30. ISSUANCE OF CLINICAL TRIAL AMENDMENT APPROVAL UNDER REGULATORY RELIANCE

The CTA Amendment is granted to Sponsor, Clinical Research Organization and/or Principal Investigator once the proposed changes to the protocol and other related documents on the conduct of clinical trial has been approved.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Sponsors, Contract Research Organizations (CROs), Principal Investigators and Importers of Pharmaceutical Products
Fees to be Paid	:	AO No.-50-2001 Php 1,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
AO -2020-0010: Regulations on the Conduct of Clinical Trials for Investigational Products Initial Clinical Trial & Import License Application Requirements 1. Cover Letter (FDA-CRS Form 2.0) 2. Application Form (Appendix D1) 3. Original Version, corresponding amendments/s and rationale in a tabulated format 4. Supporting Data 5. Proof of Payment	Applicant Company
References: 1. Administrative Order 2020-0010 - Regulations on the Conduct of Clinical Trials for Investigational Products 2. FDA Circular No.2023-004 - Guidelines on Regulatory Reliance on the Conduct of Clinical Trials	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
E-mail submission: Submits the application for preassessment through clinicalresearch@fda.gov.ph.	1 Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the preassessment, issue the Document Tracking Number (DTN), and instructs the client to proceed with the payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule, inform the client of the deficiency/ies.	None	1 working day	CRS Administrative Staff
. For accepted applications, pays the required fee through any of the following: • FDA Cashier • BANCNET • Landbank OnColl Sends proof of payment to Clinical Research Section through clinicalresearch@fda.gov.ph	1. Upon receipt of the proof of payment, the application will be encoded/update in the database.	AO 50 s. 2001 Php 1,000.00 + 1% LRF	1 working day ***Timeline starts after posting of payment**	CRS Administrative Staff
	2 Decks/Assigns the application to an evaluator.	None	1 working day	CRS Administrative Staff

3. If an electronic notice of deficiencies (ENOD) was issued by the evaluator, submits complete compliance documents to the evaluator	1 Evaluates the application according to requirements and prescribed standards *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	10 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
	2 Assignment of Scientific Advisory Committee (SAC) **The decision to assign to SAC is based upon the complexity of the amendments.*	None	1 working day	FDRO I/II/III
	SAC Review	None	9 working days	Scientific Advisory Committee (SAC)
	Reviews the evaluated application bearing the recommendation of the evaluator.	None	2 working days	Clinical Research Section Supervisor
	Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD)	None	1 working day	PRSDD Chief
	Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director

	Encodes/Updates the Database and Endorses the final output document to the FDAC Releasing Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
. Receives the letter	Releases the letter to the client	None	1 working day (per batch of applications)	FDAC Releasing Section Personnel
	TOTAL:	**PHP 1,010.00**	**15 Working Days**	

31. ISSUANCE OF INITIAL CLINICAL TRIAL APPROVAL (CTA) AND IMPORT LICENSE APPROVAL (ILA)

The CTA is granted to Sponsor, Clinical Research Organization and/or Principal Investigator to conduct a clinical trial of an investigational drug product. On the other hand, the IL is granted to Sponsor, Clinical Research Organization and/or Principal Investigator to allow importation of investigational product and ancillary supplies necessary for the conduct of clinical trial.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Sponsors, Contract Research Organizations (CROs), Principal Investigators and Importers of Pharmaceutical Products
Fees to be Paid	:	Administrative Order No.-50-2001 & FDA Circular No.2012-007-A FDA Review: Php 2,500.00 + 1% LRF Fee External Regulatory Reviewers: Php 60,000.00 Importation Clearance for Clinical Study: Php 500.00/importation + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE

AO 2020-0010: Regulations on the Conduct of Clinical Trials for Investigational Products **Initial Clinical Trial & Import License Application Requirements** 1. Table of Contents for Clinical Trial Application 2. Cover Letter for Application 3. Clinical Trial Application Form 4. Investigational Product and Ancillary Supplies Information 5. Import License Application Form 6. Proof of payment 7. Letter of Authorization 8. Clinical Trial Protocol and amendment(s), where applicable 9. GCP Certificate and Curriculum vitae (CV) for investigators of each trial site 10. Informed Consent Form/Assent Form 11. Investigator's Brochure 12. Pharmaceutical Data 13. GMP Certificate from NRA and/or evidence of GMP compliance 14. Shipping condition for IP and trial related materials 15. Labelling Materials of the Investigational product 16. Acknowledgement Receipt/Approval of the Research Ethics Committee (REC)	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an application email containing the requirements to fdac.letters.cdrr@fda.gov.ph following the correct submission schedule	1. Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgement email with the order of payment to the applicant	None		FDAC *Personnel*

2. ay for the required fee through any of the following: • FDA Cashier • BANCNET • Landbank OnColl Then send the proof of payment to the FDAC.	Receives the payment from the applicant for posting 2.2 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation	See Table Above	***Timeline starts after posting of payment**	FDA Cashier/ Landbank FDAC *Personnel*
	2.3 Receives the application from FDAC and encodes/updates the database and FIS	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.4 Decks/Assigns the application to the assigned evaluator	None	1 working day	CRS Administrative Staff

	2.5 Evaluates the application for completeness and scientific worth *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication (7 calendar days to respond to the queries)	None	2 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*
	2.6 If the application is deemed complete, assign a regulatory reviewer and issue regulatory review permit to the applicant.	None	1 working day	*FDRO I/II/III*
Submit the following document to the assigned external regulatory reviewer and pay for the review fee: • Cover Letter • Clinical Trial Protocol • Informed Consent Form/Assent Form • Investigator's Brochure • GCP Certificate and Curriculum Vitae of the PI of each site • Investigational Product Information Submit the Acknowledgement Receipt of the Regulatory Reviewer within three (3) calendar days after the receipt of the Regulatory Reviewer 3.3. Submit the Proof of Payment to the Regulatory Reviewer within 14 calendar days	3. Reviews Pharmaceutical data requirements and Import License application	See Table Above	30 working days	*FDRO I/II/III*

4. *If an electronic notice of deficiencies (E-NOD) was issued by the external regulatory reviewer, submits complete compliance documents to the evaluator	4.1. Assesses the application through the FDA CT Assessment Form, then forward the assessment to CRS though email. *Any clarifications/ deficiencies will be communicated to the clients through electronic communication (30 calendar days to respond to the queries) *This constitutes a stop clock on the processing time (based on AO 2020-0010, Section VI, Paragraph 5.6 and FDA Circular No. 2020-0029-1)		30 working days	*External Regulatory reviewer [St. Luke's Medical Center (SLMC), University of the Philippines – National Institutes of Health (UP-NIH), Philippine Heart Center (PHC)]*
	4.2 Reviews the assessment from the Regulatory reviewer	None	2 working days	*FDRO I/II/III*
	4.3 Reviews the evaluated application bearing the recommendation of the evaluator	None	1 working day	*Clinical Research Section Supervisor*
	4.4 Prints the final response and forwards it to the Product Research and Standards Development Division (PRSDD) Chief	None	1 working day	*FDRO I/II/III*

	4.5 Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	*PRSDD Chief*
	4.6 Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	4.7 Scans the document with decision and email to the applicant 4.8 Encodes/Updates the Database and Endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*
5. Receives the documents	5. Releases the appropriate CT response and IL to the client	None	1 working day	*AFS Releasing Section Personnel*
TOTAL: Service is covered under Administrative Order 2020-0010.		**PHP 63,035.00**	**40 Working days**	

32. ISSUANCE OF COMPASSIONATE SPECIAL PERMIT (CSP) OF PHARMACEUTICAL PRODUCTS [MANUAL SUBMISSION]

The CSP is granted to an institution and/ or physician the privilege to avail an unregistered or investigational drug product through a licensed importer for a certain patient suffering from a condition, with specific volume and period of use.

Center/Office/Division	:	enter for Drug Regulation and Research
Classification	:	imple
Type of Transaction	:	2B – Government-to-Businesses
Who May Avail	:	Patients, Doctors, Specialized Institutions, Specialized Society, Hospitals, Importers of Pharmaceutical Products
s to be Paid	:	Name Patient: Php 500.00/patient + 1% LRF Institutional Use: Php 500.00/product + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE

CHECKLIST OF REQUIREMENTS FOR CSP Name Patient 1. Letter of Application Should include the following: a. name of requesting party [personal/ doctor/ Specialized Institution (SI) and Specialty Society (SS)] b. name and age of the patient with a brief medical history c. itemized, detailed description of product [generic name and brand name (if applicable) with dosage form and strength (Registered from country of origin) d. an estimated quantity/ volume needed/prescribed by doctor e. A written commitment on the part of all the authorized specialists to submit a Clinical Report for every patient given the product describing the quantity administered/ use, therapeutic/desired effect and any adverse reaction, to the Institution or Specialty Society through the importer for FDA Philippines f. A waiver of FDA Philippines responsibility from any damage or injury arising from the use of the unregistered drug or device to be signed by the responsible official of the Institution or Specialty Society. Proof of Payment per patient (P500 + LRF) Names and addresses of the specialists qualified and authorized to use the product Curriculum vitae of the prescribing doctor Medical Abstract of Patient Prescription Note: In case the product is an Investigational Product, the applicant should submit a copy of the Clinical trial registry of an on-going phase 3 clinical trial where the same drug product is being used in the treatment of the target indication.	 Applicant Company Applicant Company Applicant Company Applicant Company Applicant Company/Authorized Specialists Applicant Company Applicant Company Applicant Company Prescribing Doctor Prescribing Doctor Prescribing Doctor
Institutional Use 1. Letter of Application Should include the following: a. name of requesting party [personal/ doctor/ Specialized Institution (SI) and Specialty Society (SS)]	 Applicant Company Applicant Company

b. itemized, detailed description of product [generic name and brand name (if applicable) with dosage form and strength (Registered from country of origin) c.an estimated quantity/ volume needed c. A written commitment on the part of all the authorized specialists to submit a Clinical Report for every patient given the product describing the quantity administered/ use, therapeutic/desired effect and any adverse reaction, to the Institution or Specialty Society through the importer for FDA Philippines d. A waiver of FDA Philippines responsibility from any damage or injury arising from the use of the unregistered drug or device to be signed by the responsible official of the Institution or Specialty Society. 2. Proof of Payment per product (P500 + LRF) 3. Reports as prerequisites of renewal of permit a. Reconciliation of number/volume of products requested and number used and the corresponding patients b. Additional product details – name and address of manufacturer, batch/lot number, expiry date Note: In case the product is an Investigational Product, the applicant should submit a copy of the Clinical trial registry of an on-going phase 3 clinical trial where the same drug product is being used in the treatment of the target indication.	Applicant Company Applicant Company/Authorized Specialist Applicant Company Applicant Company Applicant Company Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
. Sends an application email containing the requirements to fdac.letters.cdrr@fda.gov.ph following the correct submission schedule	1. Generates a Document Tracking Number (DTN) and sends an acknowledgement email with the order of payment to the applicant	None		FDAC *Personnel*

2. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.bizPortal Sends proof of payment to the FDAC thru fdac.letters@fda.gov.ph	2.1 Endorses the application to CDRR for evaluation.	See Table Above	1 working day	FDA Cashier/ Landbank FDAC *Personnel*
	2.2 Endorses the received application to the Center (applications which satisfactorily passed the pre-assessment).	None		FDAC *Personnel*
	2.3 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.4 Decks/Assigns the application to the assigned Clinical Research Section (CRS) evaluator	None	1 working day	*CRS Administrative Staff*
	2.5 Evaluates the application according to requirements and prescribed standards	None	1 working day	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/FDRO III (Senior Evaluator)*
	2.6 Reviews the evaluated application bearing the recommendation of the Evaluator	None	1 working day	Clinical Research Section *Supervisor*

	2.7 Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD) Chief	None	1 working day	*FDRO I/II/III*
	2.8 Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	PRSDD *Chief*
	2.9 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR *Director*
	2.10 Encodes/Updates the Database and endorses the final response to the AFS Releasing Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
3. Receives the permit or final response	3. Releases the permit or final response to the client	None	1 working day	AFS Releasing Section Personnel
	TOTAL:	Php 510	**3 Working days**	

33. ISSUANCE OF ELECTRONIC CERTIFICATE OF LISTING OF IDENTICAL DRUG PRODUCTS (E-CLIDP)

The CLIDP is granted to identical drug products as proof that its pharmaceutical product has been officially listed by FDA as identical, in terms of its manufacturer and formulation, to the pharmaceutical product already covered by the Principal CPR.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products
Fees to be Paid	:	AO No.-50-2001 and AO No.-2005-0031 Branded: Php 3,000.00/year* + 500.00 (per proposed brand name, for brand name clearance) + 1% LRF Unbranded: Php 2,000.00/year* + 1% LRF *per year – depending on the remaining validity of the Principal Certificate of Product Registration (PCPR)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Checklist of Requirements for Certificate of Listing of Identical Product (CLIDP)	
1. Proof of payment	Applicant
2. Copy of the current and valid LTO of the PCPR and Identical Drug Applicant	Applicant
3. Copy of current and valid PCPR	Applicant
4. Authenticated copy of the duly notarized Distributorship Agreement, license Agreement, or other written contract between the principal CPR holder and the identical Drug Applicant	Applicant
5. Facsimile of Labeling Materials	Applicant
6. Additional Requirement for Imported Products: Foreign GMP Clearance	Applicant

References: 1. Republic Act 9711 – Food and Drug Administration Act of 2009 Administrative Order No.-2005-0031 - Guidelines and Procedure for the Issuance of the Principal Certificate of Product Registration and the Listing of Identical Drug Products based on the Identity of Manufacturer and Pharmaceutical Formulation Bureau Circular No. 11 s. 2006 - Specific Operational Instructions Implementing Administrative Order No.-2005-0031 dated December 7, 2005, Subject: Guidelines and Procedure for the Issuance of the Principal Certificate of Product Registration and the Listing of Identical Drug Products based on the Identity of Manufacturer and Pharmaceutical Formulation FDA Advisory No.2021-1791 – Pilot Implementation of the Food and Drug Administration (FDA) eService Portal System for Certificate of Listing of Identical Drug Product (CLIDP) Applications FDA Advisory No.2022-0418 - Implementation of The Food and Drug Administration (FDA) Eservices Portal System for Certificate of Listing of Identical Drug Product (CLIDP) Applications FDA Advisory No.2022-0907 - Payment of Applications with Pre-Assessment	

APPLICANT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through (http://eservices.fda.gov.ph) "Applications"	1. Assess the completeness of documents submitted. If complete, Order of Payment will be generated and will be given to the applicant thru the eService and email notification.	None	0	
2. Select "Certificate of Product Registration" and select "Drug". Select the classification of the product to be registered then select "Certificate of Listing of Identical Drug Products (CLIDP) Of Pharmaceutical Products".	If incomplete, the application will not be accepted. A pre-assessment result indicating the grounds for non-acceptance shall be sent by the	None	0	

3. Click “I have read and accepted the terms and conditions stated on this form”. Declining the declaration shall mean forfeiture of the opportunity to proceed with the application	eServices to the email address of the applicant.	None	0	
4. Fill out all the information needed and upload the required documents as indicated on the Checklist of Requirements		None	0	
5. After providing the required information, applicants can review the duly filled out form in the Self-Assessment Review. By agreeing to the Terms and Conditions, the applicants confirm the correctness of information given. (Pre-assessment)		None	0	CDRR Pre-assesor
6. Print the Order of Payment form with Case Number or Reference Number sent through the declared e-mail address Pay the assessed fee as per the system generated Order of Payment Form through FDAC Cashier or any other means prescribed by FDA (e.g. BANCNET, LANDBANK ONCOLL).	6. Post payment in eServices for confirmed payments. Note: Acknowledgement receipt will automatically be sent to the applicant once payment is posted and will signify the start of processing time of the application. This will prompt automatic decking of application to respective Center	Branded: Php 3,000.00/year + 500.00 (per proposed brand name, for brand name clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF *per year – depending on the remaining validity of the Principal Certificate of Product Registration (PCPR)	0	FDA Cashier

7. Receives acknowledgement receipt through email Remarks: If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator.	7.1 The assigned Evaluator reviews for the correctness of the information and documents provided and recommends approval / disapproval of the application which will be forwarded to Quality Assurance (QA). Note: (1) For applications with proposed brand names, request approval from the Brand Name Clearance (BNC) evaluator. (2) Any minor deficiencies/ clarifications will be communicated through electronic communication. The Client is given 5 working days to comply. If the client complies or when there is no deficiency found, the CDRR evaluator will resume its evaluation.	None	Day 1-20 20 working days	FDRO I/II (CDRR Evaluator)
	7.2 QA reviews the recommendation and forwards the application to the CDRR Director for final decision.	None	5 working days	FDRO IV (CDRR Supervisor)
	7.3 Final Decision Once the CDRR Director approves/disapproves the application, the system automatically generates the CPR/Letter of Disapproval and sends it to the applicant's registered e-mail address for printing.	None	5 working days	Director IV

8. Receive notification and link of CPR/Letter of Disapproval for printing.		None	0	
		Total:	**30 working days**	

34. ISSUANCE OF ELECTRONIC COMPASSIONATE SPECIAL PERMIT (eCSP) OF PHARMACEUTICAL PRODUCTS

The CSP is granted to an institution and/ or physician the privilege to avail an unregistered or investigational drug product through a licensed importer for a certain patient suffering from a condition, with specific volume and period of use.

Center/Office/Division	:	enter for Drug Regulation and Research
Classification	:	imple
Type of Transaction	:	2B – Government-to-Businesses
Who May Avail	:	Patients, Doctors, Specialized Institutions, Specialized Societies, Hospitals, Department of Health, and Importers of Pharmaceutical Products
Fees to be Paid	:	Named Patient: Php 500.00/patient + 1% LRF Institutional Use: Php 500.00/product + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR CSP Basic Requirements based on the FDA Advisory No.2021-0842: Named Patient Use: 1. Accomplished e-Application Form as prescribed by FDA regulations. 2. Curriculum vitae of the Prescribing Doctor 3. Medical Abstract of the Patient 4. Medical Prescription 5. Proof of Payment Institutional Use: 1. Accomplished e-Application Form as prescribed by FDA regulations. 2. Rationale for the Volume Requested 3. Proof of other National Regulatory Authority (NRA) approval	 FDA eServices (www.fda.gov.ph) Applicant

4. Distribution Agreement 5. Clinical Study Report (if applicable) 6. Proof of Payment	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1.1. Access the online application portal through (http://eservices.fda.gov.ph) "Applications"		None		
1.2. Select the "Compassionate Special Permit" and the type of application (Named Patient Use or Institutional Use), then proceed to New Application		None		
1.3. Click "I have read and accepted the terms and conditions stated on this form". Declining the declaration shall mean forfeiture of the opportunity to proceed with the application		None		
1.4. Fill-out all the information needed and upload the required documents as indicated on the Checklist of Requirements		None		

1.5.	After providing the required information, applicants can review the duly filled out form in the Self-Assessment Review. By agreeing to the Terms and Conditions, the applicants confirm the correctness of information given.	1. Pre-assess the completeness and veracity of documents submitted. If complete, Order of Payment will be generated and will be given to the client thru the eService and Email notification. If incomplete, the application will not be received and will be returned to the client. Notice of deficiency will be given to the client thru eServices and Email notification.	None		FDA Evaluator (CRS Staff)
2.1.	Print the Order of Payment form with Reference Number sent through the declared e-mail address		None		
2.2.	Pay the assessed fee as per the system generated Order of Payment Form through payment channels prescribed by FDA (e.g. BANCNET, LANDBANK ONCOLL, Landbank Link.bizPortal). Then, email a copy of the proof of payment to clinicalresearch@fda.gov.ph cashierposting@fda.gov.ph and cashierposting2@fda.gov.ph	2.1 FDA Cashier receives the payment for FDAC Cashier payments/ receives notification of payment for bank payments;	Php 510		FDA Cashier/CRS Staff

	2.2. Post payment in eServices for confirmed payments. This will prompt automatic decking of application to respective Center Note: Acknowledgement receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.	None		FDA Cashier/CRS Staff
3. Receives acknowledgement receipt through email	3.1. Evaluates, Checks and quality assurance of the information and documents provided	None	3 working days	CRS Staff/ PRSDD Chief
	3.2. Approval of CSP If application is disapproved, notifies the applicant through email and will receive the Letter of Denial	None		CDRR Director
4. Receives notification and link of CSP for printing.				
	TOTAL:		**3 Working days**	

35. ISSUANCE OF ELECTRONIC PRINCIPAL CERTIFICATE OF PRODUCT REGISTRATION (e-PCPR) CONVERSION FOR PHARMACEUTICAL PRODUCTS

This Certificate of Product Registration is granted to Marketing Authorization Holders for the conversion from Regular CPR [DR-XY] to a Principal Certificate of Product Registration (PCPR) [DRP].

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of Pharmaceutical Products with a valid regular CPR
Fees to be Paid	:	AO No.-50-2001 and AO No.-2005-0031 Php 500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
Checklist of Requirements for Principal Certificate of Product Registration (PCPR) Conversion	
1. Copy of current and valid CPR 2. Copies of the respective current and valid License to Operate (LTO) of the principal CPR applicant and toll manufacturer (if applicable) 3. Proof of payment	Applicant Applicant Cashier

References:	
1. Republic Act 9711 – Food and Drug Administration Act of 2009 2. A.O No.-2005-0031 – Guidelines and Procedure for the Issuance of the Principal Certificate of Product Registration and the Listing of Identical Drug Products based on the Identity of Manufacturer and Pharmaceutical Formulation. 3. FDA-Advisory-No.2021-1790 – Guidelines on Principal Certificate of Product Registration Conversion Application using e-Services Portal System. 4. FDA-Advisory-No.2022-0417 – Implementation of The Food and Drug Administration (FDA) e-Services Portal System for Principal Certificate of Product Registration (PCPR) Conversion Applications for Drug Products 5. FDA-Advisory-No.2022-0907 – Payment of Applications with Pre-Assessment	

APPLICANT STEPS	AGENCY ACTION	FEES TO BE PAID	)CESSING TIME	PERSON RESPONSIBLE
1.1. Access the online application portal through (http://eservices.fda.gov.ph) “Applications“		None		
1.2. Select “Certificate of Product Registration” and select “Drug”. Select the Product Category, Click on the Principal Certificate of Product Registration (PCPR) Conversion		None		
1.3. Click “I have read and accepted the terms and conditions stated on this form”. Declining the declaration shall mean forfeiture of the opportunity to proceed with the application		None		

1.4. Fill-out all the information needed and upload the required documents as indicated on the Checklist of Requirements		None		
1.5. After providing the required information, applicants can review the duly filled out form in the Self-Assessment Review. By agreeing to the Terms and Conditions, the applicants confirm the correctness of information given. (Pre-assessment)	1. Assess the completeness and veracity of documents submitted. If complete, Order of Payment will be generated and will be given to the applicant thru the eService and email notification. If incomplete, the application will not be accepted. A pre-assessment result indicating the grounds for non-acceptance shall be sent by the eServices to the email address of the applicant.	None		CDRR Pre-assessor
2. Print the Order of Payment form with Case Number or Reference Number sent through the declared e-mail address		None		
3. Pay the assessed fee as per the system generated Order of Payment Form through FDAC Cashier or any other means prescribed by FDA (e.g. BANCNET, LANDBANK ONCOLL).	3.1. FDA Cashier receives the payment for FDAC Cashier payments/ receives notification of payment for sbank payments;	Php 500.00 + 1% LRF		FDA Cashier

	3.2. Post payment in eServices for confirmed payments. This will prompt automatic decking of application to respective Center Note: Acknowledgement receipt will automatically be sent to the applicant once payment is posted and will signify the start of processing time of the application.	None		FDA Cashier
	c. This will prompt automatic decking of application to respective Center	None		ICTMD (eService)
4. Receives acknowledgement receipt through email	4.1. The assigned Evaluator reviews for the correctness of the information and documents provided and recommends approval / disapproval of the application which will be forwarded to Quality Assurance. *Any minor deficiencies/clarification will be communicated to the clients through electronic communication (e-NOD).	None	5 working days	CDRR Evaluator

	4.2. QA reviews the recommendation and forwards the application to the CDRR Director for final decision.	None	3 working days	CDRR Supervisor
	4.3. Final Decision Once the CDRR Director approves/disapproves the application, the system automatically generates the CPR/Letter of Disapproval and sends it to the applicant's registered e-mail address for printing.	None	2 working days	CDRR Director
5. Receive notification and link of CPR/Letter of Disapproval for printing. Note: Once approved, applicants are required to surrender the original copy of the Certificate of Product Registration (CPR) within 3 working days.		None	0	
	TOTAL:		10. **Working days**	

36. ISSUANCE OF FOREIGN GOOD MANUFACTURING PRACTICE (GMP) CLEARANCE (DESKTOP EVALUATION) [FOR NON-PIC/S-MEMBER COUNTRIES]

This Clearance is issued to Drug Importers to assure GMP compliance of their Foreign Drug Manufacturers who sell or offer for sale their drug products to the Philippines through submitted documentary evidences and GMP Inspection, as appropriate. This is a requirement for product registration.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Importers of Pharmaceutical Products
Fees t o be Paid	:	FDA-Circular-No.-2014-016 Initial Application of GMP Clearance Php 5,000.00 (per importer per manufacturer per site) + 1% LRF + Php 5,000.00 (FGC Unit review) + 1% LRF Renewal: Php 2,000.00 + 1% LRF Re-issuance of GMP Clearance: Php 1,000.00 + 1% LRF If recommended for Foreign Drug Manufacturer GMP Inspection Application Fee for inspection: Php 3,000.00 + 1% LRF (per application per importer per site) Inspector's Fees ASEAN: US$ 3,500.00 + UNDP-DSA* Asia Pacific: US$ 7,000.00 + UNDP-DSA* Others: US$ 10,500.00 + UNDP-DSA* Accommodations, travel, translator (if necessary), and other incurred fees: Shall be accomplished by importer(s) * UNDP-DSA is per inspector; the fixed fee is per inspection

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE

GENERAL REQUIREMENTS DURING FILING AND RECEIVING OF APPLICATIONS AT THE FOOD AND DRUG ACTION CENTER (FDAC) [as per FDA-Circular-No.-2014-003]: 1. Complete application documentary requirements in a preferred document format stored in USB device (see complete list of requirements below). 2. Original copy(ies) of proof of payment of appropriate fees and charges (machine validated OnColl payment slip or the original copy of the official receipt issued by the FDA Cashier by the Central Receiving for endorsement to Accounting	FDA Website/Applicant Company FDA Cashier/Other FDA-Authorized Payment Portals or Banks
CHECKLIST OF REQUIREMENTS FOR FGMP CLEARANCE APPLICATIONS 1. Foreign GMP Evidence Evaluation ○ Letter of Request ○ Annex B ○ Annex E ○ GMP Evidence ○ Annex C (for Non-PIC/S countries) 2. Foreign GMP Inspection ○ Letter of Request	Applicant Company Applicant Company

• Annex C • Notice of Foreign Inspection • Annex D 3. Renewal of GMP Clearance ○ Letter of Request ○ Annex B ○ Annex E ○ GMP Evidence ○ Copy of GMP Clearance previously issued ○ Annex C (for Non-PIC/S countries) 4. Proof of payment (based on FDA-Circular-No.-2014-016)	Applicant Company FDA Cashier/Other FDA-Authorized Payment Portals or Banks

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits the application for pre-assessment through fdac.letters.cdrr@fda.gov.ph on the assigned submission date as per FDA-Circular-No.-2020-026, Annex A.	1.1 Pre-assesses the completeness of the application.			FDAC *Personnel*

	1.2 Releases the result of the pre-assessment If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*
2. For accepted applications, pays the required fee through any of the following: BANCNET Landbank OnColl Landbank Link.BizPortal Sends proof of payment to the FDAC.	2.1 Endorses the application to CDRR for evaluation.	See Table Above	1 working day	FDA Cashier/ Landbank FDAC *Personnel*
.	2.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3 Decks/Assigns the application to the assigned evaluator	None	1working day	CDRR Director/ CRR Unit Personnel

.	2.4 Evaluates the application according to requirements and prescribed standards	None	50 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
3. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 When the approval of the application is recommended, prepares certification. When the application does not merit an approval recommendation, prepare a Letter of Disapproval (LOD). When the application is recommended for foreign inspection, prepare a Notice of Inspection. **Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication (5 working days to respond to the queries)*	None	1 working day	FDRO I/II/III
	3.2 Encodes and prints the appropriate document for issuance	None	1 working day	FDRO I/II/III
	3.3 Reviews the final output document, affixes initial, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	FDRO III
	3.4 Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	LRD Chief
	3.5 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director

	3.6 Encodes/Updates the Database and Endorses the final output document to the ICTMD (for Certification/ Extension of Validity)/ or Releasing Section (for Notice of Inspection/LOD) *Aside from the hard copy, Notice for Inspection will also be e-mailed to the client	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	3.7 Scans the Releases the Certification/ Extension of validity and updates the database and website	None	1 working day (per batch of applications)	AFS-Records Personnel
4. Receives the Certification/ Notice of Inspection/LOD/Extension of Validity	4. Releases the Certification/Notice of Inspection/LOD/ Extension of Validity to the client *This excludes the application for Foreign GMP Inspection and the inspection proper. The applicant is given 90 working days upon receipt of Notice for Inspection to apply for Foreign GMP Inspection	None	1 working day	FDAC Releasing Section Personnel
5. Endorse Recommendation with complete documents and requirements *Recommendation after on-site inspection	5.1 Accepts the endorsement with complete documents and requirements and encodes/updates the database	None	1 working day	Field Regulatory Operations Office and Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit Personnel
	5.2 Decks/Assigns the application to the assigned evaluator	None	1 working day	CDRR Director/ CRR Unit Personnel

	5.3 Evaluates the application according to requirements and prescribed standards	None	50 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
	5.4 When the approval of the application is recommended, prepares certification. When the application does not merit an approval recommendation, prepare a Letter of Disapproval (LOD). *Any clarifications will be communicated to Drug GMP Inspectorate Task Force	None	1 working day	FDRO I/II/III
	5.5 Encodes and prints the appropriate document for issuance	None	1 working day	FDRO I/II/III
	5.6 Reviews the final output document, affixes initial, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	FDRO III
	5.7 Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	LRD Chief
	5.8 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
.	5.9 Encodes/Updates the Database and Endorses the final output document to the FDA Records Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	5.10 Scans and Endorses the Certification/LOD to AFS-Releasing Section	None	1 working day (per batch of applications)	FDA Records Personnel

6. Receives the Certification/LOD	6. Releases the Certification/LOD	None	1 working day	AFS Releasing Section Personnel
TOTAL: Service is covered under Article 31 (c) of RA 7394 wherein instead of 180 working days, a processing time of 120 working days was proposed.			120 working days	

37. ISSUANCE OF FOREIGN GOOD MANUFACTURING PRACTICE (GMP) COMPLIANCE (DESKTOP EVALUATION) [FOR PIC/S-MEMBER COUNTRIES]

This Clearance is issued to Drug Importers to assure GMP compliance of their Foreign Drug Manufacturers who sell or offer for sale their drug products to the Philippines through submitted documentary evidences and GMP Inspection, as appropriate. This is a requirement for product registration.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Importers of Pharmaceutical Products
Fees to be Paid	:	FDA-Circular-No.-2014-016 Initial Application of GMP Clearance Php 5,000.00 (per importer per manufacturer per site) + 1% LRF + Php 5,000.00 (FGC Unit review) + 1% LRF Renewal: Php 2,000.00 + 1% LRF Re-issuance of GMP Clearance: Php 1,000.00 + 1% LRF If recommended for Foreign Drug Manufacturer GMP Inspection Application Fee for inspection: Php 3,000.00 + 1% LRF (per application per importer per site) Inspector's Fees ASEAN: US$ 3,500.00 + UNDP-DSA* Asia Pacific: US$ 7,000.00 + UNDP-DSA* Others: US$ 10,500.00 + UNDP-DSA* Accommodations, travel, translator (if necessary), and other incurred fees: Shall be accomplished by importer(s) * UNDP-DSA is per inspector; the fixed fee is per inspection

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE

GENERAL REQUIREMENTS DURING FILING AND RECEIVING OF APPLICATIONS AT THE FOOD AND DRUG ACTION CENTER (FDAC) [as per FDA-Circular-No.-2014-003]: Complete application documentary requirements in a preferred document format stored in USB device (see complete list of requirements below). Original copy(ies) of proof of payment of appropriate fees and charges (machine validated OnColl payment slip or the original copy of the official receipt issued by the FDA Cashier - One copy of the OnColl payment slip will be collected by the Central Receiving for endorsement to Accounting.	FDA Website/ Applicant Company FDA Cashier/Other FDA-Authorized Payment Portals or Banks
CHECKLIST OF REQUIREMENTS FOR FGMP CLEARANCE APPLICATIONS 1. Foreign GMP Evidence Evaluation Letter of Request Annex B Annex E GMP Evidence 2. Foreign GMP Inspection Letter of Request Annex C Notice of Foreign Inspection Annex D 3. Renewal of GMP Clearance Letter of Request Annex B Annex E GMP Evidence Copy of GMP Clearance previously issued	Applicant Company Applicant Company Applicant Company

4. Proof of payment (based on FDA-Circular-No.-2014-016)	FDA Cashier/Other FDA-Authorized Payment Portals or Banks

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits the application for pre-assessment through fdac.letters.cdrr@fda.gov.ph on the assigned submission date as per FDA-Circular-No.-2020-026, Annex A.	1.1 Pre-assesses the completeness of the application.			FDAC *Personnel*
	1.2 Releases the result of the pre-assessment If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*
2. For accepted applications, pays the required fee through any of the following:	2.1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above	1 working day	FDA Cashier/ Landbank

• BANCNET • Landbank OnColl • Landbank Link.BizPortal Sends proof of payment to the FDAC.				FDAC *Personnel*
	2.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.3 Decks/Assigns the application to the assigned evaluator	None	1 working day	CDRR Director/ CRR Unit *Personnel*
	2.4 Evaluates the application according to requirements and prescribed standards	None	50 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*
3. If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 When the approval of the application is recommended, prepares certification approval. When the application does not merit an approval recommendation, prepare a Letter of Disapproval (LOD). When the application is recommended for foreign inspection, prepare a Notice of Inspection.	None	1 working day	*FDRO I/II/III*

	*Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication			
	3.2 Encodes and prints the appropriate document for issuance	None	1 working day	*FDRO I/II/III*
	3.3 Reviews the final output document, affixes initial, and forwards it to the Licensing and Registration (LRD) Chief	None	1 working day	*FDRO III*
	3.4 Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	*LRD Chief*
	3.5 Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	3.6 Encodes/Updates the Database and Endorses the final output document to the FDA Records Section	None	1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*
	3.7 Scans and Endorses the Certification / Extension of Validity and updates the database and website	None	1 working day (per batch of applications)	FDA Records *Personnel*
4. Receives the Certification / Notice of Inspection/LOD/ Extension of Validity	4. Releases the Certification/ Notice of Inspection/LOD/ Extension of Validity to the client	None	1 working day	*AFS - Releasing Section Personnel*
Service is covered Article 31 (c) of RA 7394 wherein instead of 180 working days, a processing time of 60 working days was proposed.		**TOTAL:**	**60 working days**	

38. ISSUANCE OF IMPORT LICENSE AMENDMENT

The IL Amendment is granted to Sponsor, Clinical Research Organization and/or Principal Investigator once the proposed changes to the initial IL issued in terms of its validity (two-year extension of the validity of the IL is issued upon submission of an application within 120 calendar days prior to the expiration of the validity of the Initial IL) and request of additional quantity, or update of information of investigational drug products and ancillary supplies needed for the conduct of clinical trial has been approved.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Sponsor, Contract Research Organizations, Importer, and Principal Investigator
Fees to be Paid	:	AO No.-50-2001 Php 500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Administrative Order 2020-0010: Regulations on the Conduct of Clinical Trials for Investigational Products Import License Amendment (Extension of Validity and Addition of Quantity/Item) 1.Cover Letter (FDA-CRS Form 2.0) 2. Investigational Product Information (FDA-CRS Form 4.0) 3. Import License Application Form (FDA-CRS Form 5.0) 4. Rationale for the request and/or supporting data 5. Proof of payment	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. E-mail submission: Sends an application e-mail containing the requirements to fdac.letters.cdrr@fda.gov.ph	1. Generates a Document Tracking Number (DTN) and sends an acknowledgement e-mail with the order of payment to the applicant	None		*FDAC Personnel*
2. Pays the required fee through any of the following: • FDA Cashier • BANCNET • Landbank OnColl Sends proof of payment to the FDAC.	2.1 Receives the payment from the applicant for posting. Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		*FDA Cashier/Landbank* *FDAC Personnel*
	2.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	*Center for Drug Regulation and Research (CDRR)* – *Central Receiving and Releasing (CRR) Unit Personnel*
	2.3 Decks/Assigns the application to the assigned Clinical Research Section (CRS) evaluator	None	1 working day	*CRS Administrative Staff*

3. If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 Evaluates the application according to requirements and prescribed standards *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication (clock stops) *The applicant is expected to respond to the query/queries within seven (7) calendar days. If no response is received from the applicant within the required period, the application shall be disapproved.	None	13 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*
	3.2 Reviews the evaluated application bearing the recommendation of the evaluator	None	2 working days	Clinical Research Section Supervisor
	3.3 Prints the final response and transmittal, and forwards the application to the Product Research and Standards Development Division (PRSDD) Chief	None	1 working day	FDRO I/II/III
	3.4 Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	PRSDD Chief
	3.5 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	3.6 Scans the document with decision and email to the applicant 3.7 Encodes/Updates the Database and Endorses the final output document to the FDAC Releasing Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel

4. Receives the letter	4. Releases the IL Amendment response to the client	None	1 working day	AFS Releasing Section Personnel
	TOTAL:	**PHP 510.00**	**20 working days**	

39. PROCESSING OF IMPORT LICENSE NOTIFICATION

The IL Notification is submitted by the Sponsor or Clinical Research Organization quarterly of every shipment of investigational drug products and ancillary supplies entering the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Simple
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All licensed establishments
Fees to be Paid	:	AO 50 s. 2001, FDA Circular 2012-007-A Php 500.00 + 1% LRF per shipment

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Administrative Order 2020-0010: Regulations on the Conduct of Clinical Trials for Investigational Products	
Import License Notification Requirements	
. Cover Letter (FDA-CRS Form 2.0)	Applicant Company
. Proof of Payment	Applicant Company
. Investigational Product Importation Report (FDA-CRS Form 9.0, Appendix D3	Applicant Company
. Ancillary Supplies Importation Report (FDA-CRS Form 10.0, Appendix D4), if applicable	Applicant Company
. Copy of Proforma Invoice/s	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. E-mail submission: Sends an application e-mail containing the requirements to fdac.letters.cdrr@fda.gov.ph	1. Generates a Document Tracking Number (DTN) and sends an acknowledgement e-mail with the order of payment to the applicant	None		*FDAC Personnel*

2. Pays the required fee through any of the following: • FDA Cashier • BANCNET • Landbank OnColl Sends proof of payment to the FDAC.	2.1 Endorses the application to CDRR for evaluation.	See Table Above		*FDA Cashier/ Landbank FDAC Personnel*
	2.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	*Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit*
	2.3 Decks/Assigns the application to the assigned Clinical Research Section (CRS) evaluator	None	1 working day	*CRS Administrative Staff*
	2.4 Evaluates the application according to requirements and prescribed standards	None	1 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*
	2.5 Encodes/Updates the Import License Database	None	1 working days	*FDRO I/II/III Evaluator)*
	TOTAL:	**PHP 510.00/ shipment**	**3 working days**	

40 . ISSUANCE OF INITIAL CLINICAL TRIAL APPROVAL (CTA) AND IMPORT LICENSE APPROVAL (ILA) UNDER REGULATORY RELIANCE

The CTA is granted to Sponsor, Clinical Research Organization and/or Principal Investigator to conduct a clinical trial of an investigational drug product. On the other hand, the IL is granted to Sponsor, Clinical Research Organization and/or Principal Investigator to allow importation of investigational product and ancillary supplies necessary for the conduct of clinical trial. The Philippine FDA recognizes the other National Regulatory Authority decision in the issuance of CT approval based on the criteria set under FDA Circular 2023-004.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Sponsors, Contract Research Organizations (CROs), Principal Investigators and Importers of Pharmaceutical Products
Fees to be Paid	:	AO No.-50-2001 & FDA Circular No.2012-007-A : Php 2,500.00 + 1% LRF Fee for External Regulatory Reviewers: Php 60,000.00 Import License for Clinical Study: Php 500.00/importation + 1% LRF

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
AO 2020-0010 : Regulations on the Conduct of Clinical Trials for Investigational Products Initial Clinical Trial & Import License Application Requirements 1. Table of Contents for Clinical Trial Application 2. Cover Letter for Application 3. Clinical Trial Application Form 4. Investigational Product and Ancillary Supplies Information 5. Import License Application 6. Proof of payment 7. Letter of Authorization 8. Clinical Trial Protocol and amendment(s), where applicable 9. GCP Certificate and Curriculum vitae (CV) for investigators of each trial site	Applicant Company

10. Informed Consent Form/Assent Form 11. Investigator's Brochure 12. Pharmaceutical Data 13. GMP Certificate from NRA and/or evidence of GMP compliance 14. Shipping condition for IP and trial related materials 15. Labelling Materials of the Investigational product	
Additional requirements based on FDA Circular No.2023-004 16. A formal letter written request from the applicant notifying the FDA of its intent to avail of the abridged review, identifying the RDRA. 17. Copy of the clinical trial approval or any equivalent from the identified RDRA. Proof of conduct of the clinical trial in the country of RDRA such as clinical trial registry. 18. A Sworn Assurance duly signed by the Sponsor or the authorized CRO stating the requirements under Section V.A.7.b and A.7.c of the Circular	
References: 1. Administrative Order 2020-0010 - Regulations on the Conduct of Clinical Trials for Investigational Products 2. FDA Circular No.2023-004 - Guidelines on Regulatory Reliance on the Conduct of Clinical Trials	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. E-mail submission: Submits the application for preassessment through clinicalresearch@fda.gov.ph.	Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the preassessment, issue the Document Tracking Number (DTN), and instructs the client to proceed with the payment. If the application did not satisfactorily pass the pre-assessment, inform the client of the deficiency/ies.	None	1 working day	CRS Administrative Staff

For accepted applications, pays the required fee through any of the following: • FDA Cashier • BANCNET • Landbank OnColl Sends proof of payment to Clinical Research Section through clinicalresearch@fda.gov.ph	1 Upon receipt of the proof of payment, the application will be encoded/update in the database.	Php 2,500.00 + 1% LRF Import License for Clinical Study: Php 500.00/importation + 1% LRF	1 working day ***Timeline starts after posting of payment**	CRS Administrative Staff
	2.2 Decks/Assigns the application to an evaluator.	None	1 working day	CRS Administrative Staff
	2.3 Evaluates the application for completeness and scientific worth *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication (3 working days to respond to the queries)	None	1 working day	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
	2.4 If the application is deemed complete, assign a regulatory reviewer and issue regulatory review permit to the applicant.	None	1 working day	FDRO I/II/III
	2.5 Reviews Pharmaceutical data requirements and Import License application	None	15 working days	FDRO I/II/III

3. If an electronic notice of deficiencies (E-NOD) was issued by the external regulatory reviewer, submits complete compliance documents to the evaluator.	3. Assesses the application though the FDA CT Assessment Form *Any clarifications/ deficiencies will be communicated to the clients through electronic communication (10 calendar days to respond to the queries)	Fee for External Regulatory Reviewers: Php 60,000.00 (direct to External reviewers) FDA Circular 2012-007-A	15 working days	External Regulatory reviewer *[St. Luke's Medical Center (SLMC), University of the Philippines – National Institutes of Health (UP-NIH), Philippine Heart Center (PHC)]*
	*This constitutes a stop clock on the processing time (based on AO 2020-0010, Section VI, Paragraph 5.6)			
	3.1 Reviews the assessment from the Regulatory Reviewer	None	1 working day	FDRO I/II/III
	3.2 Reviews the evaluated application bearing the recommendation of the evaluator	None	1 working day	Clinical Research Section Supervisor
	3.4 Prints the final response and forwards it to the Product Research and Standards Development Division (PRSDD) Chief	None	1 working day	FDRO I/II/III
	3.5 Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	PRSDD Chief

	3.6 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	3.7 Encodes/Updates the Database and Endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
4. Receives the approval	4. Releases the appropriate CT response and IL to the client	None	1 working day	AFS Releasing Section Personnel
	TOTAL:	**PHP 63,035.00**	**20 Working days**	

41. ISSUANCE OF POST-MARKETING SURVEILLANCE (PHASE IV Clinical Study) Application Approval [as post-approval requirement if additional activity(ies) are necessary based on FDA Circular No. 2021-020]

This Approval of Post-Marketing Surveillance (Phase IV Clinical Study) Application is issued to applicants as part of the post-approval requirements in the issuance of a Certificate of Product Registration for Monitored-Release/New Chemical Entities applications if additional activity(ies) are necessary based on FDA-Circular-No.2021-020.

Center/Office/Division	:	l Regulation and Research
Classification	:	al
Type of Transaction	:	nent-to-Businesses
Who May Avail	:	All Sponsors, Contract Research Organizations (CROs), and Importers of Pharmaceutical Products Note: This is only applicable if additional PV activity(ies) are determined to be necessary by FDA based on FDA-Circular-No.2021-020
Fees to be Paid	:	nistrative-Order-No.-50-2001 Protocol for MR/Post Marketing Surveillance: Php 2,500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE

Time schedule or duration of clinical trial. Duties and responsibilities of research personnel. a. The investigator must conduct the studies in conformance with the “Declaration of Helsinki” or the laws and regulations of the country in which the research is conducted, whichever represent the greater protection of the individual b. The investigator must keep careful records of his study and retain them for at least two years after the new drug application is approved. The records must be available promptly to the drug sponsor (usually the drug manufacturer) and to the drug regulatory agency. Progress reports must be sent to the sponsor at intervals not exceeding one year. c. The investigator must send emergency reports to the sponsor and the regulatory agency when dangerous adverse effects are observed. d. The investigators must observe the regulations regarding consent of human subjects being given an investigational drug. Bibliography List of Hospital Resources/Personnel Required. List of Basic Sciences Resources Appendices including informed consent form, patient/case report form, flowchart of activities, questionnaire, dummy tables and graphs. A statement that the protocol was reviewed and approved by the Research Committee and the Director (and Dean, if applicable) of the institution/hospital. Informed Consent Form compliant to the ICH E6(R2) section 4.8 Case Report Form Proof of Payment	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submits application with complete requirements. The requirements should be included in the MR/NCE application. If application fee is not included in the MR/NCE application payment, pay for the required fee through any of the following: FDA Cashier BANCNET Landbank OnColl Then, send the proof of payment to FDAC.	1.1 Endorses the application to CDRR for evaluation.	AO 50 s. 2001 Protocol for MR/Post Marketing Surveillance: Php 2,500.00 +1% LRF	*Timeline starts after posting of payment	FDAC Personnel
	1.2 Receives the application from FDAC.	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit Personnel
	1.3 Endorses the PMS (Phase IV Clinical Study) application requirements to the Clinical Research Section (CRS) of the PRSDD.	None		Licensing and Registration Division (LRD) Evaluator; and/or CDRR-CRR Unit Personnel
	1.4 Decks/assigns the application to the evaluators of the CRS.	None	1 working day	Clinical Research Section (CRS) Supervisor
If an electronic Notice of Deficiencies (eNOD) was issued by the evaluator, submits complete compliance documents to the evaluator.	2.1 Evaluates the application for completeness and scientific worth.	None	29 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator) or FDRO III /

				Medical Specialist II (Senior Evaluator)
	2.2 Reviews the evaluated application bearing the recommendation of the evaluator. *After checking of the CRS supervisor, any minor deficiencies/ clarifications will be communicated to the clients through electronic communication (5 working days to respond to the queries, unless client requested for extension).	None	5 working days	CRS Supervisor
	2.3 Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD) Chief.	None	1 working day	FDRO I/II/III or MS II
	2.4 Checks and recommends the decision of the evaluator/s by affixing initial/signature.	None	1 working day (per batch of applications)	PRSDD Chief
	2.5 Signs and approves the final decision.	None	1 working day (per batch of applications)	CDRR Director
	2.6 Encodes/updates the database and endorses the Approval/Disapproval Letter (final output document) to the AFS Releasing Section. The scanned copy of this document is sent electronically to the client.	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
Receives the documents.	3. Releases the hard copy of the Approval/Disapproval Letter to the client.	None	1 working day	AFS Releasing Section Personnel
TOTAL: (Simultaneously processed with the Monitored-Release Registration application within the 180-day timeline of Monitored-Release application; or processed as post-approval requirement if additional PV activities will be required based on FDA Circular No. 2021-020; Service is covered under RA 3720 and 7394).		Php 2,525.00	At least 40 Working Days	

42. ISSUANCE OF SALES PROMO PERMIT OF PHARMACEUTICAL PRODUCTS (INITIAL AND AMENDMENT)

This permit is issued to concerned parties for the conduct of their sales promotion activities of applicable drug products.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, Traders, and Retailers of Pharmaceutical Products

Fees to be Paid	:	As per DTI-DOH JAO NO. 1 s. 2000: Prescribing a Schedule of Fees and Charges for Sales Promotion Activities Initial: The permit fees for the conduct of sales promotion schemes shall be as follows: Coverage: (Fees) NCR only or in several regions in NCR and Nationwide — Php 1,000 + 1% LRF More than one (1) region in NCR and Nationwide — Php 750 + 1% LRF Several provinces/cities/municipalities within a single region — Php 500 + 1% LRF Single province/city/municipality — Php 250 + 1% LRF The amount of fees for sales promotions (except for discount scheme type of promotion) which includes variables covered by blanket approval (covering a period of one (1) year as prescribed by the Consumer Act) shall be in accordance with the enumerated hereunder or in accordance with geographical areas, whichever is higher: Amount of Prices: (Fees) Up to Php 50,000 — Php 250 + 1% LRF Php 50,000 - Php 150,000 — Php 500 + 1% LRF Php 150,000 - below Php 300,000 — Php 1,000 + 1% LRF Php 300, 001 -Php 500,000 — Php 2,000 + 1% LRF Php 500,001 - Php 1,000,000 — Php 3,000 + 1% LRF Above Php 1,000.000 — Php 5,000 + 1% LRF Amendment: Php 310

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR SALES PROMO PERMIT	
INITIAL	
Accomplished Integrated Application Form	Applicant Company
Letter of Intent for application of Promo Permit	Applicant Company
List of Participating Products in Excel Format (Sheet 3 of Information Sheet)	Applicant Company
Copy of the valid product notification/registration/ exemption	Applicant Company
Information Sheet and Mechanics of the Sales Promotion	Applicant Company
Layout of Promo materials (if applicable)	Applicant Company
Proof of payment	Applicant Company
Self-Assessment Form for Sales Promo Permit	Applicant Company
AMENDMENT	
Accomplished Integrated Application Form	Applicant Company
Letter of Intent specifying the type of amendment	Applicant Company
Copy of previously issued valid promo permit	Applicant Company
Supporting documents for the requested amendment	Applicant Company
Proof of payment	Applicant Company
Self-Assessment Form for Sales Promo Permit	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
. Secure a schedule of appointment / submission to FDAC	1. Sends the scheduled date of submission for pre-assessment	None		FDAC Personnel

2. E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR Personnel
3. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.bizPortal Sends proof of payment to the FDAC.	1 Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above		FDA Cashier/ Landbank FDAC Personnel
	3.2 Receives the application from FDAC and encodes/updates the database	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	3.3 Decks/Assigns the application to the assigned evaluator	None	1 working day	CRR Unit Personnel

4. If an electronic notice of deficiencies (E-NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4.1 Evaluates the application according to requirements and prescribed standards *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	11 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)
	4.2 Prints the final response and transmittal, and forwards it to the Senior Evaluator	None	1 working day	
	4.3 Reviews the evaluated application bearing the recommendation of the junior evaluator and forwards the application to the Licensing and Registration (LRD) Chief	None	2 working days	FDRO III (Senior Evaluator)
	4.4 Checks and recommends the decision of the senior evaluator/s by affixing initial/signature		1 working day (per batch of applications)	LRD Chief
	4.5 Signs and approves the final decision	None	1 working day (per batch of applications)	CDRR Director
	4.6 Encodes/Updates the Database and endorses the final response to the AFS Releasing Section	None	1 working day (per batch of applications)	CDRR-CRR Unit Personnel
5. Receives the final response (sales promo permit or letter of disapproval)	5. Releases the final response to the client (sales promo permit or letter of disapproval)	None	1 working day	AFS Releasing Section Personnel
	TOTAL:		**20 working days**	

43. PROCESSING OF PRODUCT CLASSIFICATION APPLICATION

The Product Classification is granted to Marketing Authorization Holder in order to identify if the product is classified as a drug, medical device, food supplement or cosmetics or non-registrable in FDA.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All licensed establishments
Fees to be Paid	:	Administrative Order No.-50-2001 Php 500.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Product Classification Requirements 1. Letter of intent 2. Complete Technical Profile of the Product, shall include the following: description, formulation/list of ingredients with corresponding amount per unit dose, indication, direction for use, claims (if any), labelling materials/brochures 3. Classification of the product in the country of origin 1. List of countries where the product is currently marketed and the corresponding classification of the product 2. Representative sample 3. Proof of Payment	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an application email containing the requirements to fdac.letters.cdrr@fda.gov.ph following the correct submission schedule	1. Generates a Document Tracking Number (DTN) and sends an acknowledgement email with the order of payment to the applicant	None		FDAC *Personnel*

2. Pay for the required fee through any of the following: FDA Cashier BANCNET Landbank OnColl Then send the proof of payment to the FDAC.	2.1 Receives the payment from the applicant for posting Upon receipt of the proof of payment, endorses the application to CDRR for evaluation	See Table Above	*Timeline starts after posting of payment	FDA Cashier/ Landbank FDAC *Personnel*
	2.3 Receives the application from FDAC and encodes/updates the database and FIS	None	1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	2.4 Decks/Assigns the application to the assigned evaluator	None	1 working day	CRS Administrative Staff
3. If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	3.1 Evaluates the application according to requirements and prescribed standards *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	13 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)*
	3.2 Reviews the evaluated application bearing the recommendation of the evaluator	None	2 working days	*Clinical Research Section Supervisor*

	3.3 Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD) Chief	None	1 working day	*FDRO I/II/III*
	3.4 Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	1 working day (per batch of applications)	*PRSDD Chief*
	3.5 Signs and approves the final decision	None	1 working day (per batch of applications)	*CDRR Director*
	3.6 Scans the document with decision and email to the applicant Encodes/Updates the Database and Endorses the final output document to the AFS Releasing Section	None	1 working day (per batch of applications)	*CDRR-CRR Unit Personnel*
4. Receives the letter	4. Releases the letter to the client	None	1 working day	AFS Releasing Section Personnel
TOTAL:		PHP 510.00	20 working days	

CENTER FOR FOOD REGULATION AND RESEARCH
EXTERNAL

1. ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR)

1.1. ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) – AMENDMENT (INITIAL APPLICATION APPROVED FROM MODIFIED E-REGISTRATION (VERSION 2))

'Registration' means the process of approval of an application to register health products prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable, the use, testing, promotion, advertisement, and/or sponsorship of health products. (Republic Act No. 9711)

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Government to Business
Type of Transaction	:	Highly Technical
Who May Avail	:	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	:	In accordance to Administrative Order 50 s. 2001 + Legal Research Fee (LRF). Change or Extension of Shelf-life: Php 1,000.00 + 1% LRF Other Types of Amendment: Php 200.00 + 1% LRF

GENERAL GUIDELINES *Please refer to:* A. General Guidelines, B. Specific Guidelines, and C. Procedural Guidelines, IV. GUIDELINES, pages 2-10 of FDA Circular No. 2020-033 || Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products"; and 2) III. General Guidelines, and IV. Specific Guidelines of FDA Circular No. 2020-033-A || Addendum to FDA Circular No. 2020-033, "Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products" to include Guidelines for Pre-assessment and Reiteration of Pre-Assessment Procedures in Applying for Certificate of Product Registration for Food		
CHECKLIST OF REQUIREMENTS FOR ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION: RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS		
GENERAL REQUIREMENTS	BASIS/ISSUANCE	WHERE TO SECURE
☑ Accomplished Application Form as prescribed by FDA regulations e.g. E-Registration System	Administrative No. Order 2014-0029	https://www.fda.gov.ph/

☑ Proof of Payment of Fees as prescribed by current FDA regulations.		Administrative Order 50 s. 2001	Systems/Means prescribed by FDA
☑ Scanned Application Letter stating the intended changes (indicate ALL the changes/amendments to be made)		Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company
☑ VALID AND APPROPRIATE FDA LICENSE TO OPERATE (LTO) (REQUIRED FOR ALL TYPES OF CPR APPLICATION) *The product being applied must be listed in the FDA approved Product Line/Category.		Administrative No. Order 2014-0029 Republic Act 9711	FDA Philippines
ADDITIONAL Requirements per Amendment Type			
AMENDMENT TYPE	☑ ADDITIONAL REQUIREMENTS	BASIS	WHERE TO SECURE
2a. Change in Brand Name	☑ Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations ☑ Authority from the source or the owner of the brand (imported & local) ☑ IPO registration, if available.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company Source/Supplier/Brand Owner IPO/Source/ Supplier
2b. Change in Product Name/Additional Product Description	☑ Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations *Change in % Alcohol Content and Vintage in Wines as per FDA Circular No. 2020-033-B.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2c. Change in Company Name/Business Name	☑ Proof of change in business name (e.g. License to Operate)	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier

	☑Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations		
2d. Change in/Additional Supplier	☑ Any of the following scanned copy of the original documents: Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement from the new supplier.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2e. Change in Packaging Material and/or Additional Packaging Type	☑ Clear and complete proposed loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations ☑ Pictures of the product in all angles and in different packaging sizes, and from at least two different perspectives allowing visual recognition of a product as the same with the one being registered. ☑ Proof of suitability of packaging material for food, including stability of the product in the new packaging.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2f. Change of Packaging in Commercial Presentation (Change/Additional Packaging Size)	☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2g. Change or Extension in Shelf-Life	☑ Stability study results with conclusion to support extension or change in shelf-life	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier

2h. Change in/Additional Packaging design	☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations *Change in % Alcohol Content and Vintage in Wines as per FDA Circular No. 2020-033-B.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hi. Addition of Claims for Logos	☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. ☑ Valid Certificate (e.g. HALAL, Sangkap pinoy seal, Organic, Kosher, etc.)	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hii. Change in Label Color	☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hiii. Change in Font Size for Product Information	☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hiv. Change/Additional Claims for Source of Vitamins/Minerals and Health and Nutrition Claims	☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier

	☑ Certificate of Analysis (duly signed by competent technical staff including the complete name with appropriate parameters and result) or documents to substantiate claims.		
2hv. Change /Update in Nutrition Information (Vitamin and Mineral)	☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. ☑ Certificate of Analysis (duly signed by competent technical staff including the complete name with appropriate parameters and result).	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hvi. Change/Additional Menu or Serving suggestion (Photograph)	☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hvii. Compliance to CPR Remarks	☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hviii. Declaration of Distributor	☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. ☑ Distributorship Agreement (Notarized, signed by the MAH/	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier

	Applicant Company and distributor reflecting the correct address		
2hix. Change of Manufacturer's Name	☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. ☑ Attestation letter from the manufacturer stating the reason for change in manufacturer's name, **and/or** ANY of the scanned copy of the original document issued by the Regulatory/ Health Authority/Recognized Issuing body/ Attested by recognized Association or duly authenticated by the Philippine Consulate from the country of origin: Certificate of Registration with GMP Compliance or its equivalent or Valid Sanitary Phyto-Sanitary Certificate or Health Certificate or ISO 22000 Certificate or FSSC Certificate or HACCP Certificate or Certificate of Free Sale.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hx. Locally Produced with Additional Activity for Export	☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. ☑ LTO as food exporter if the company is not manufacturer.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier

2hxi. Declaration of "Exclusively Distributed by"	☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. ☑ Terms of Agreement/Exclusive Distributorship Agreement.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2hxii. Declaration of Manufacturer's Office Address on the Label	☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2i. Transfer of Ownership of a Registered Product	☑ Proof of Agreement between previous and current owners of the product transferring ownership ☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2j. Change in Importer/Distributor/Trader	☑ Termination of agreement/Deed of assignment ☑ Agreement of new manufacturer/importer/distributor or Appointment letter ☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier

2k. For Change in Importer/Distributor/Trader using a new user account:	☑ Termination of agreement/Deed of assignment ☑ Agreement of new manufacturer/importer/distributor or Appointment letter ☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations. ☑ Upload ALL INITIAL requirements	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2l. Change in Company Address/Business Address (Not Applicable to Manufacturer and Repacker)	☑ Proof of change in business name (e.g. License to Operate) ☑ Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2m. Change in LTO Number and/or LTO Validity	☑ Copy of updated License to Operate	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier
2n. Exportation of Previously Registered Product Initially for Local Distribution.	☑ Clear and complete loose labels or artworks as applicable, of all packaging sizes, or equivalents as defined by FDA regulations or reflecting compliance to labelling requirements of importing country (if label is different from the approved one) ☑ Copy of License to Operate as Food Exporter	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier

2o. Other Cases as Declared in Succeeding FDA Issuances (Examples but not limited to the following; as long as there is no change in formulation and no change in manufacturer's address)	e.g. Change in Product Specification ☑ Copy of updated Product Specification Sheet e.g. Change in Lot Code and Interpretation ☑ Copy of updated Product Specification Sheet ☑ Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Source/Supplier

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1.1. Files using the specific product/CASE NUMBER in the INBOX folder, and then accomplishes (including uploading of the COMPLETE documentary requirements) the E-Registration System through the E-Portal https://eportal.fda.gov.ph based on the desired type of application in accordance to current FDA regulation/s on the use of the E-Registration Portal/E-Services. 1.2. Forwards the application to **PRE-ASSESSMENT**.	**1.** Pre-assesses ONLY the completeness of the submitted documents through E-Registration System/E-Portal https://eportal.fda.gov.ph. Result of Pre-assessment will be received by the account holder.	Day 0	Center for Food Regulation and Research (CFRR) PRE-ASSESSOR (e.g. Food-Drug Regulation Officer (FDRO))

A system generated E-mail notification from FDA will be received by the client upon submission of application for Pre-Assessment.			
2. (If COMPLETE) Receives the Order of Payment. (If INCOMPLETE) Receives result of Pre-Assessment (Letter of Denial)	2. If found **COMPLETE**, Generates Order of Payment through the email of the account holder/client. If found **INCOMPLETE**, Generates result of Pre-Assessment.	Day 0	CFRR PRE-ASSESSOR (e.g. FDRO)
3. Pays the assessed fee through Systems/Means prescribed by FDA.	3.1. Receives the payment/Official Receipt (OR)/ proof of payment through Systems/Means prescribed by FDA, and then posts the payment. 3.2. Forwards application to CFRR, **once payment is posted**.	Day 0 ***Refer to FDA Cashier 's Citizen Charter***	Administrative and Finance Services (AFS) STAFF
4. Receives Acknowledgement Receipt with the application and pre-assessment details.	4.1. Evaluates the application and ALL the submitted documentary requirements in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, drafts recommendation if the application is for Approval or Disapproval, and then forwards the same to the CHECKER.	8 Working Days	LRD EVALUATOR (e.g. FDRO)
	4.2. Checks application, ALL the submitted documentary requirements, the drafted recommendation of the EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, drafts recommendation if the application is for Approval or Disapproval, and then forwards the same to the APPROVING AUTHORITY.	7 Working Days	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)

	4.3 Reviews the checked application, ALL the submitted documentary requirements, the drafted recommendation of the CHECKER, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, and then finalizes the application by issuing **Certificate of Product Registration (CPR) (for APPROVED application)** or **Letter of Denial (LOD) (for DISAPPROVED application)**, through the E-Registration System.	5 Working Days	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
5. If the application is **APPROVED**, Receives an e-mail notification from FDA indicating that the application is approved, and other pertinent information. If **DISAPPROVED**, receives a Letter of Denial/Disapproval (LOD) and another e-mail notification containing pertinent information about the application.	5. Generates electronically signed CPR or LOD.		Information and Communication Technology Management Division (ICTMD) STAFF
		TOTAL: 20 Working Days	
Always refer to the current FDA regulation/s on the use of the E-Registration System/E-Services: https://www.fda.gov.ph/			

1.2. ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) – AUTOMATIC RENEWAL APPLICATION (INITIAL APPLICATION APPROVED FROM MODIFIED E-REGISTRATION (VERSION 2))

'Registration' means the process of approval of an application to register health products prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable, the use, testing, promotion, advertisement, and/or sponsorship of health products. (Republic Act No. 9711)

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Government to Business
Type of Transaction	**:**	Highly Technical
Who May Avail	**:**	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	**:**	In accordance to Administrative Order 50 s. 2001 + Legal Research Fee (LRF). Conventional Food (Category 1): Php 1,000.00/5 years of validity + 1% LRF Conventional Food (Category 2): Php 1,250.00/5 year of validity + 1% LRF Food Supplement: Php 5,000.00/5 years of validity + 1% LRF Bottled Water: Php 5,000.00/5 years of validity + 1% LRF

GENERAL GUIDELINES

Please refer to:

1) A. General Guidelines, B. Specific Guidelines, and C. Procedural Guidelines, IV. GUIDELINES, pages 2-10 of FDA Circular No. 2020-033 || Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products"; and

2) III. General Guidelines, and IV. Specific Guidelines of FDA Circular No. 2020-033-A || Addendum to FDA Circular No. 2020-033, "Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products" to include Guidelines for Pre-assessment and Reiteration of Pre-Assessment Procedures in Applying for Certificate of Product Registration for Food

GENERAL REQUIREMENTS	BASIS/ISSUANCE	WHERE TO SECURE
☑ Accomplished Application Form as prescribed by FDA regulations. e.g. E-Registration System. Select "RENEWAL" as type of application	FDA Circular No.2020-033 FDA Circular No.2020-033-A	https://www.fda.gov.ph/

using the same case number used in initial application.		
☑ Proof of payment of fees as prescribed by current FDA regulations	Administrative Order 50 s. 2001	Systems/Means prescribed by FDA
☑ Valid and appropriate FDA License to Operate (required for all types of CPR application) *The product being applied must be listed in the FDA approved Product Line/Category.	Administrative No. Order 2014-0029 Republic Act 9711	FDA Philippines
☑ A sworn statement indicating no change in or variation whatsoever in the product is attached to the application.	Implementing Rules and Regulations of Republic Act No. 9711	Applicant Company

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1.1. Files using the specific product/CASE NUMBER in the INBOX folder, and accomplishes (including uploading of the COMPLETE documentary requirements) the E-Registration System through the E-Portal https://eportal.fda.gov.ph based on the desired type of application in accordance to current FDA regulation/s on the use of the E-Registration Portal/E-Services. 1.2. Forwards the application to **PRE-ASSESSMENT**. A system generated E-mail notification from FDA will be received by the client	1. Pre-assesses ONLY the completeness of the submitted documents through E-Registration System/E-Portal https://eportal.fda.gov.ph. Result of Pre-assessment will be received by the account holder.	Day 0	Center for Food Regulation and Research (CFRR) PRE-ASSESSOR (e.g. Food-Drug Regulation Officer (FDRO))

upon submission of application for Pre-Assessment.			
2. (If COMPLETE) Receives the Order of Payment. (If INCOMPLETE) Receives result of Pre-Assessment (Letter of Denial)	2. If found **COMPLETE**, Generates Order of Payment through the email of the account holder/client. If found **INCOMPLETE**, Generates result of Pre-Assessment.	Day 0	CFRR PRE-ASSESSOR (e.g. FDRO)
3. Pays the assessed fee through Systems/Means prescribed by FDA	**3.1.** Receives the payment/Official Receipt (OR)/ proof of payment through Systems/Means prescribed by FDA, and then posts the payment. 3.2. Forwards application to CFRR, **once payment is posted**.	Day 0 ***Refer to FDA Cashier 's Citizen Charter***	Administrative and Finance Services (AFS) STAFF
4. Receives Acknowledgement Receipt with the application and pre-assessment details.	4. Finalizes the application by issuing **Certificate of Product Registration (CPR) (for APPROVED application)** or **Letter of Denial (LOD) (for DISAPPROVED application)**, through the E-Registration System.	3 Working Days	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
5. If the application is **APPROVED**, Receives an e-mail notification from FDA regarding the issuance of Certificate of Product Registration (CPR), and other pertinent information. If **DISAPPROVED**, Receives an e-mail notification from FDA regarding the issuance of Letter of Denial/Disapproval (LOD), and other pertinent information.	5. Generates electronically signed CPR or LOD.		Information and Communication Technology Management Division (ICTMD) STAFF

		TOTAL: 3 Working Days	
Always refer to the current FDA regulation/s on the use of the E-Registration System/E-Services: https://www.fda.gov.ph/			

1.3. ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR): AUTOMATIC RENEWAL (DATA CAPTURE)

'Registration' means the process of approval of an application to register health products prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable, the use, testing, promotion, advertisement, and/or sponsorship of health products. (Republic Act No. 9711)

(DATA CAPTURE in the modified e-Registration System/Portal (Version 2) refers to applications processed in the old e-Registration Portal (Version 1) or thru manual registration system)

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Government to Business
Type of Transaction	:	Highly Technical
Who May Avail	:	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	:	In accordance to Administrative Order 50 s. 2001 + Legal Research Fee (LRF). Conventional Food (Category 1): Php 1,000.00/5 years of validity + 1% LRF Conventional Food (Category 2): Php 1,250.00/5 year of validity + 1% LRF Food Supplement: Php 5,000.00/5 years of validity + 1% LRF Bottled Water: Php 5,000.00/5 years of validity + 1% LRF

GENERAL GUIDELINES
Please refer to:
1) A. General Guidelines, B. Specific Guidelines, and C. Procedural Guidelines, IV. GUIDELINES, pages 2-10 of FDA Circular No. 2020-033 || Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products"; and

2) III. General Guidelines, and IV. Specific Guidelines of FDA Circular No. 2020-033-A || Addendum to FDA Circular No. 2020-033, "Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products" to include Guidelines for Pre-assessment and Reiteration of Pre-Assessment Procedures in Applying for Certificate of Product Registration for Food

CHECKLIST OF REQUIREMENTS FOR ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION: RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS		
GENERAL REQUIREMENTS	**BASIS/ISSUANCE**	**WHERE TO SECURE**
☑ Accomplished Application Form as prescribed by FDA regulations. e.g. E-Registration System.	FDA Circular No.2020-033 FDA Circular No. 2020-033-A	https://www.fda.gov.ph/
☑ Proof of payment of fees as prescribed by current FDA regulations	Administrative Order 50 s. 2001	Systems/Means prescribed by FDA
☑ Valid and appropriate FDA License to Operate (LTO) (required for all types of CPR application) *The product being applied must be listed in the FDA approved Product Line/Category.	Administrative No. Order 2014-0029 Republic Act No. 9711	FDA
☑ A sworn statement indicating no change in or variation whatsoever in the product is attached to the application.	Implementing Rules and Regulations of Republic Act No. 9711	Applicant Company
☑ Upload **ALL INITIAL** requirements.	Administrative No. Order 2014-0029 FDA Circular No. 2020-033	Applicant Company/ In reference to the previously filed and approved INITIAL application (The validity of the documents to be submitted must be in accordance to current FDA regulation/s).

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1.1. Accomplishes (including uploading of the COMPLETE documentary requirements) the E-Registration System through the E-Portal https://eportal.fda.gov.ph based on the desired type of application in accordance to current FDA regulation/s on the use of	1. Pre-assesses ONLY the completeness of the submitted documents through E-Registration System/E-Portal https://eportal.fda.gov.ph. Result of Pre-assessment will be received by the account holder.		Center for Food Regulation and Research (CFRR) PRE-ASSESSOR (e.g. Food-Drug Regulation Officer (FDRO))

the E-Registration Portal/E-Services. 1.2. Forwards the application to **PRE-ASSESSMENT**. A system generated E-mail notification from FDA will be received by the client upon submission of application for Pre-Assessment.			
2. (If COMPLETE) Receives the Order of Payment. (If INCOMPLETE) Receives result of Pre-Assessment (Letter of Denial)	2. If found **COMPLETE**, Generates Order of Payment through the email of the account holder/client. If found **INCOMPLETE**, Generates result of Pre-Assessment. To refile, the applicant must **start a NEW CASE** and upload initially submitted documentary requirements together with the documents for compliance to the deficiencies mentioned.		CFRR PRE-ASSESSOR (e.g. FDRO)
3. Pays the assessed fee through Systems/Means prescribed by FDA	3.1. Receives the payment/Official Receipt (OR)/ proof of payment through Systems/Means prescribed by FDA, and then post the payment. 3.2. Forwards application to CFRR, **once payment is posted.**	***Refer to FDA Cashier 's Citizen Charter***	Administrative and Finance Services (AFS) STAFF
4. The applicant company receives Acknowledgement Receipt with the application and pre-assessment details.	4.1 Evaluates the application and ALL the submitted documentary requirements in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, then drafts recommendation if the application is for Approval or Disapproval, and then forwards the same to the CHECKER.	3 Working Days	LRD EVALUATOR (e.g. FDRO)

	4.2 Reviews the evaluated application, ALL the submitted documentary requirements, and the drafted recommendation of the EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, then drafts recommendation if the application is for Approval or Disapproval, and then forwards the same to the APPROVING AUTHORITY.	2 Working Days	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)
	4.3 Reviews the checked application, ALL the submitted documentary requirements, and the drafted recommendation of the CHECKER, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, and then finalizes the application by issuing **Certificate of Product Registration (CPR) (for APPROVED application)** or **Letter of Denial (LOD) (for DISAPPROVED application)**, through the E-Registration System.	2 Working Days	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
5. If the application is **APPROVED**, Receives an e-mail notification from FDA regarding the issuance of Certificate of Product Registration (CPR), and other pertinent information. If **DISAPPROVED**, Receives an e-mail notification from FDA regarding the issuance of Letter of Denial/Disapproval (LOD), and other pertinent information.	5. Generates electronically signed CPR or LOD.		Information and Communication Technology Management Division (ICTMD) STAFF
		TOTAL: 7 Working Days	
Always refer to the current FDA regulation/s on the use of the E-Registration System/E-Services: https://www.fda.gov.ph/			

1.4. CERTIFICATE OF PRODUCT REGISTRATION (CPR) – INITIAL/ RENEWAL DATA CAPTURE (REGULAR)/ AMENDMENT DATA CAPTURE/ RE-APPLICATION DATA CAPTURE

'Registration' means the process of approval of an application to register health products prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable, the use, testing, promotion, advertisement, and/or sponsorship of health products. (Republic Act No. 9711)

(DATA CAPTURE in the modified e-Registration System/Portal refers to applications processed in the old e-Registration Portal (Version 1) or thru manual registration system).

RENEWAL DATA CAPTURE (REGULAR) in the modified e-Registration System/Portal refers to applications processed in the old e-Registration Portal (Version 1) or thru manual registration system) which is not qualified to the General Guideline/s of AUTOMATIC RENEWAL.

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Government to Business
Type of Transaction	**:**	Highly Technical
Who May Avail	**:**	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	**:**	In accordance to Administrative Order No. 50 s. 2001 + Legal Research Fee (LRF). Conventional Food (Category 1): Php 200.00/year of validity + 1% LRF Conventional Food (Category 2): Php 250.00/year of validity + 1% LRF Food Supplement: Php 1,000.00/year of validity + 1% LRF Bottled Water: Php 1,000.00/year of validity + 1% LRF

GENERAL GUIDELINES

Please refer to:

1) A. General Guidelines, B. Specific Guidelines, and C. Procedural Guidelines, IV. GUIDELINES, pages 2-10 of FDA Circular No. 2020-033 || Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products"; and

2) III. General Guidelines, and IV. Specific Guidelines of FDA Circular No. 2020-033-A || Addendum to FDA Circular 2020-033, "Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No.

2016-014 “Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products” to include Guidelines for Pre-assessment and Reiteration of Pre-Assessment Procedures in Applying for Certificate of Product Registration for Food.		
CHECKLIST OF REQUIREMENTS FOR ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION: RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS		
GENERAL REQUIREMENTS FOR APPLICATION OF CERTIFICATE OF PRODUCT REGISTRATION	**BASIS/ISSUANCE**	**WHERE TO SECURE**
☑ ANNEX D - REQUIREMENTS FOR APPLICATION OF CERTIFICATE OF PRODUCT REGISTRATION	Administrative Order No. 2014-0029	
☑ Accomplished Initial Application Form as prescribed by current FDA regulations. e.g. E-Registration System	FDA Circular No.2020-033 FDA Circular No.2020-033-A	https://www.fda.gov.ph/
☑ Proof of Payment of Fees as prescribed by FDA regulations. Please refer to the table ***Fees to be Paid:***	Administrative Order No. 50 s. 2001	Systems/Means prescribed by FDA
☑ Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations.	Administrative Order No. 2014-0030; and other existing FDA regulation/s with specific labelling requirement/s (e.g. Republic Act No. 8172 Republic Act No. 8976 and its IRR Department Circular No. 2008-0006 Bureau Circular	Applicant Company/ Manufacturer/Source/Supplier

	No. 2 s. 1999 and etc.)	
☑ Pictures of the product in all angles and in different packaging sizes, and from at least two different perspectives allowing visual recognition of a product as the same with the one being registered, as applicable.	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
☑ For FOOD SUPPLEMENT, a sample in actual commercial presentation shall be submitted.	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
☑ As applicable, documents to substantiate claims, such as technical, nutritional or health studies or reports, market-research studies, Certificate of Analysis, quantitative analysis and computations, scientific report or studies published in peer-reviewed scientific journals, certificates or certification to support use of logo/seal on Diamond Sangkap Pinoy Seal, Sangkap Pinoy, Saktong Iodine sa Asin, Halal, Organic, or Kosher food and in compliance with current labeling regulations.	Administrative Order No. 2014-0029 Administrative Order No. 2014-0030	Applicant Company/ Manufacturer/Source/Supplier
☑ VALID AND APPROPRIATE FDA LICENSE TO OPERATE (LTO) (REQUIRED FOR ALL TYPES OF CPR APPLICATION) *The product being applied must be listed in the FDA approved Product Line/Category.	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
For locally produced products: ☑ Distributorship Agreement or Contract Agreement signed by duly authorized representative of the establishment or Certificate of Distributorship or Appointment Letter or Memorandum of Agreement from each supplier. e.g. For WHOLESALER: • Valid, notarized, and duly signed Distributorship Agreement or Memorandum of Agreement For TRADER: • Valid, notarized, and duly signed Toll Manufacturing Agreement	FDA Circular No. 2020-033 FDA Circular No. 2016-007	Applicant Company/ Manufacturer/Source/Supplier

For imported products: ☑ Distributorship Agreement or Contract Agreement signed by duly authorized representative of the establishment or Foreign Agency Agreement, Certificate of Distributorship or Appointment Letter or Proforma Invoice or Memorandum of Agreement from each supplier; and ☑ Scanned copy of ANY of the following original and valid documents issued to the source by the regulatory or health authority from the country of origin per source: i) Valid manufacturer's certificate of registration with Good Manufacturing Practices (GMP) compliance or its equivalent; or ii) Valid Sanitary Phytosanitary Certificate/ Health Certificate; or iii) Valid ISO 22000 Certification/FSSC Certificate; or iv) Valid Hazard Analysis and Critical Control Point (HACCP) Certificate; or v) Certificate of Free Sale (CFS issued by the Regulatory/Health Authority attested by recognized Association or duly authenticated by the Philippine Consulate from the country of origin)	FDA Circular No. 2020-033 FDA Circular No. 2016-007	Applicant Company/ Manufacturer/Source/Supplier
*For export market only product, indicate the term FOR EXPORT MARKET ONLY as part of the product name in the data entry. Otherwise, your application will be evaluated as for local market distribution.		
*For institutional use only products, indicate the term FOR INSTITUTIONAL USE ONLY as part of the product name in the data entry. Otherwise, your application will be evaluated as conventional food for retail market distribution.		

ADDITIONAL REQUIREMENT/S PER FOOD CATEGORY: RAW MATERIAL, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS

RAW MATERIALS FOOD CATEGORIES	☑ ADDITIONAL REQUIREMENT/S	BASIS/ISSUANCE	WHERE TO SECURE
RAW MATERIALS *- all substances that are employed in the processing of a finished product, packed in bulk containers and not labelled as finished product. Raw materials or ingredients would have product specifications that comply with the client requirements and not necessarily a single component.*	☑ As applicable, certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food and in compliance with current labelling regulations.	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier

(Source: IV. Definition of terms, No. 36, page 6 of AO No. 2014-0029)			
RM01 – Fats, Oils and Fat Emulsions e.g. Cooking Oils (Coconut, Palm, Soybean and Corn)	☑ Valid Certificate of Analysis for Vitamin A fortificant used for **COOKING OILS** (e.g. Coconut, Palm, Soybean and Corn) *Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low-Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Republic Act No. 8976 Implementing Rules and Regulation of Republic Act No. 8976	Applicant Company/ Manufacturer/Source/Supplier
RM02 - Processed Fruits, Vegetable and Edible Fungi, Seaweeds and Nuts	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low-Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
RM03 - Confectionery	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low-Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier

	E-Registration data entry (e.g. under Product Specifications).		
RM04 - Cereals	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low-Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
RM05 - Bakery Wares and Bakery Related Products e.g. Wheat Flour	☑ Valid Certificate of Analysis for Vitamin A and Iron fortificant used for **WHEAT FLOUR** *Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low-Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Republic Act No. 8976 Implementing Rules and Regulation of Republic Act No. 8976	Applicant Company/ Manufacturer/Source/Supplier
RM06 - Sweeteners including Honey e.g. Refined Sugar, Brown Sugar, Cane Sugar	☑ Valid Certificate of Analysis for Vitamin A fortificant used for **REFINED SUGAR** *Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for	Republic Act No. 8976 Implementing Rules and Regulation of Republic Act No. 8976	Applicant Company/ Manufacturer/Source/Supplier

	Low-Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).		
RM07 - Salt, Spices, Soups, Sauces, Salads and Protein Products e.g. Iodized Salt, Soy Sauce	☑ Valid Certificate of Analysis for Iodine Content used for **IODIZED SALT** *Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low-Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Republic Act No. 8172 FDA Circular No. 2013-007	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for 3MCPD content of **SOY SAUCE**	FDA Memorandum No. 2011-028	Applicant Company/ Manufacturer/Source/Supplier
RM08 - Beverages (excluding Dairy Products) Non-Alcoholic	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low-Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier

RM09 - Beverages (excluding Dairy Products) Alcoholic	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low-Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
RM10- Dairy products and Analogues	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low-Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
RM11- Frozen Desserts	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low-Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
RM12 - Processed Fish and Fish Products Including Molluscs, Crustaceans and Echinoderms	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low-Risk, Medium-Risk and High-Risk Food Products. Compliance	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier

	must be through declaration in the E-Registration data entry (e.g. under Product Specifications).		
RM13 - Herbal Products	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low-Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
RM14 - Vitamins and Minerals	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low-Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
RM15 - Products with Nutritional Substances	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low-Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
RM16 - Food Additives	*Finished food products in bulk intended for further processing shall conform with the applicable	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier

	Administrative Orders set forth for Low-Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).		
RM17 - Edible Casings (except natural casings from animal sources)	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low-Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
RM18 - Processed Meat and Meat Products, including poultry and game	*Finished food products in bulk intended for further processing shall conform with the applicable Administrative Orders set forth for Low-Risk, Medium-Risk and High-Risk Food Products. Compliance must be through declaration in the E-Registration data entry (e.g. under Product Specifications).	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
LOW RISK FOOD PRODUCTS	**☑ ADDITIONAL REQUIREMENT/S**	**BASIS/ISSUANCE**	**WHERE TO SECURE**
LOW RISK FOOD PRODUCTS - foods that are unlikely to contain pathogenic microorganisms and will not normally support their growth because of food characteristics and foods that are unlikely to contain harmful chemicals.			

A1 - Butter oil, anhydrous milkfat, ghee *"The milkfat products anhydrous milkfat, anhydrous butter oil and butter oil are products derived exclusively from milk and/or products obtained from milk by a process that almost completely removes water and nonfat solids. Ghee is a product obtained exclusively from milk, cream or butter by a process that almost completely removes water and nonfat solids; it has a specially developed flavour and physical structure" (Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=41)*	☑ In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: %Milk Fat by weight; % Milk Solids not fat by weight; % water by weight; Salt (optional) for **BUTTER** (Whipped, Pasteurized)	Administrative Order 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: %Milk Fat by weight; % Milk Solids not fat by weight; % water by weight; Salt (optional) for **WHEY BUTTER**	Administrative Order 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: % Fat; % Moisture for **MARGARINE** *The product shall conform with the standards for optional	Administrative Order No. 232 s. 1974	Applicant Company/ Manufacturer/Source/Supplier

	ingredients and additional label declaration for MARGARINE.		
A2 - Vegetable Oils and Fats e.g. Coconut, Palm, Soybean and Corn *"Edible fats and oils obtained from edible plant sources. Products may be from a single plant source or marketed and used as blended oils that are generally designated as edible, cooking, frying, table or salad oils. Virgin oils are obtained by mechanical means (e.g., pressing or expelling), with application of heat only so as not to alter the natural composition of the oil. Virgin oils are suitable for consumption in the natural state. Cold pressed oils are obtained by mechanical means without application of heat. Examples include: virgin olive oil, cottonseed oil, peanut oil, and vanaspati."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=42)*	☑ Valid Certificate of Analysis for Vitamin A fortificant (in mg RE/L) used for **COOKING OILS** (e.g.Coconut, Palm, Soybean and Corn) *The specific form of Vitamin A fortificant used (e.g. Retinol Palmitate) shall be declared in the Electronic Registration Data Entry.	Republic Act No. 8976 Implementing Rules and Regulation of Republic Act No. 8976	Applicant Company/ Manufacturer/Source/Supplier
A3 - Animal Fats *"All animal fats and oils should be derived from animals in good health at the time of slaughter and intended for human consumption. Lard is fat rendered from the fatty tissue of swine. Edible beef fat is obtained from fresh bovine fatty tissue covering the abdominal cavity and surrounding the kidney and heart, and from other compact, undamaged fat tissues. Such fresh fat obtained at the time of slaughter is the "killing fat." Prime beef fat (premiere jus or oleo stock) is obtained by low-heat rendering (50-55C) of killing fat and selected fat trimmings (cutting fat). Secunda beef fat is a product with typical beef fat odor and taste obtained by rendering (60-65C) and purifying beef fat. Rendered pork fat is fat obtained from the tissue and bones of swine. Edible tallow (dripping) is produced by the*	☑ In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: Saponification Value; Iodine Value for **LARD**	Administrative Order No. 231 s. 1974	Applicant Company/ Manufacturer/Source/Supplier

rendering of fatty tissue (excluding trimmings and cutting fat), attached muscles and bones of bovine animals or sheep. Fish oils are derived from suitable sources such as herring, sardines, sprat, and anchovies. Other examples include: tallow and partially defatted beef or pork fatty tissue." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=43)*			
A4 - Fat emulsions mainly of type oil-in-water *"Includes fat-based counterparts of dairy-based foods excluding dessert products."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=50)* e.g. Imitation milk - a fat-substituted milk produced from nonfat milk solids by addition of vegetable fats (coconut, safflower or corn oil), non-dairy whipped cream, non-dairy toppings and vegetable cream	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
A5 - Fat emulsions mainly of type water-in-oil *"Include all emulsified products excluding fat-based counterparts of dairy products and dairy desserts."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=44)* e.g., Margarine, reduced-fat based desserts	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
A6 - Fat-based desserts excluding dairy-based desserts *"Includes fat-based counterparts of dairy-based desserts. Includes ready-to-eat products and their mixes. Also includes non-dairy fillings for desserts."* *e.g., ice cream-like product made with vegetable fats* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=51)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
B1 - Dehydrated fruits or vegetables, including candied fruits	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

"Includes glazed fruits (fruit treated with a sugar solution and dried), candied fruit (dried glazed fruit immersed in a sugar solution and dried so that the fruit is covered by a candy-like sugar shell), and crystallized fruit is prepared (dried glazed fruit rolled in icing or granulated sugar and dried).Examples include: cocktail (maraschino) cherries, candied citrus peel, candied citrons (e.g. used in holiday fruitcakes), and mostarda di frutta." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=66)*			
B2 - Jams, jellies, marmalades *"Jams, preserves and conserves are thick, spreadable products prepared by boiling whole fruit or pieces of fruit, fruit pulp or puree, with or without fruit juice or concentrated fruit juice, and sugar to thicken, and to which pectin and fruit pieces may be added. Jelly is a clear spreadable product prepared similarly to jam, except that it has a smoother consistency and does not contain fruit pieces. Marmalade is a thick spreadable fruit slurry prepared from whole fruit, fruit pulp or puree (usually citrus), and boiled with sugar to thicken, to which pectin and fruit pieces and fruit peel pieces may be added.38,40 Includes dietetic counterparts made with non-nutritive high-intensity sweeteners. Examples include: orange marmalade, grape jelly, and strawberry jam"* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=64)*	☑ In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: Soluble Solids for **JELLY/JELLIES** *The product shall conform with the standard of quality and additional label declaration for JELLY/JELLIES.	Administrative Order No. 239 s. 1975	Applicant Company/ Manufacturer/Source/Supplier
	☑ In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: Soluble Solids for **PRESERVES OR JAMS**	Administrative Order No. 238 s. 1975	Applicant Company/ Manufacturer/Source/Supplier

	*The product shall conform with the standard of quality and additional label declaration for PRESERVES OR JAMS.		
B3 - Dehydrated vegetable protein products e.g., Textured Vegetable Protein	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
B4 - Fruits or Vegetables in vinegar, oil or brine *"Products prepared by treating raw vegetables with salt solution excluding fermented soybean products."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=80)* Note: Fruits or vegetables in vinegar, oil or brine in canned, bottled or hermetically sealed containers must be file under Medium Risk Food Product - MRC3	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
B5 - Fruit-based spreads excluding jams, jellies and marmalades *"Includes all other fruit-based spreads, such as apple butter and lemon curd. Also includes condiment-type fruit products such as mango chutney and raisin chutney."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=65)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
B6 - Fruit Preparations e.g. fruit pulp, purees, fruit toppings, fruit sauce, fruit syrup, coconut milk and cream *"Fruit pulp is not usually intended for direct consumption. It is a slurry of lightly steamed and strained fresh fruit, with or without added preservatives. Fruit puree (e.g., mango puree, prune puree) is produced in the same way, but has a smoother, finer texture, and may be used as fillings for pastries, but is not limited to this use. Fruit sauce (e.g., pineapple sauce or strawberry sauce) is made from boiled fruit pulp with or without added*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

sweeteners and may contain fruit pieces. Fruit sauce may be used as toppings for fine bakery wares and ice cream sundaes. Fruit syrup (e.g., blueberry syrup) is a more liquid form of fruit sauce that may be used as a topping e.g., for pancakes.Non-fruit toppings are included in category 05.4 (sugar- and chocolate-based toppings) and sugar syrups (e.g. maple syrup) are included in category 11.4. Coconut milk and coconut cream are products prepared using a significant amount of separated, whole, disintegrated macerated or comminuted fresh endosperm (kernel) of coconut palm and expelled, where most filterable fibers and residues are excluded, with or without coconut water, and/or with additional water. Coconut milk and coconut cream are treated by heat pasteurization, sterilization or ultrahigh temperature (UHT) processes. Coconut milk and coconut cream may also be produced in concentrated or skim (or "light") forms. Examples of traditional foods in this sub-category are: tamarind concentrate (clean extract of tamarind fruit with not less than 65% total soluble solids), tamarind powder (tamarind paste mixed with tapioca starch), tamarind toffee (mixture of tamarind pulp, sugar, milk solids, antioxidants, flavours, stabilizers and preservatives), and fruit bars (a mixture of fruit (mango, pineapple, or guava) pulp mixed with sugar, flavours and preservatives, dried into a sheet)." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=67)*			
B7 - Cooked fruits *"Fruit that is steamed, boiled, baked, or fried, with or without a coating, for presentation to the consumer. Examples include: baked apples, fried apple rings, and*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

peach dumplings (baked peaches with a sweet dough covering." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=71)*			
B8 - Frozen vegetables, seaweeds, and nuts and seeds *"Fresh vegetables are usually blanched and frozen. Examples include: quick-frozen corn, quick-frozen French-fried potatoes, quick frozen peas, and quick frozen whole processed tomatoes."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=78)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
B9 - Vegetable seaweeds, nut and seed in pulps and preparations other than food in HR Letter B2 e.g. Aloe extract, potato pulp, horseradish pulp	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
B10 - Cooked or fried vegetables and seaweeds *"Vegetables that are steamed, boiled, baked, or fried, with or without a coating, for presentation to the consumer. Examples include: simmered beans, pre-fried potatoes, fried okra, and vegetables boiled down in soy sauce (tsukudani)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=85)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
C1 - Confectionery *"Includes all types of products that mainly contain sugar and other dietetic counterparts and may or may not contain cocoa (e.g. Hard candy, soft candy, nougats and marzipans"* *Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=93*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
C2 - Chewing gum *"Product made from natural or synthetic gum base containing flavours, sweeteners (nutritive or non-*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

nutritive), aroma compounds, and other additives. Includes bubble gum and breath-freshener gum products." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=97)*			
C3 - Decorations, toppings (non-fruit), and sweet sauces *"Includes ready-to-eat icings and frostings for cakes, cookies, pies and bread and flour confectionery, as well as mixes for these products."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=98)* e.g., Ready-to-eat icings and frostings for cakes, cookies etc, maple, caramel and flavoured syrups	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
D1 - Flour, starches (including soybean powder) and flour mixes *"The basic milled products of cereal grains, roots, tubers, pulses, pith or soft core of palm tree or legumes sold as such or used as ingredients (e.g. in baked goods)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=101)* e.g. Wheat flour, corn flour, bran	☑ Valid Certificate of Analysis for Vitamin A fortificant (in mg/kg as retinol) and Iron fortificant (in mg Fe/kg) used for **WHEAT FLOUR** *The specific form of Vitamin A fortificant used (e.g. Retinol Palmitate) and Iron fortificant used (e.g. Elemental Iron, Ferrous Sulfate, Ferrous Fumarate) shall be declared in the Electronic Registration Data Entry.	Republic Act No. 8976 Implementing Rules and Regulation of Republic Act No. 8976	Applicant Company/ Manufacturer/Source/Supplier
D2 - Breakfast cereals including rolled oats *"Includes all ready-to-eat, instant, and regular hot breakfast cereal products. Examples include: granola-type breakfast cereals, instant oatmeal, farina, corn flakes, puffed wheat or rice, multi-grain (e.g. rice, wheat and corn) breakfast cereals, breakfast cereals made*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

from soy or bran, and extruded-type breakfast cereals made from grain flour or powder." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=104)* e.g. granola type breakfast cereals, corn flakes, multi-grain			
D3a - Fresh pastas and noodles and like products *"Products that are untreated (i.e. not heated, boiled, steamed, cooked, pre-gelatinized or frozen) and are not dehydrated. These products are intended to be consumed soon after preparation. Examples include: unboiled noodles, and "skins" or crusts for spring rolls, wontons, and shuo mai."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=106)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
D3b - Dried pastas and noodles and like products *"Products that are untreated (i.e. not heated, boiled, steamed, cooked, pre-gelatinized or frozen) and are dehydrated."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=107)* e.g. spaghetti pasta, bean vermicelli, rice vermicelli, macaroni, rice noodles	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
D3c - Pre-cooked pastas and noodles and like products *"Products that are treated (i.e. heated, boiled, steamed, cooked, pre-gelatinized or frozen). These products may be sold directly to the consumer (e.g. pre-cooked, chilled gnocchi to be heated prior to consumption), or may be the starch component of prepared meals (e.g., heat-and-*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

serve frozen dinner entrees containing spaghetti, macaroni or noodles; canned spaghetti and meatballs entrée). Also includes instant noodles (sokuseki-men; e.g. pre-cooked ramen, udon, rice noodles), that are pre-gelatinized , heated and dried prior to sale to the consumer." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=108)* e.g. Instant noodles			
D4 - Cereal and starch-based desserts *"Dessert products containing cereal, starch or grain as the main ingredient. Also includes cereal- or starch based fillings for desserts. Examples include: rice pudding, semolina pudding, tapioca pudding, rice flour dumplings (dango), a steamed yeast-fermented wheat flour dough dessert (musipan), and a starchy pudding based dessert (namagashi)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=109)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
D5 - Batters *"Products containing flaked or ground cereal or grain that when combined with other ingredients (e.g., egg, water, milk) are used as a coating for fish or poultry. Products are usually sold as dry mix of the cereal or grain component. Examples include breading for tempura batter."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=110)* e.g. for breading or batters for fish or poultry	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

D6 - Pre-cooked or processed rice products e.g. Prepackaged Rice in Retail Size, Iron Rice Premix	☑ Valid Certificate of Analysis for Iron fortificant (in mg Fe/kg) used for **RICE** *The specific form of Iron fortificant used (e.g. Ferrous Sulfate) shall be declared in the Electronic Registration Data Entry.	Republic Act No. 8976 Implementing Rules and Regulation of Republic Act No. 8976	Applicant Company/ Manufacturer/Source/Supplier
	☑ In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: Iron Content (in mg Iron (Fe)/100g and Moisture Content for **IRON RICE PREMIX** *The specific form of Iron fortificant used (e.g. Ferrous Sulfate) shall be declared in the Electronic Registration Data Entry. **The product shall conform with the Composition and Quality Factors for Iron Rice Premix	FDA Circular No. 2007-010-A	Applicant Company/ Manufacturer/Source/Supplier
D7a - Soybean based beverages *"Products prepared from dried soybeans that are soaked in water, pureed, boiled and strained, or prepared from soybean flour, soybean concentrate, or soybean isolate."*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=269)			
D7b - Soybean based film *"Film formed on the surface of boiling soybean-based beverage that is dried."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=270)* e.g. Fuzhu - asian food which is a protein–lipid film isolated from soymilk surface through high-temperature incubation	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
D7c - Soybean curd (tofu) *"Soybean curd is prepared from dried soybeans that are soaked in water, pureed, and strained to produce soybean-based beverage, which is then made into a curd with a coagulant, and placed in a mould. Soybean curds may be of a variety of textures (e.g. soft, semi-firm, firm)"* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=271)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
D7d - Semi-dehydrated soybean curd *"Soybean curd that has been pressed while being moulded into blocks so that some moisture has been removed, but so that it is not completely dried. Semi-dehydrated soybean curd typically contains 62% water, and has a chewy texture."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=272)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
D7e - Dehydrated soybean curd	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

"Soybean curd from which all moisture has been removed through the process of freezing, aging, and dehydrating. It may be reconstituted with water or sauce for consumption, or is used directly in prepared dishes. It may also be deep-fried or simmered in sauce." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=276)*			
D7f - Other soybean protein products *"Other products from soybeans composed mainly of soybean protein such as extruded, textured, concentrated, and isolated soybean protein."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=279)* e.g. Soy-based "chicken" meat	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
F1a - Breads and rolls - yeast leavened breads and specialty breads, soda breads *"Includes yeast-leavened and specialty breads and soda bread."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=115)* e.g. White bread, raisin bread, whole wheat bread, hamburger rolls, hotdog buns	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
F1b - Crackers excluding sweet crackers *"The term "cracker" refers to a thin, crisp wafer, usually of unsweetened dough."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=118* e.g. Soda Crackers, Rye Crisps, Matzohs	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
F1c - Other ordinary bakery products *"Includes all other ordinary bakery wares, such as*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

cornbread and biscuits. The term "biscuit" in this category refers to a small cake of shortened bread, leavened with baking powder or baking soda. It does not refer to the British "biscuit," which is a "cookie" or "sweet cracker"" *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=119)* e.g. Bagels, pita, English muffins			
F1d - Bread-type products, including bread stuffing and bread crumbs *"Includes bread-based products such as croutons, bread stuffing and stuffing mixes, and prepared doughs (e.g. for biscuits)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=120)* e.g. Croutons	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
F1e - Steamed bread and buns *"Oriental-style leavened wheat or rice products that are cooked in a steamer. Products may be made with or without filling. In China, products without filling are called steamed bread (mantou), and those with filling are called steamed buns (baozi or bao). Twisted rolls of various shapes (huajuan) may also be prepared. Examples include: filled dumplings and steamed bun with meat, jam or other filling (manjyu)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=121)* Other e.g., Siopao	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
F1f - Mixes for bread and ordinary bakery wares *"Includes all the mixes containing the dry ingredients to*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

which wet ingredients (e.g., water, milk, oil, butter, eggs) are added to prepare a dough for baked goods." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=122)*			
F2 - Fine bakery wares and mixes - Mixes for fine bakery wares *"Mixes containing the dry ingredients to which wet ingredients (e.g. water, milk, oil, butter, eggs) are added to prepare a dough for fine baked goods."* *e.g. cake mix, flour confectionery mix, pancake mix, pie mix, and waffle mix* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=126)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
G1 - Refined and raw sugars *"Nutritive sweeteners, such as fully or partially purified sucrose (derived from sugar beet and sugar cane), glucose (derived from starch), or fructose."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=174)* e.g. Refined Sugar, Raw Cane Sugar	☑ Valid Certificate of Analysis for Vitamin A fortificant used for **REFINED SUGAR**	Republic Act No. 8976 Implementing Rules and Regulation of Republic Act No. 8976	Applicant Company/ Manufacturer/Source/Supplier
G2 - Brown Sugar *"Includes large-grain, brown or yellow lump sugars, such as Demerara sugar"* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=182)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
G3 - Sugar solutions and syrups *"Includes co-products of the sugar refining process (e.g. treacle and molasses), invert sugar (equimolar mixture of glucose and fructose produced from the hydrolysis of*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

sucrose), and other sweeteners, such as high fructose corn syrup, high fructose inulin syrup and corn sugar." (Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=183) e.g. Maple Syrup, Vanilla Syrupm Flavoured Syrups			
G4 - Other sugars and syrups including coconut sugar e.g. Coloured sugar crystals for cookies	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
G5- Honey *"Honey is the natural sweet substance produced by honeybees from the nectar of blossoms or secretions of plants. The honeybees collect the nectar or secretions, transform it by combination with specific substances of the bees' own, and store it in a honeycomb to ripen and mature." (Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=185)* e.g. Wildflower Honey and Clover Honey	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
G6- Table-top sweeteners, including those containing high-intensity sweeteners *"Includes products that are preparations of high-intensity sweeteners (e.g. acesulfame potassium) and/or of polyols (e.g. sorbitol) which may contain other additives and/or nutritive ingredients, such as carbohydrates. These products, which are sold to the final consumer, may be in powder, solid (e.g. tablets or cubes), or liquid form." (Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=186)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

I1 - Salt and Salt substitutes Salt - *"Primarily food-grade sodium chloride. Includes table salt, iodized and fluoride iodized salt, and dendritic salt."* *(Source URL:* https://www.fao.org/gsfaonline/foods/details.html?id=189 *)* *"Salt substitutes are seasonings with reduced sodium content intended to be used on food in place of salt."* *(Source URL:* https://www.fao.org/gsfaonline/foods/details.html?id=190 *)*	☑ Valid Certificate of Analysis for Iodine Content for **SALT, ROCK SALT, SEA SALT** (Excluding Himalayan Pink Salt, Gourmet Salt) * "All food manufacturers processors using food-grade salt are also required to use iodized salt in the processing of their products and must comply with the provisions of this Act not later than one (1) year from its effectivity. Provided, That the use of iodized salt shall not prejudice the quality and safety of their food products: Provided, however, That the burden of proof and testing for any prejudicial effects due to iodized salt fortification lies on the said food manufacturers/processor." – RA No. 8172	Republic Act No. 8172 FDA Circular No. 2013-007	Applicant Company/ Manufacturer/Source/Supplier
I2 - Herbs, spices, seasonings and condiments *"Herbs and spices are usually derived from botanical sources, and may be dehydrated, and either ground or whole. Examples of herbs include basil, oregano and thyme. Examples of spices include cumin and caraway seeds. Spices may also be found as blends in powder or paste form."* *(Source URL:* https://www.fao.org/gsfaonline/foods/details.html?id=192 *)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

"Condiments and seasonings are mixtures of herbs and spices together with other food ingredients (such as salt, vinegar, lemon juice, molasses, honey or sugar, and sweeteners). Examples include meat tenderizers, onion salt, garlic salt, Oriental seasoning mix (dashi), topping to sprinkle on rice (furikake, containing, e.g. dried seaweed flakes, sesame seeds and seasoning), and seasoning for noodles. The term "condiments" as used in the Food Category System does not include condiment sauces (e.g. ketchup, mayonnaise, mustard) or relishes." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=193)*			
I3 – Vinegars *"Liquid produced from fermentation of ethanol from a suitable source (e.g. wine, cider). Examples include, cider vinegar, wine vinegar, malt vinegar, spirit vinegar, grain vinegar, raisin vinegar, and fruit (wine) vinegar."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=194)*	☑ In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological , declare the results (under specification) for the following Parameters: % Acidity; % Total Solids; % Ash; Lead Content; Copper Content and Arsenic Content; *Additional for **Malt Vinegar**: Phosphorus Pentoxide and Nitrogen Contents for **VINEGAR**	Administrative Order No. 134 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
I4 – Mustards *"Condiment sauce prepared from ground, often defatted mustard seed that is mixed into a slurry with water, vinegar, salt, oil and other spices and refined. Examples include Dijon mustard, and "hot" mustard (prepared from seeds with hulls)."*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=195)			
I5 - Soups and broths *"Concentrated soup to be reconstituted with water and/or milk, with or without addition of other optional ingredients (e.g. vegetables, meat, noodles). Examples include: bouillon powders and cubes; powdered and condensed soups (e.g. mentsuyu); and stock cubes and powders."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=198)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
I6a - Mixes for sauces and gravies *"Concentrated product, usually in powdered form, to be mixed with water, milk, oil or other liquid to prepare a finished sauce or gravy. Examples include mixes for cheese sauce, hollandaise sauce, and salad dressing (e.g. Italian or ranch dressing)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=202)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
I6b - Clear Sauces (Fish Sauce) *"Includes thin, non-emulsified clear sauces that may be water-based. These sauces may be used as condiments or ingredients rather than as finished gravy (for use e.g. on roast beef). Examples include: oyster sauce, and Thai fish sauce (nam pla)."* *Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=203)*	☑ In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological , declare the results (under specification) for the following Parameters: Specific Gravity; Total Solids; Salt Content; Protein Content for **PATIS**	Administrative Order No. 325 s. 1977	Applicant Company/ Manufacturer/Source/Supplier

I7 - Yeast and like products *"Includes baker's yeast and leaven used in the manufacture of baked goods. Includes the Oriental products koji (rice or wheat malted with A. oryzae) used in the production of alcoholic beverages."* *(Source URL:* https://www.fao.org/gsfaonline/foods/details.html?id=205 *)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
I8a - Fermented Soybean Paste (e.g. Miso) *"The product is made of soybeans, salt, water and other ingredients, using the process of fermentation. The product includes dou jiang (China), doenjang (Republic of Korea), or miso (Japan), which maybe used in the preparation of soups or dressings, or as a seasoning."* *(Source URL:* https://www.fao.org/gsfaonline/foods/details.html?id=207 *)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
I8b- Soybean Sauce *"A liquid seasoning obtained by fermentation of soybeans, non-fermentation (e.g. hydrolysis) of soybeans, or by hydrolysis of vegetable protein"* *(Source URL:* https://www.fao.org/gsfaonline/foods/details.html?id=211 *)*	☑ Valid Certificate of Analysis for 3-MCPD for **SOY SAUCE**	FDA Memorandum 2011-028	Applicant Company/ Manufacturer/Source/Supplier
I9- Protein products other than from soybeans, marinades *"Includes, for example, milk protein, cereal protein and vegetable protein analogues or substitutes for standard products, such as meat, fish or milk. Examples include: vegetable protein analogues, fu (a mixture of gluten (vegetable protein) and flour that is sold dried (baked) or raw, and is used as an ingredient, e.g. in miso soup) and proteinaceous meat and fish substitutes."*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=218) e.g. Vegetable Protein Analogues			
J1a - Non-alcoholic (soft) beverages without herbal ingredients e.g. Roasted coffee beans, coffee grounds, Freeze-dried coffee	☑ In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: Moisture Content (%w/w); Caffeine (%w/w dry basis); Ash (%w/w dry basis; Water-insoluble Solids (%w/w, dry basis); pH; Solubility; Sensory Attributes; Arsenic Content; Lead Content for **INSTANT COFFEE**	Administrative Order No. 136-A s. 1985	Applicant Company/ Manufacturer/Source/Supplier
	☑ In the Electronic Registration Data Entry – Product Specifications Physical/Chemical/Microbiological, declare the results (under specification) for the following Parameters: Moisture Content (%w/w); Caffeine (%w/w, dry basis); Ash (%w/w, dry basis; Water-insoluble Solids (%w/w, dry basis); Carbohydrates (% w/w, dry basis); pH; Solubility; Sensory Attributes; Arsenic Content; Lead Content for **SOLUBLE COFFEE**	Administrative Order No. 136-B s. 1985	Applicant Company/ Manufacturer/Source/Supplier

	WITH ADDED CARBOHYDRATES		
J1b - Non-alcoholic (soft) beverages with herbal ingredients e.g. Green Tea, Chamomile Tea	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
J2a - Beer and Malt Beverages *"Alcoholic beverages brewed from germinated barley (malt), hops, yeast, and water. Examples include: ale, brown beer, weiss beer, pilsner, lager beer, oud bruin beer, Obergariges Einfachbier, light beer, table beer, malt liquor, porter, stout, and barleywine."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=254)*	☑ For **IMPORTED ALCOHOLIC BEVERAGE**S: a) Technical specifications of raw materials and finished product (including methanol content); b) a certificate of compliance with the country of origin's standards and regulation for alcoholic beverages; c) copy of standards and regulation stated in (b)	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
	☑ For **LOCALLY MANUFACTURED ALCOHOLIC BEVERAGE**: a) Technical specifications of raw materials and finished product (including methanol content); b) source of ethyl alcohol, used as raw material for compounded alcoholic beverages	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
J2b - Cider and Perry *"Fruit wines made from apples (cider) and pears (perry). Also includes cidre bouche."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=255)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

J2c - Grape Wines *"Alcoholic beverage obtained exclusively from the partial or complete alcoholic fermentation of fresh grapes, whether crushed or not, or of grape must (juice)."* *(Source URL:* https://www.fao.org/gsfaonline/foods/details.html?id=256 *)* e.g. Still grape wine, sparkling and semi-sparkling grape wines, fortified grape wine, grape liquor wine, sweet grape wine, red wine, white wine, rose wine	☑ For **IMPORTED ALCOHOLIC BEVERAGES**: a) Technical specifications of raw materials and finished product (including methanol content); b) a certificate of compliance with the country of origin's standards and regulation for alcoholic beverages; c) copy of standards and regulation stated in (b)	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
	☑ For **LOCALLY MANUFACTURED ALCOHOLIC BEVERAGE**: a) Technical specifications of raw materials and finished product (including methanol content); b) source of ethyl alcohol, used as raw material for compounded alcoholic beverages	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
J2d - Wines other than grape *"Includes wines made from fruit other than grapes, apples and pears, and from other agricultural products, including grain (e.g. rice). These wines may be still or sparkling. Examples include: rice wine (sake), and sparkling and still fruit wines."* *(Source URL:* https://www.fao.org/gsfaonline/foods/details.html?id=260 *)* e.g. Fruit wine, rice wine	☑ For **IMPORTED ALCOHOLIC BEVERAGES**: a) Technical specifications of raw materials and finished product (including methanol content); b) a certificate of compliance with the country of origin's standards and regulation for alcoholic beverages; c) copy of standards and regulation stated in (b)	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
	☑ For **LOCALLY MANUFACTURED ALCOHOLIC BEVERAGE**: a) Technical	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier

	specifications of raw materials and finished product (including methanol content); b) source of ethyl alcohol, used as raw material for compounded alcoholic beverages		
J2e - Mead *"Alcoholic liquor made from fermented honey, malt and spices, or just of honey. Includes honey wine."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=261)* e.g. Honey wine	☑For **IMPORTED ALCOHOLIC BEVERAGES**: a) Technical specifications of raw materials and finished product (including methanol content); b) a certificate of compliance with the country of origin's standards and regulation for alcoholic beverages; c) copy of standards and regulation stated in (b)	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
	☑For **LOCALLY MANUFACTURED ALCOHOLIC BEVERAG**E: a) Technical specifications of raw materials and finished product (including methanol content); b) source of ethyl alcohol, used as raw material for compounded alcoholic beverages	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
J2f - Distilled spirituous beverages (>15%alcohol) *"Includes all distilled spirituous beverages derived from grain (e.g. corn, barley, rye, wheat), tubers (e.g. potato), fruit (e.g. grapes, berries) or sugar cane that contain greater than 15% alcohol."*	☑ For **IMPORTED ALCOHOLIC BEVERAGES**: a) Technical specifications of raw materials and finished product (including methanol content); b) a certificate of compliance with the country of origin's standards and regulation	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier

(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=262) e.g. Brandy, whisky, rhum, tequila, vodka	for alcoholic beverages; c) copy of standards and regulation stated in (b)		
	☑ For **LOCALLY MANUFACTURED ALCOHOLIC BEVERAGE**: a) Technical specifications of raw materials and finished product (including methanol content); b) source of ethyl alcohol, used as raw material for compounded alcoholic beverages	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
J2g - Aromatized alcoholic beverages *"Includes all non-standardized alcoholic beverage products."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=263)* e.g. Aperitif wine	☑ For **IMPORTED ALCOHOLIC BEVERAGES**: a) Technical specifications of raw materials and finished product (including methanol content); b) a certificate of compliance with the country of origin's standards and regulation for alcoholic beverages; c) copy of standards and regulation stated in (b)	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier
	☑ For **LOCALLY MANUFACTURED ALCOHOLIC BEVERAGE**: a) Technical specifications of raw materials and finished product (including methanol content); b) source of ethyl alcohol, used as raw material for compounded alcoholic beverages	Memorandum Circular No. 13 s. 1989	Applicant Company/ Manufacturer/Source/Supplier

K1 - Snacks - potato - cereal - or starch-based (from roots and tubers, pulses and legumes) *"Includes all savoury snacks, with or without added flavourings, but excludes unsweetened crackers. Examples include potato chips, popcorn, pretzels, rice crackers (senbei), flavoured crackers (e.g. cheese-flavoured crackers), bhujia (namkeen; snack made of a mixture of flours, maize, potatoes, salt, dried fruit, peanuts, spices, colours, flavours, and antioxidants), and papads (prepared from soaked rice flour or from black gram or cow pea flour, mixed with salt and spices, and formed into balls or flat cakes)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=265)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
K2 - Chicharon e.g. Pork chicharon, mushroom chicharon	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
K3 - Snacks - fish-based *"This describes savoury crackers with fish, fish products or fish flavouring."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=267)* e.g. Fish Crackers, dried fish chips	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
MEDIUM RISK FOOD PRODUCTS	**☑ ADDITIONAL REQUIREMENT/S**	**BASIS/ISSUANCE**	**WHERE TO SECURE**
MEDIUM RISK FOOD PRODUCTS - *foods that may contain pathogenic micro-organisms but will not normally support their growth because of food characteristics; or food that is unlikely to contain pathogenic micro-organisms because of food type or processing, but may support the formation of toxins or*			

the growth of pathogenic micro-organisms. (AO No. 2014-0029)			
A1a - Condensed milk (plain) *"Condensed milk is obtained by partial removal of water from milk to which sugar may have been added. For evaporated milk, the water removal may be accomplished by heating."* *"Includes partially dehydrated milk, evaporated milk, sweetened condensed milk, and khoa (cow or buffalo milk concentrated by boiling)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=13)*	☑ Valid Certificate of Analysis for % Total Milk Solids and % Milk Fat for **EVAPORATED MILK, EVAPORATED WHOLE MILK, EVAPORATED FULL CREAM MILK, UNSWEETENED CONDENSED WHOLE MILK, UNSWEETENED FULL CREAM CONDENSED MILK**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Total Milk Solids and % Milk Fat for **SWEETENED CONDENSED MILK, SWEETENED CONDENSED WHOLE MILK, SWEETENED FULL CREAM CONDENSED MILK** *The product shall conform with the standards for optional ingredients and additional label declaration for Sweetened Condensed Milk, Sweetened Condensed Whole Milk, Sweetened Full Cream Condensed Milk.	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Milk Solids for **EVAPORATED SKIMMED MILK,**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier

	UNSWEETENED CONDENSED SKIMMED MILK		
	☑ Valid Certificate of Analysis for % Milk Solids for **SWEETENED CONDENSED SKIMMED MILK**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for %Milk Fat and % Solids-Not-Fat for **RECONSTITUTED, RECONSTRUCTED OR RECOMBINED EVAPORATED MILK** *The product shall conform with the standards for optional ingredients and additional label declaration for Reconstituted, Reconstructed or Recombined Evaporated Milk.	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Milk Fat and % Solids-Not-Fat for **RECONSTITUTED, RECONSTRUCTED OR RECOMBINED SWEETENED CONDENSED MILK**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Milk Solids for **RECONSTITUTED, RECONSTRUCTED OR RECOMBINED EVAPORATED SKIMMED MILK**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier

	☑ Valid Certificate of Analysis for % Non-Fat Milk Solids, Vitamin A and Vitamin D (if added) for **EVAPORATED FILLED MILK** *The % Total Oil Content shall be declared in the Electronic Registration Data Entry. **The product shall conform with the identity, standards for optional ingredients and additional label declaration for Evaporated Filled Milk.	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Non-Fat Milk Solids, Vitamin A and Vitamin D (if added) for **SWEETENED CONDENSED FILLED MILK** *The % Total Oil Content shall be declared in the Electronic Registration Data Entry. **The product shall conform with the identity, standards for optional ingredients and additional label declaration for Sweetened Condensed Filled Milk.	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **SWEETENED CONDENSED MILK:** Coliforms CFU/g, Yeast & Mold Count CFU/g & Aerobic Plate Count CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	☑ Valid Certificate of Analysis for Microbiological parameters for **LIQUID MILK (EVAPORATED)**: Commercial Sterility	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
A1b - Beverage whiteners *"Milk or cream substitute consisting of a vegetable fat-water emulsion in water with milk protein and lactose or vegetable proteins for use in beverages such as coffee and tea. Also includes the same type of products in powdered form."* *"Includes condensed milk analogues, blends of evaporated skimmed milk and vegetable fat and blends of sweetened condensed skimmed milk and vegetable fat."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=14)* e.g. Condensed creamer	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
A2 - Milk powder and cream powder and powder analogues (plain) *"Includes plain milk powders, cream powders, or combination of the two, and their analogues. Includes products based on skim, part-skim, low-fat and whole milk."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=20)* *"Milk cream powder analogues are products based on a fat-water emulsion and dried for use other than as a beverage whitener. Examples include imitation dry cream mix and blends of skimmed milk and vegetable fat in powdered form."*	☑ Valid Certificate of Analysis for % Milk Solids, % Milk Fat and % Water for **WHOLE MILK POWDER (DRIED FULL CREAM MILK, FULL CREAM MILK POWDER, DRY WHOLE MILK, MILK POWDER, DRIED MILK)**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Solids, % Fat and % Water for **SKIMMED MILK POWDER**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Milk Solids, % Milk Fat and % Water for **PARTLY SKIMMED MILK POWDER**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier

(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=22)	☑ Valid Certificate of Analysis for % Milk Fat and Moisture Content for **MALTED MILK POWDER**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Butterfat, % Total Milk Solids and Moisture Content for **BUTTERMILK POWDER (DRIED BUTTERMILK)**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **MILK POWDER (e.g. WHOLE, NONFAT, FILLED MILK, BUTTERMILK, WHEY & WHEY PROTEIN AND MILK INTENDED FOR CHILDREN MORE THAN 36 MONTHS OF AGE AND ADULTS)**: Salmonella/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
A3 - Milk products for specific age groups or target population e.g. Powdered milk for children above 3 years and pregnant women	☑ Valid Certificate of Analysis for Microbiological parameters for **MILK POWDER (e.g. WHOLE, NONFAT, FILLED MILK, BUTTERMILK, WHEY & WHEY PROTEIN AND MILK INTENDED FOR CHILDREN MORE THAN 36 MONTHS OF AGE AND ADULTS)**: Salmonella/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis to support Nutrition Information declaration on the label	Administrative Order No. 2014-0029 Administrative	Applicant Company/ Manufacturer/Source/Supplier

		Order No. 2014-0030	
B1 - Non-Dairy based frozen desserts *"Includes fat-based counterparts of dairy-based desserts. Includes ready-to-eat products and their mixes. Also includes non-dairy fillings for desserts. An example is an ice cream-like product made with vegetable fats."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=51)*	☑ Valid Certificate of Analysis for Microbiological parameters for **ICE CREAM & SHERBET (PLAIN AND FLAVORED)**: Coliforms CFU/g, Listeria monocytogenes/25g, Salmonella/25g, Aerobic Plate Count CFU/g & S. aureus CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **ICE CREAM WITH ADDED INGREDIENTS (NUTS, FRUITS, COCOA ETC.):** Coliforms CFU/g, S. aureus CFU/g, Salmonella/25g, Aerobic Plate Count CFU/g & Listeria monocytogenes/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
B2 - Edible ices - popsicles *"This category includes water-based frozen desserts, confections and novelties, such as "Italian"-style ice, and flavoured ice."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=52)* e.g. Ice candy, ice popsicles	☑ Valid Certificate of Analysis for Microbiological parameters for **FLAVORED ICE:** Aerobic Plate Count CFU/g, Coliforms MPN/g or CFU/g or /25g, Yeast and Mold Count CFU/g & Salmonella/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
C1 - Tomato products e.g. Tomato Catsup, tomato sauce, tomato paste	☑ Valid Certificate of Analysis for Total Soluble Solids, Specific Gravity, Total Acidity in terms of acetic acid, Arsenic Content, Lead Content, Copper Content, Zinc Content and Tin Content for **TOMATO CATSUP**	Administrative Order No. 233 s. 1974	Applicant Company/ Manufacturer/Source/Supplier

	*The product shall conform with the identity and standard of quality of Tomato Catsup.		
C2 - Frozen fruits *"Fruit that may or may not be blanched prior to freezing. The product may be frozen in a juice or sugar syrup. Examples include frozen fruit salad and frozen strawberries."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=60)*	☑ Valid Certificate of Analysis for Microbiological parameters for **FROZEN FRUITS (pH >4.5)**: E. coli CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
C3 - Canned or bottled (pasteurized) or retort pouch fruit and vegetable preserve in juice, syrup, brine *"Fully preserved product in which fresh fruit is cleaned and placed in cans or jars with natural juice or sugar syrup (including artificially sweetened syrup) and heat-sterilized or pasteurized. Includes products processed in retort pouches. Examples include: canned fruit salad, and applesauce in jars."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=63)* *"Fully preserved product in which fresh vegetables are cleaned, blanched, and placed in cans or jars in liquid (e.g. brine, water, oil or sauce), and heat-sterilized or pasteurized. Examples include: canned chestnuts, canned chestnut puree, asparagus packed in glass jars, canned and cooked pink beans, canned tomato paste (low acid), and canned tomatoes (pieces, wedges or whole)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=81)*	☑ Valid Certificate of Analysis for Microbiological parameters for **FRUITS AND VEGETABLE PRODUCTS IN HERMETICALLY SEALED CONTAINERS**: Commercial Sterility	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

e.g. Mushroom whole in brine, Lychee in heavy syrup, Pitted green olives in brine			
C4 - Fruit-based desserts, gelatin *"Includes the ready-to-eat products and mixes. Includes the ready-to-eat products and mixes. Includes fruit-flavoured gelatin, rote gruze, frutgrod, fruit compote, nata de coco, and mitsumame (gelatin-like dessert of agar jelly, fruit pieces and syrup)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=68)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
C5 - Fermented fruit products *"Type of pickled product produced by preservation in salt by lactic acid fermentation. Examples include: fermented plums."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=69)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
C6 - Fruit fillings for pastry *"Includes the ready-to-eat products and mixes. Includes all type of fillings excluding purees. These fillings usually include whole fruit or fruit pieces. Examples include: cherry pie filling and raisin filling for oatmeal cookies."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=70)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
C7 - Fermented vegetable products and seaweed products, excluding fermented soybean products MR Letter E.1 and E.2 (fermented soybeans and fermented soybean curd) and LR Letters I.8.b. 1 to 3) (soybean sauces) *"Fermented vegetables are a type of pickled product, formed by the action of lactic acid bacteria, usually in the presence of salt. Examples include: red pepper paste, fermented vegetable products, kimchi (fermented*	☑ Valid Certificate of Analysis for Microbiological parameters for **FERMENTED VEGETABLE (READY TO EAT) (e.g. KIMCHI)**: Yeast and Mold Count CFU/g, Coliforms MPN/g or CFU/g or /25g, E. coli MPN/g or CFU/g or /25g, Salmonella/25g & S. aureus cfu/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

Chinese cabbage and vegetable preparation), and sauerkraut (fermented cabbage)." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=84)*			
C8 - Vegetable protein products (canned and frozen)	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
D - Cocoa products and chocolate products *"Cocoa Mixes (powders) and cocoa mass/cake: Includes a variety of products that are used in the manufacture of other chocolate products or in the preparation of cocoa-based beverages."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=88)* **Cocoa Mixes (syrups)** *"Products that may be produced by adding a bacterial amylase to cocoa liquor. The enzyme prevents the syrup from thickening or setting by solubilizing and dextrinizing cocoa starch. Includes products such as chocolate syrup used to prepare chocolate milk or hot chocolate."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=89)* **Cocoa-based spreads, including fillings** *"Products in which cocoa is mixed with other ingredients (usually fat-based) to prepare a spreadable paste that is used as a spread for bread or as a filling for fine bakery wares. Examples include: cocoa butter, fillings for bonbons and chocolates, chocolate pie filling, and nut-chocolate based spreads for bread (Nutella-type product)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=90)*	☑ Valid Certificate of Analysis for Microbiological parameters for **COCOA POWDER**: Molds CFU/g, Salmonella/25g, Coliforms, MPN/g or CFU/g & Aerobic Plate Count CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for **CHOCOLATE PRODUCTS:** Molds CFU/g, Salmonella/25g, Coliforms MPN/g or CFU/g & Aerobic Plate Count CFU/g. ☑ Valid Certificate of Analysis for Microbiological parameters for **CHOCOLATE CONFECTIONARIES:** Molds CFU/g, Osmophilic yeast CFU/g, Salmonella/25g, Coliforms MPN/g or CFU/g & Aerobic Plate Count CFU/g	FDA Circular No. 2022-012 FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier Applicant Company/ Manufacturer/Source/Supplier

Cocoa and Chocolate Products Chocolate *"Chocolate is produced from cocoa nibs, mass, press cake, powder, or liquor with or without addition of sugar, cocoa butter, aroma or flavouring substances, and optional ingredients (e.g. nuts). This category is for chocolate as defined in the Standard for Chocolate and Chocolate Products (CODEX STAN 87-1981) and for confectionery that meet the standard and may contain other contain other ingredients, for example chocolate-covered nuts and fruit (e.g. raisins). This category includes only the chocolate portion of any confectionery within the scope of food category 05.2. Examples include: bonbons, cocoa butter confectionery (composed of cocoa butter, milk solids and sugar), white chocolate, chocolate chips (e.g. for baking), milk chocolate, cream chocolate, sweet chocolate, bitter chocolate, enrobing chocolate, chocolate covered in a sugar-based "shell" or with coloured decorations, filled chocolate (chocolate with a texturally distinct center and external coating, and chocolate with added edible ingredients."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=91)* **Imitation Chocolate, Chocolate substitute products** *"Includes chocolate-like products that may or may not be cocoa-based, but have similar organoleptic properties as chocolate, such as carob chips, and cocoa-based products that contain greater than 5% vegetable fat. These chocolate-like products may contain additional optional ingredients and may include filled confectionery. Examples include: compound chocolate, flavoured and coloured compound chocolate, compound chocolate*			

coatings, and imitation chocolate covered nuts and fruit (e.g. raisins)." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=92)*			
E1 - Fermented soybeans *"The product is prepared from soybeans that have been steamed and fermented with certain fungi or bacteria (starter).* *The soft, whole beans have a distinctive aroma and taste. It includes products such as dou chi (China), natto (Japan), and tempe (Indonesia)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=277)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
E2 - Fermented soybean curd *"The product is prepared by forming soybean curd into a loaf during the fermentation process. It is a soft, flavoured product, either in red, rice-yellow, or grey-green."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=278)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
F1ai - Cured (including salted) non-heat treated processed meat, poultry and game products in whole pieces or cuts *"Salted products are treated with sodium chloride. Dry cured (dry pickled) products are prepared by rubbing salt directly on the meat surface. Wet pickle cured products are prepared by submerging the meat in a brine solution. Pump cured products are prepared by*	☑ Valid Certificate of Analysis for Microbiological parameters for **PACKAGED COOKED, CURED/SALTED MEAT (HAM, BACON)**: S. aureus CFU/g, Salmonella/25g & Listeria monocytogenes/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

injecting brine into the meat. Curing may also be achieved by addition of additives. Smoked products are also included here. Examples include: bacon (cured, dry-cured, immersion-cured, pump-cured); side bacon; corned beef; marinaded beef; and different types of Oriental pickled products: miso-pickled meat (miso-zuke), koji-pickled meat (koji-zuke), and soy sauce-pickled meat (shoyu-zuke)." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=133)*	☑ Valid Certificate of Analysis for Microbiological parameters for **CURED/SMOKED POULTRY**: S. aureus CFU/g & Salmonella/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Nitrate and/or Nitrite Content (if utilized)	Administrative Order No. 154 s. 1971 and Bureau Circular No. 2006-016	Applicant Company/ Manufacturer/Source/Supplier
F1aii - Cured (including salted) and dried non-heat treated processed meat, poultry and game products in whole pieces or cuts *"The meat cuts may be cured or salted and then dried, or they may only be dried. Drying is achieved either in hot air or in vacuum. Examples include: dried salt pork, dehydrated meat, stuffed loin, Iberian ham, and proscuitto-type ham."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=134)*	☑ Valid Certificate of Analysis for Microbiological parameters for **PACKAGED COOKED, CURED/SALTED MEAT (HAM, BACON)**: S. aureus CFU/g, Salmonella/25g & Listeria monocytogenes/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **CURED/SMOKED POULTRY**: S. aureus CFU/g & Salmonella/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Nitrate and/or Nitrite Content (if utilized)	Administrative Order No. 154 s. 1971 and Bureau Circular No. 2006-016	Applicant Company/ Manufacturer/Source/Supplier
F1aiii - Fermented non-heat treated processed meat, poultry and game products - processed meat in whole pieces or cuts *"Fermented products are a type of pickled product produced by the action of lactic acid bacteria in the*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

presence of salt. Examples include: potted beef and pickled (fermented) pig's feet." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=135)*			
F2ai - Cured (including salted) non-heat treated processed comminuted meat, poultry and game products *"Salted products are treated with sodium chloride. Dry cured (dry pickled) products are prepared by rubbing salt directly on the meat surface. Wet pickle cured products are prepared by submerging the meat in a brine solution. Pump cured products are prepared by injecting brine into the meat. Curing may also be achieved by addition of additives. Smoked products are also included here. Examples include: bacon (cured, dry-cured, immersion-cured, pump-cured); side bacon; corned beef; marinaded beef; and different types of Oriental pickled products: miso-pickled meat (miso-zuke), koji-pickled meat (koji-zuke), and soy sauce-pickled meat (shoyu-zuke)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=133)* e.g. chorizos (spicy pork sausages), salami-type products, salchichon, tocino (fresh, cured sausage), pepperoni, and smoked sausage.	☑ Valid Certificate of Analysis for Microbiological parameters for **MINCED MEAT AND MEAT PREPARATIONS MADE FROM POULTRY MEAT INTENDED TO BE EATEN COOKED:** Aerobic Plate Count, CFU/g, E.coli, CFU/g, Salmonellas/25g ☑ Valid Certificate of Analysis for Microbiological parameters for **MINCED MEAT AND MEAT PREPARATIONS MADE FROM SPECIES OTHER THAN POULTRY INTENDED TO BE EATEN COOKED**: Aerobic Plate Count, CFU/g, E.coli, CFU/g, Salmonellas/25g Aerobic Plate Count, CFU/g, E.coli, CFU/g, Salmonellas/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Nitrate and/or Nitrite Content (if utilized)	Administrative Order No. 154 s. 1971 and Bureau Circular No. 2006-016	

F2aii - Cured (including salted) and dried non-heat treated processed comminuted meat, poultry and game products (jerky, shredded beef/pork) *"The comminuted or mechanically deboned products may be cured or salted as described for category 08.3.1.1, and then dried, or they may only be dried. Drying is achieved either in hot air or in vacuum. Examples include: pasturmas, dried sausages, cured and dried sausages, beef jerky, Chinese sausages (including traditional cured or smoked pork sausage), and sobrasada."* *(Source URL; https://www.fao.org/gsfaonline/foods/details.html?id=141)*	☑ Valid Certificate of Analysis for Microbiological parameters for **DRIED ANIMAL PRODUCTS:** S. aureus CFU/g, Clostridium perfringens CFU/g and Salmonella/25 ☑ Valid Certificate of Analysis for Microbiological parameters for **MINCED MEAT AND MEAT PREPARATIONS MADE FROM POULTRY MEAT INTENDED TO BE EATEN COOKED:** Aerobic Plate Count, CFU/g, E.coli, CFU/g, Salmonellas/25g ☑ Valid Certificate of Analysis for Microbiological parameters for **MINCED MEAT AND MEAT PREPARATIONS MADE FROM SPECIES OTHER THAN POULTRY INTENDED TO BE EATEN COOKED:** Aerobic Plate Count, CFU/g, E.coli, CFU/g, Salmonellas/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Valid Certificate of Analysis for Nitrate and/or Nitrite Content (if utilized)	Administrative Order No. 154 s. 1971 and Bureau Circular No. 2006-016	

F2aiii - Fermented non-heat treated processed comminuted meat, poultry and game products *"Fermented products are a type of pickled product produced by the action of lactic acid bacteria in the presence of salt. Certain types of sausages may be fermented."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=142)* e.g., pre-grilled beef patties; foie gras and pates; brawn and head cheese; cooked, cured chopped meat; chopped meat boiled in soy sauce (tsukudani); canned corned beef; luncheon meats; meat pastes; cooked meat patties; cooked salami-type products; cooked meatballs; saucises de strasbourg; breakfast sausages; brown-and-serve sausages; and terrines (a cooked chopped meat mixture).	☑ Valid Certificate of Analysis for Microbiological parameters for **FERMENTED, COMMINUTED MEAT, NOT COOKED (DRY & SEMI-DRY FERMENTED SAUSAGES)**: E. coli MPN/g, S. aureus CFU/g & Salmonella/25gCFU/g & Salmonella/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Valid Certificate of Analysis for Nitrate and/or Nitrite Content (if utilized)	Administrative Order No. 154 s. 1971 and Bureau Circular No. 2006-016	Applicant Company/ Manufacturer/Source/Supplier
H1a - Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans and echinoderms *"Smoked fish are usually prepared from fresh deep frozen or frozen fish that are dried directly or after boiling, with or without salting, by exposing the fish to freshly-generated sawdust smoke. Dried fish are prepared by exposing the fish to sunlight or drying directly or after boiling in a special installation; the fish may be salted prior to drying. Salted fish are either rubbed with salt or placed in a salt solution. This manufacturing process is different from that described in food category 09.3 for marinated and pickled fish. Cured fish is prepared by salting and then smoking fish. Examples include: salted anchovies, shrimp, and shad; smoked chub, cuttlefish and octopus; fish ham; dried*	☑ Valid Certificate of Analysis for Microbiological parameters for **ETHNIC FOOD PRODUCTS - DRIED, SALTED FISH:** Aerobic Plate Count CFU/g, Yeast and Mold Count CFU/g, Coliforms MPN/g, E. coli MPN/g and S. aureus MPN/g ☑ Valid Certificate of Analysis for Microbiological parameters for **SMOKED FISH:** Aerobic Plate Count CFU/g, Salmonella/25g, E. coli MPN/g and S. aureus CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

and salted species of the Gadidae species; smoked or salted fish paste and fish roe; cured and smoked sablefish, shad, and salmon; dried shellfish, dried bonito (katsuobushi), and boiled, dried fish (niboshi)." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=158)*	☑ Valid Certificate of Analysis for Microbiological parameters for **SALT FERMENTED FISH AND SHRIMPS (BAGOONG):** Aerobic Plate Count CFU/g and Coliforms CFU/g		
H2a - Fish and fish products, includings molluscs, crustaceans and echinoderms - marinated and/or in jelly *"Marinated products are manufactured by soaking the fish in vinegar or wine with or without added salt and spices. They are packaged in jars or cans and have a limited shelf life. Products in jelly may be manufactured by tenderizing fish products by cooking or steaming, adding vinegar or wine, salt and preservatives, and solidifying in a jelly. Examples include: "rollmops" (a type of marinated herring), sea eel (dogfish) in jelly and fish aspic."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=160)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
H2b - Fish and fish products, includings molluscs, crustaceans and echinoderms - pickled and/or in MH2brine *"Pickled products are sometimes considered a type of marinaded product. Pickling results from the treatment of the fish with with a salt and vinegar or alcohol (e.g., wine) solution. Examples include: different types of Oriental pickled products: koji-pickled fish (koji-zuke), lees-pickled fish (kasu-zuke), miso-pickled fish (miso-zuke), soy sauce-pickled fish (shoyu-zuke), and vinegar-*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

pickled fish (su-zuke); pickled whale meat; and pickled herring and sprat." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=161)*			
H2c - Salmon substitutes, caviar and other fish roe products *"Roe is usually produced by washing, salting and allowing to ripen until transparent. The roe is then packaged in glass or other suitable containers. The term "caviar" refers only to the roe of the sturgeon species (e.g. beluga). Caviar substitues are made of roe of various sea and freshwater fish (e.g., cod and herring) that are salted, spiced, dyed and may be treated with a preservative. Examples include: salted salmon roe (sujiko), processed, salted salmon roe (ikura), cod roe, salted cod roe (tarako) and lumpfish caviar."* *Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=162)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
H2d - Semi-preserved fish and fish products, including molluscs, crustaceans and echinoderms, excluding products under MR Letter H.1 a to c. *"Examples include fish or crustacean pates and traditional Oriental fish paste. The latter is produced from fresh fish or the residue from fish sauce production, which is combined with other ingredients such as wheat flour, bran, rice or soybeans. The product may be further fermented."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=163)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

e.g. fish or crustacean pates and traditional Oriental fish paste			
I1 - Preserved eggs, including alkaline, salted and canned eggs (salted eggs, century eggs) *"Includes traditional Oriental preserved products, such as salt-cured duck eggs (Hueidan), and alkaline treated "thousand-year-old-eggs" (pidan)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=171)* e.g. salt-cured duck eggs (Hueidan), and alkaline treated "thousand-year-old-eggs" (pidan)	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
I2 - Egg-based desserts *"Includes ready-to-eat products and products to be prepared from a dry mix. Examples include: flan and egg custard. Also includes custard fillings for fine bakery wares (e.g. pies)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=172)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
Ja - Cakes, cookies, pies pastries, doughnuts, sweet rolls, scones, muffins, waffles - plain/without filling e.g. pancakes, waffles, filled sweet buns (anpan), Danish pastry, wafers or cones for ice cream, flour confectionery, and trifles	☑ Valid Certificate of Analysis for Microbiological parameters for **BAKED GOODS**: Yeast CFU/g, Mold CFU/g, Aerobic Plate Count, CFU/g, Coliforms CFU/g & Salmonella/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
Jb - Frozen dough	☑ Valid Certificate of Analysis for Microbiological parameters for **FROZEN AND REFRIGERATED DOUGHS**: Salmonella/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
K1 - Soups and broths *"Water- or milk-based products consisting of vegetable,*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

meat or fish broth with or without other ingredients (e.g. vegetables, meat, noodles). Examples include: bouillon, broths, consommés, water- and cream-based soups, chowders, and bisques." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=197)*			
K2a - Emulsified sauces and dips *"Sauces, gravies, dressings, and dips based, at least in part, on a fat- or oil-in water emulsion. Examples include: salad dressing (e.g., French, Italian, Greek, ranch style), fat-based sandwich spreads (e.g., mayonnaise with mustard), salad cream, fatty sauces and snack dips (e.g., bacon and cheddar dip, onion dip)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=200)*	☑ In the Electronic Registration Data Entry – under Complete List of Ingredients, declare the % by weight of edible vegetable oil content of the finished product for **MAYONNAISE** ☑ Valid Certificate of Analysis for calcium disodium EDTA (calcium disodium ethylenediaminetetraacetate) or disodium EDTA (disodium ethylenediaminetetraacetate) content, IF ADDED in **MAYONNAISE** *The product shall conform with the identity, standards for optional ingredients and additional label declaration for MAYONNAISE.	Administrative Order No. 235 s. 1975	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **EMULSIFIED SAUCE PH ≤ 4.6 (E.G. MAYONNAISE, THOUSAND ISLAND, RANCH,**	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	FRENCH): Aerobic Plate Count CFU/g, Yeast and Mold Count CFU/g, Salmonella/25g & Listeria monocytogenes/25g ☑ Valid Certificate of Analysis for Microbiological parameters for **SALADS AND SANDWICH SPREADS (excluding cocoa milk based sadwich spreads):** Aerobic Plate Count CFU/g, Yeast and Mold Count CFU/g, Salmonella/25g & Listeria monocytogenes/25g		
K2b - Non-emulsified sauces (ketchup, cheese sauce, cream sauce, brown gravy) *"Include water-, coconut milk-, and milk-based sauces, gravies and dressings. Examples include: barbecue sauce, tomato ketchup, cheese sauce, Worcestershire sauce, Oriental thick Worcestershire sauce (tonkatsu sauce), chili sauce, sweet and sour dipping sauce, and white (cream-based) sauce (sauce consisting primarily of milk or cream, with little added fat (e.g. butter) and flour, with or without seasoning or spices)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=201)*	☑ Valid Certificate of Analysis for Total Solids; Titratable Acidity (as acetic acid); pH for **BANANA SAUCE/BANANA CATSU**P *The product shall conform with the standards for the identity, essential composition, quality factors and label declaration for BANANA SAUCE/BANANA CATSUP.	Administrative Order No. 123-A s. 1985	Applicant Company/ Manufacturer/Source/Supplier
K3 - Salads (e.g. macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads under HR Letter B.8 (peanut butter) and MR D.1.c (cocoa-based spreads) *"Includes prepared salads, milk-based sandwich*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

spreads, non-standardized mayonnaise-like sandwich spreads, and dressing for coleslaw (cabbage salad)" (Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=204)			
L1a - Fruit and vegetable juices - (fruit juice, vegetable juice, concentrates for fruit juice, concentrates for vegetable juice) **FRUIT JUICE** *"Fruit juice is the unfermented but fermentable liquid obtained from the edible part of sound, appropriately mature and fresh fruit or of fruit maintained in sound condition by suitable means. The juice is prepared by suitable processes, which maintain the essential physical, chemical, organoleptical and nutritional characteristics of the juices of the fruit from which it comes. The juice may be cloudy or clear, and may have restored (to the normal level attained in the same kind of fruit) aromatic substances and volatile flavour components, all of which must be obtained by suitable physical means, and all of which must have been recovered from the same kind of fruit. Pulp and cells obtained by suitable physical means from the same kind of fruit may be added. A single juice is obtained from one kind of fruit. A mixed juice is obtained by blending two or more juices or juices and purees, from different kinds of fruit. Fruit juice may be obtained, e.g. by directly expressing the juice by mechanical extraction processes, by reconstituting concentrated fruit juice*	☑ Valid Certificate of Analysis for Microbiological parameters for **NON-ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS)**: Yeast and Mold Count CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **FROZEN JUICE CONCENTRATES**: Aerobic Plate Count CFU/ml & Yeast and Mold Count CFU/ml	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **JUICES IN HERMETICALLY SEALED CONTAINERS (TETRA PACK ETC.):** Commercial Sterility	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate for Microbiological parameters for **POWDERED BEVERAGES (e.g. ICED TEA, POWDERED JUICES/MIXES):** Aerobic Plate	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

(food category 14.1.2.3) with water, or in limited situations by water extraction of the whole fruit (e.g., prune juice from dried prunes). Examples include: orange juice, apple juice, black currant juice, lemon juice, orange-mango juice, and coconut water." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=239 , you may also refer to AO No. 90-A s. 1980)* **VEGETABLE JUICE** *"Vegetable juice is the liquid unfermented but fermentable product intended for direct consumption obtained by mechanical expression, crushing, grinding, and/or sieving of one or more sound fresh vegetables or vegetables preserved exclusively by physical means. The juice may be clear, turbid, or pulpy. It may have been concentrated and reconstituted with water. Products may be based on a single vegetable (e.g. carrot) or blends of vegetables (e.g. carrots, celery)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=240)* **CONCENTRATES FOR FRUIT JUICE** *"It is prepared by the physical removal of water from fruit juice in an amount to increase the Brix level to a value at least 50% greater than that established for reconstituted juice from the same fruit. In the production of juice that is to be concentrated, suitable processes are used, and may be combined, with simultaneous diffusion of the pulp cells or fruit pulp by water, provided that the water-extracted soluble fruit solids are added in-line to the primary juice, before the concentration procedure. Fruit*	Count CFU/g, Yeast and Mold Count CFU/g & Coliforms CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for **FRUIT BEVERAGE PRODUCTS:** Aerobic Plate Count CFU/ml, Yeast and Mold Count CFU/ml, Coliforms CFU/ml & E.coli CFU/ml.	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

juice concentrates may have restored (to the normal level attained in the same kind of fruit) aromatic substances and volatile flavour components, all of which must be obtained by suitable physical means, and all of which must be recovered from the same kind of fruit. Pulp and cells obtained by suitable physical means from the same kind of fruit may be added. Sold in liquid, syrup and frozen forms for the preparation of a ready-to-drink juice by addition of water. Examples include: frozen orange juice concentrate, and lemon juice concentrate." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=241)* **CONCENTRATES FOR VEGETABLE JUICE** *"Prepared by the physical removal of water from vegetable juice. Sold in liquid, syrup and frozen forms for the preparation of a ready-to-drink juice by addition of water. Includes carrot juice concentrate."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=242)*			
L1b - Fruit and vegetable nectars (fruit nectar, vegetable nectar, concentrates for fruit nectar, concentrates for vegetable nectar) **FRUIT NECTAR** *"Fruit nectar is the unfermented but fermentable product obtained by adding water with or without the addition of sugar, honey, syrups, and/or sweeteners to fruit juice, concentrated fruit juice, fruit purees or concentrated fruit*	☑ Valid Certificate of Analysis for Microbiological parameters for **NON-ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS)**: Yeast and Mold Count CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

purees, or a mixture of those products. Aromatic substances, volatile flavour components, pulp and cells, all of which must have been recovered from the same kind of fruit and obtained by suitable physical means, may be added. Products may be based on a single fruit or on fruit blends. Examples include: pear nectar and peach nectar." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=244)* **VEGETABLE NECTAR** *"Product obtained by adding water with or without the addition of sugar, honey, syrups, and/or sweeteners to vegetable juice or concentrated vegetable juice, or a mixture of those products. Products may be based on a single vegetable or on a blend of vegetables."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=245)* **CONCENTRATES FOR FRUIT NECTAR** *"Prepared by the physical removal of water from fruit nectar or its starting materials. Sold in liquid, syrup and frozen forms for the preparation of a ready-to-drink nectar by addition of water. Examples: pear nectar concentrate and peach nectar concentrate."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=246)* **CONCENTRATES FOR VEGETABLE NECTAR**	☑ Valid Certificate of Analysis for Microbiological parameters for **FROZEN JUICE CONCENTRATES**: Aerobic Plate Count CFU/ml & Yeast and Mold Count CFU/ml	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **JUICES IN HERMETICALLY SEALED CONTAINERS (TETRA PACK ETC.):** Commercial Sterility	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate for Microbiological parameters for **POWDERED BEVERAGES (e.g. ICED TEA, POWDERED JUICES/MIXES):** Aerobic Plate Count CFU/g, Yeast and Mold Count CFU/g & Coliforms CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **FRUIT BEVERAGE PRODUCTS:** Aerobic Plate Count CFU/ml, Yeast and Mold Count CFU/ml, Coliforms CFU/ml & E.coli CFU/ml.	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

"Prepared by the physical removal of water from vegetable nectar. Sold in liquid, syrup and frozen forms for the preparation of ready-to-drink nectars by addition of water." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=247)*			
L1c - "Sport," "energy", or "electrolyte drinks" *"Includes so-called "energy" drinks that are carbonated and contain high levels of nutrients and other ingredients (e.g. caffeine, taurine, carnitine)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=249)*	☑ Valid Certificate of Analysis for Microbiological parameters for **NON-ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS)**: Yeast and Mold Count CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Valid Certificate of Analysis for Caffeine and Vitamin B and/or mineral/s (whichever is applicable) content	Administrative No. Order 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
	Label bearing the Precaution Statement: "Excessive intake of caffeine may cause sleeplessness, palpitation and other similar side effects. Not recommended for children, pregnant and lactating women, people who may have heart problems and/or those sensitive to caffeine."	Administrative Order No. 2014-0030	Applicant Company/ Manufacturer/Source/Supplier

L1ci - Carbonated water-based flavored drinks *"Includes water-based flavored drinks with added carbon dioxide with nutritive, non-nutritive and/or intense sweeteners and other permitted food additives. Includes gaseosa (water-based drinks with added carbon dioxide, sweetener, and flavour), and sodas such as colas, pepper-types, root beer, lemon-lime, and citrus types, both diet/light and regular types. These beverages may be clear, cloudy, or may contain particulated matter (e.g. fruit pieces). Includes so-called "energy" drinks that are carbonated and contain high levels of nutrients and other ingredients (e.g. caffeine, taurine, carnitine). (Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=249)* e.g. colas, pepper-types, root beer, lemon-lime, and citrus types, both diet/light and regular types)	☑ Valid Certificate of Analysis for Microbiological parameters for **NON-ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS)**: Yeast and Mold Count CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	Valid Certificate of Analysis for Caffeine Content for **COLA-TYPE BEVERAGE**	Administrative Order 88-A s. 1984	Applicant Company/ Manufacturer/Source/Supplier
L1cii - Non-carbonated water-based flavored drinks *"Include water-based flavoured drinks without added carbon dioxided, fruit and vegetable juice-based drinks (e.g. almond, aniseed, coconut-based drinks, and ginseng drink), fruit flavoured ades (e.g. lemonade, orangeade), squashes (citrus-based soft drinks), capile groselha, lactic acid beverage, ready-to-drink coffee and tea drinks with or without milk or milk solids, and herbal-based drinks (e.g. iced tea, fruit-flavoured iced tea, chilled canned cappucino drinks) and "sports" drinks containing electrolytes. These beverages may be clear or contain particulated matter (e.g. fruit pieces), and may be unsweetened or sweetened with sugar or a non-nutritive high-intensity sweetener. Includes so-called "energy" drinks that are non-carbonated and contain*	☑ Valid Certificate of Analysis for Microbiological parameters for **NON-ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS)**: Yeast and Mold Count CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL ☑ Valid Certificate of Analysis for Microbiological parameters for **CHILLED YOUNG COCONUT WATER (BUKO JUICE):** Aerobic	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

high levels of nutrients and other ingredients (e.g. caffeine, taurine, carnitine)." *(Source URL:* https://www.fao.org/gsfaonline/foods/details.html?id=250*)*	Plate Count CFU/mL, Yeast and Mold Count CFU/mL and Coliforms CFU/mL		
L1ciii - Concentrates (liquid or solid) for water-based flavored drinks *"Include powder, syrup, liquid and frozen concentrates for the preparation of carbonated or non-carbonated water-based non-alcoholic beverages by addition of water or carbonated water. Examples include: fountain syrups (e.g. cola syrup), fruit syrups for soft drinks, frozen or powdered concentrate for lemonade and iced tea mixes."* *(Source URL:* https://www.fao.org/gsfaonline/foods/details.html?id=251*)*	☑ Valid Certificate of Analysis for Microbiological parameters for **FROZEN JUICE CONCENTRATES**: Aerobic Plate Count CFU/ml & Yeast and Mold Count CFU/ml ☑ Valid Certificate for Microbiological parameters for **POWDERED BEVERAGES (e.g. ICED TEA, POWDERED JUICES/MIXES)**: Aerobic Plate Count CFU/g, Yeast and Mold Count CFU/g & Coliforms CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
L1d - Powdered cocoa drink mixes (cocoa) *"Examples include: drinking chocolate powder; breakfast cocoa; cocoa dust (fines), nibs, mass, press cake; chocolate liquor; cocoa mixes (powders for preparing the hot beverage); cocoa-sugar mixture; and dry mixes for sugar-cocoa confectionery."* *(Source URL:* https://www.fao.org/gsfaonline/foods/details.html?id=88*)*	☑ Valid Certificate for Microbiological parameters for **POWDERED BEVERAGES (e.g. ICED TEA, POWDERED JUICES/MIXES):** Aerobic Plate Count CFU/g, Yeast and Mold Count CFU/g & Coliforms CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for **COCOA POWDER**: Molds CFU/g, Salmonella/25g, Coliforms,	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	MPN/g or CFU/g & Aerobic Plate Count CFU/g		
M1 - Vitamins and minerals as Food Supplement *"Includes vitamin and mineral supplements in unit dose forms such as capsules, tablets, powders, solutions etc., where national jurisdictions regulate these products as food"* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=232)* *"means a processed food product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamin, mineral, herb, or other botanical, amino acid, and dietary substance to increase the total daily intake in amounts conforming to the latest Philippine recommended energy and nutrient intakes or internationally agreed minimum daily requirements. It usually is in the form of capsules, tablets, liquids, gels, powders or pills and not represented for use as a conventional food or as the sole item of a meal or diet or replacement of drugs and medicines."* *(Source URL: https://www.officialgazette.gov.ph/2009/08/18/republic-act-no-9711/)* e.g. Vitamin C + Zinc Food Supplement Capsule	☑ Valid Shelf life study with stability data containing relevant information on the critical parameters of the finished product, period conducted and conclusion	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis of the physico-chemical (Vitamins or Minerals or Amino Acids Assays) and/or microbiological parameters of the finished product (whichever is applicable) *The amount of Vitamins shall conform with the prescribed level of Office Order No. 22 s 1991	Administrative Order No. 2014-0029 Office Order No. 22 s 1991 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
	☑ Clear and complete loose labels or artworks declaring the term “Food Supplement” and the phrase “NO APPROVED THERAPEUTIC CLAIMS” based on	Bureau Circular No. 2 s 1999	Applicant Company/ Manufacturer/Source/Supplier
	☑ Sample in actual commercial presentation *for the procedure on submission, please refer to: IV. Guidelines, C. Procedural Guidelines 2. L. ii., Pages 7-8 of FDA Circular No. 2020-033	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier

M2 - Amino acids as Food Supplement *"Includes vitamin and mineral supplements in unit dose forms such as capsules, tablets, powders, solutions etc., where national jurisdictions regulate these products as food"* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=232)* *"means a processed food product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamin, mineral, herb, or other botanical, amino acid, and dietary substance to increase the total daily intake in amounts conforming to the latest Philippine recommended energy and nutrient intakes or internationally agreed minimum daily requirements. It usually is in the form of capsules, tablets, liquids, gels, powders or pills and not represented for use as a conventional food or as the sole item of a meal or diet or replacement of drugs and medicines."* *(Source URL: https://www.officialgazette.gov.ph/2009/08/18/republic-act-no-9711/)* e.g. Branched-Chain Amino Acids (BCAA) Food Supplement Powder	☑ Valid Shelf life study with stability data containing relevant information on the critical parameters of the finished product, period conducted and conclusion	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis of the physico-chemical (Vitamins or Minerals or Amino Acids Assays) and/or microbiological parameters of the finished product (whichever is applicable) *The amount of Vitamins shall conform with the prescribed level of Office Order No. 22 s 1991	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
	☑ Clear and complete loose labels or artworks declaring the term “Food Supplement” and the phrase “NO APPROVED THERAPEUTIC CLAIMS” based on	Bureau Circular No. 2 s 1999	Applicant Company/ Manufacturer/Source/Supplier
	☑ Sample in actual commercial presentation *for the procedure on submission, please refer to: IV. Guidelines, C. Procedural Guidelines 2. L. ii., Pages 7-8 of FDA Circular No. 2020-033	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
N - Processed nuts, including coated nuts and nut mixtures (with e.g. dried fruits)	☑ Valid Certificate of Analysis for Microbiological parameters for **SNACK FOODS**: Molds, CFU/g,	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

e.g. Yoghurt-, cereal-, and honey-covered nuts, and dried fruit-nut-and-cereal snacks (e.g. “trail mixes”)	Yeast & Yeast-like fungi, CFU/g, Coliforms, CFU/g, Aerobic Plate Count, CFU/g.		
HIGH RISK FOOD PRODUCTS	**☑ ADDITIONAL REQUIREMENTS**	**BASIS/ISSUANCE**	**WHERE TO SECURE**
HIGH RISK FOOD PRODUCTS - *foods that may contain pathogenic microorganisms and will support the formation of toxins and or the growth or pathogenic microorganisms and foods that may contain harmful chemicals.* (AO No. 2014-0029)			
A1a - Milk (plain) and buttermilk (plain) *"Plain fluid milk obtained from milking animals (e.g., cows, sheep, goats, buffalo) that has been processed. Includes pasteurized, ultra-high temperature (UHT) treated, sterilized, homogenized, or fat adjusted milk. Includes, but is not limited to, skim, part-skim, low-fat and whole milk."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=3)* *"Includes plain recombined fluid milks, plain reconstituted fluid milks, plain composite milks, non-flavoured vitamin and mineral fortified fluid milks, protein adjusted milks, lactose reduced milk, and plain milk-based beverages."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=4)*	☑ Valid Certificate of Analysis for % Milk Solids Not Fat and % Milk Fat for **MILK, CARABAO'S AND/OR BUFFALO'S MILK AND GOAT'S (NATIVE) MILK**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Milk Solids Not Fat and % Milk Fat for **SKIM MILK OR SKIMMED MILK**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Milk Solids Not Fat and % Milk Fat for **RECONSTITUTED, RECONSTRUCTED OR RECOMBINED MILK**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Milk Solids Not Fat for **RECONSTITUTED, RECONSTRUCTED OR RECOMBINED SKIMMED MILK**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Milk Solids Not Fat for **BUTTERMILK**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier

	☑ Valid Certificate of Analysis for % Milk Fat for **LOWFAT MILK AND RECONSTITUTED, RECONSTRUCTED OR RECOMBINED LOWFAT MILK**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Non-Fat Milk Solids, Vitamin A and Vitamin D (if added) for **FILLED MILK** *The % Total Oil Content shall be declared in the Electronic Registration Data Entry. **The product shall conform with the identity, standards for optional ingredients and additional label declaration for Filled Milk.	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	***PASTEURIZED MILK AND STERILISED MILK** shall conform with the prescribed standard of identity and quality	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **LIQUID MILK (EVAPORATED & READY TO DRINK)-UHT/STERILIZED:** Commercial Sterility	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **PASTEURIZED MILK:** Coliforms CFU/mL, Salmonella/25mL, Listeria monocytogenes/25mL,	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	Psychrotrophic bacteria cfu/mL & Aerobic Plate Count CFU/g **(Plain/Flavored)**		
A1b - Dairy-based drinks, flavored and/or fermented *"Includes all mixes and ready-to-drink fermented or not fermented milk-based drinks with flavourings and/or food ingredients that intentionally impart flavour, excluding mixes for cocoa. Examples, include but are not limited to, chocolate milk, chocolate malt drinks, strawberry-flavoured yoghurt drink, lactic acid bacteria drinks, whey-based drinks, and lassi (liquid obtained by whipping curd from the lactic acid fermentation of milk, and mixing with sugar or intense sweetener)." (Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=6)*	***FLAVORED MILK, FLAVORED RECONSTITUTED MILK, FLAVORED DRINK OR FLAVORED DAIRY DRINK, AND CHOCOLATE DRINK OR CHOCOLATE FLAVORED DRINK** shall conform with the prescribed standard of identity and quality	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **LIQUID MILK (READY TO DRINK)-UHT/STERILIZED**: Commercial Sterility	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **NON-ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS)**: Yeast and Mold Count CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
A2ai - Fermented milk (plain), non heat-treated after fermentation *"Includes fluid and non-fluid plain products, such as yoghurt and plain drinks based on fermented milk." (Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=9)*	☑ Valid Certificate of Analysis for % Milk Fat Content by weight; % Milk Solids Non-Fat Content by weight; Acidity of the product when solid for **YOGURT AND FLAVORED YOGURT**	Administrative Order No. 132 s. 1970	

			Applicant Company/ Manufacturer/Source/Supplier
	*__Toned Milk__ shall conform with the prescribed standard of identity and quality	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **YOGURT AND OTHER FERMENTED MILK**: S. aureus CFU/mL, Coliforms CFU/mL, Salmonella/25mL & Lactic acid CFU/mL (required minimum level: ≥10^6 CFU/mL)	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
A2aii - Fermented milks (plain), heat-treated after fermentation *Includes fluid and non-fluid plain products, such as yoghurt and plain drinks based on fermented milk. - "except that they have been heat-treated (e.g. sterilized or pasteurized) after fermentation."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=10)*	☑ Valid Certificate of Analysis for % Milk Fat Content by weight; % Milk Solids Non-Fat Content by weight; Acidity of the product when solid for **YOGURT AND FLAVORED YOGURT**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	*__Toned Milk__ shall conform with the prescribed standard of identity and quality	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **HEAT TREATED, FERMENTED MILK (STERILIZED, UHT):** Commercial Sterility	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
A2b - Renneted milk (plain) *"Plain, coagulated milk produced by the action of milk coagulating enzymes. Includes curdled milk."*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=11)			
A3a - Pasteurized cream (plain) *"Cream subjected to pasteurization by appropriate heat treatment or made from pasteurized milk. Includes milk cream and "half-and-half.""* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=16)*	☑ Valid Certificate of Analysis for Microbiological parameters for **PASTEURIZED CREAM**: Coliforms CFU/g, Salmonella/25g, Listeria monocytogenes/25g, Aerobic Plate Count CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
A3b - Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain) *"Includes every cream, regardless of fat content, which has undergone a higher heat-treatment than pasteurization. Also includes pasteurized creams with a reduced fat content, as well as every cream intended for whipping or being whipped. Sterilized cream is subjected to appropriate heat-treatment in the container in which it is presented to the consumer. Ultra-heat treated (UHT) or ultrapasteurized cream is subjected to the appropriate heat treatment (UHT or ultrapasteurization) in a continuous flow process and aseptically packaged. Cream may also be packaged under pressure (whipped cream). Includes whipping cream, heavy cream, whipped pasteurized cream, and whipped cream-type dairy toppings and fillings."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=17)*	☑ Valid Certificate of Analysis for % Butterfat for **CREAM**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Butterfat for **LIGHT CREAM TABLE CREAM OR COFFEE CREAM**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Milk Fat for **WHIPPING CREAM**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Butterfat for **LIGHT WHIPPING CREAM**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Milk Fat for **HEAVY CREAM OR HEAVY WHIPPING CREAM**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Milk Fat for **HALF-AND HALF**	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	CREAM (UHT/STERILIZED): Commercial Sterility		
A3c - Clotted cream (plain) *"Thickened, viscous cream formed from the action of milk coagulating enzymes. Includes sour cream (cream subjected to lactic acid fermentation."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=18)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
A3d - Cream analogues *"Cream substitute consisting of a vegetable fat-water emulsion in liquid or powdered form for use other than as a beverage whitener. Includes instant whipped cream toppings and sour cream substitutes."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=19)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
A4a - Unripened cheese *"Unripened cheese, including fresh cheese, is ready for consumption soon after manufacture. Examples include cottage cheese (a soft, unripened, coagulated curd cheese), creamed cottage cheese (cottage cheese covered with a creaming mixture), cream cheese (rahmfrischkase, an uncured, soft spreadable cheese), mozzarella and scamorza cheeses. Includes the whole unripened cheese and unripened cheese rind (for those unripened cheeses with a "skin" such as mozzarella). Most products are plain, however, some, such as cottage cheese and cream cheese, may be flavoured or contain ingredients such as fruit, vegetables or meat."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=24)*	☑ Valid Certificate of Analysis for % Milk Fat and % Moisture for **CREAM CHEESE** *The product shall conform with the identity and standards for optional ingredients for Cream Cheese.	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Milk Fat and % Moisture for **COTTAGE CHEESE DRY CURD or DRY CURD COTTAGE CHEESE** *The product shall conform with the identity, standards for optional ingredients and additional label	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier

	declaration for Cottage Cheese Dry Curd or Dry Curd Cottage Cheese.		
	☑ Valid Certificate of Analysis for % Milk Fat and % Moisture for **COTTAGE CHEESE** *The product shall conform with the identity, standards for optional ingredients and additional label declaration for Cottage Cheese.	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Milk Fat and % Moisture for **LOW FAT COTTAGE CHEESE** *The product shall conform with the identity, standards for optional ingredients and additional label declaration for Low Fat Cottage Cheese.	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Milk Fat for **SKIM MILK CHEESE** *The product shall conform with the identity for Skim Milk Cheese.	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **SOFT CHEESE (FROM PASTEURIZED MILK):** Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	monocytogenes/ 25g & S. aureus CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for **HARD AND SEMI-HARD CHEESE:** Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for **CREAM CHEESE PRODUCTS:** Coliforms CFU/g or MPN/g or /25g. E. coli CFU/g or MPN/g or /25g and Yeast and Molds CFU/g		
	☑ Valid Certificate of Analysis for Microbiological parameters for **ALL RAW MILK CHEESE; RAW MILK UN-RIPENED CHEESE W/ MOISTURE > 50%, pH > 5.0:** Campylobacter/25g, Listeria monocytogenes/25g, Salmonella/25g & S. aureus CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
A4bi - Ripened cheese, includes rind *"Refers to ripened (including mould-ripened) cheese, including rind, or any part thereof, such as cut, shredded, grated or sliced cheese. Examples of ripened cheese include: blue cheese, brie, gouda, havarti, hard grating cheese, and Swiss cheese."*	☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for **CHEDDAR CHEESE** *The product shall conform with the identity and standards for	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier

(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=26)	optional ingredients for Cheddar Cheese.		
	☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for WASHED CURD **CHEESE (SOAKED CURD CHEESE)** *The product shall conform with the identity and standards for Washed Curd Cheese (Soaked Curd Cheese).	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for **COLBY CHEESE** *The product shall conform with the identity and standards for Colby Cheese.	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for **GRANULAR CHEESE (STIRRED CURD CHEESE)** *The product shall conform with the identity and standards for Granular Cheese (Stirred Curd Cheese).	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for **BRICK CHEESE**	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier

	*The product shall conform with the identity and standards for optional ingredients for Brick Cheese.		
	☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for **SWISS CHEESE** *The product shall conform with the identity and standards for optional ingredients Swiss Cheese.	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for **GRUYERS CHEESE** *The product shall conform with the identity and standards for optional ingredients Gruyers Cheese.	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for **EDAM CHEESE** *The product shall conform with the identity and standards for optional ingredients Edam Cheese.	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Moisture and % Milk Fat (of solids) for **PARMESAN CHEESE**	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier

	*The product shall conform with the identity and standards for optional ingredients Parmesan Cheese.		
	☑ Valid Certificate of Analysis for Microbiological parameters for **SOFT CHEESE (FROM PASTEURIZED MILK):** Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for **HARD AND SEMI-HARD CHEESE:** Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for **CREAM CHEESE PRODUCTS:** Coliforms CFU/g or MPN/g or /25g. E. coli CFU/g or MPN/g or /25g and Yeast and Molds CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **ALL RAW MILK CHEESE; RAW MILK UN-RIPENED CHEESE W/ MOISTURE > 50%, pH > 5.0:**	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	Campylobacter/25g, Listeria monocytogenes/25g, Salmonella/25g & S. aureus CFU/g		
A4bii - Rind of ripened cheese *"Refers to the rind only of the cheese. The rind of the cheese is the exterior portion of the cheese mass that initially has the same composition as the interior portion of the cheese, but which may dry after brining and ripening."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=27)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
A4biii - Cheese powder (for reconstitution) *"Dehydrated product prepared from a variety or processed cheese. Product is intended either to be reconstituted with milk or water to prepare a sauce, or used as-is as an ingredient (e.g. with cooked macaroni, milk and butter to prepare a macaroni and cheese casserole). Includes spray-dried cheese."* *Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=28)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
A4c - Whey cheese *"A solid or semi-solid product obtained by concentration of whey with or without the addition of milk, cream or other materials of milk origin, and moulding of the concentrated product. Includes the whole cheese and the rind of the cheese."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=29)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
A4di - Plain processed cheese	☑ Valid Certificate of Analysis for % Moisture Content, % Fat Content in Dry Matter and %	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier

"Processed cheese product that does not contain added flavours, seasonings, fruit, vegetables and/or meat. Examples include: American cheese, requeson." (Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=31)	Lactose for **PASTEURIZED PROCESS CHEESE** *The product shall conform with the identity, standards for optional ingredients and additional label declaration for Pasteurized Process Cheese.		
	☑ Valid Certificate of Analysis for % Moisture Content, % Fat Content and % Milk Fat (when the food contains other foodstuffs) for **PASTEURIZED PROCESS CHEESE FOOD** *The product shall conform with the identity, standards for optional ingredients and additional label declaration for Pasteurized Process Cheese Food.	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Moisture Content and % Fat Content for **PASTEURIZED PROCESS CHEESE SPREAD** *The product shall conform with the identity, standards for optional ingredients and additional label declaration for Pasteurized Process Cheese Spread.	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier

	☑ Valid Certificate of Analysis for Microbiological parameters for **SOFT CHEESE (FROM PASTEURIZED MILK):** Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for **HARD AND SEMI-HARD CHEESE:** Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for **CREAM CHEESE PRODUCTS:** Coliforms CFU/g or MPN/g or /25g. E. coli CFU/g or MPN/g or /25g and Yeast and Molds CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **ALL RAW MILK CHEESE; RAW MILK UN-RIPENED CHEESE W/ MOISTURE > 50%, pH > 5.0:** Campylobacter/25g, Listeria monocytogenes/25g, Salmonella/25g & S. aureus CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	☑ Valid Certificate of Analysis for Microbiological parameters for **PROCESSED CHEESE SPREAD:** Coliforms CFU/g, S. aureus CFU/g & Aerobic Plate Count CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
A4dii - Flavored processed cheese *"Processed cheese product that contains added flavours, seasonings, fruit, vegetables and/or meat. Examples include: neufchatel cheese spread with vegetables, pepper jack cheese, cheddar cheese spread with wine, and cheese balls (formed processed cheese coated in nuts, herbs or spices)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=32)*	☑ Valid Certificate of Analysis for % Moisture Content, % Fat Content in Dry Matter and % Lactose for **PASTEURIZED PROCESS CHEESE** *The product shall conform with the identity, standards for optional ingredients and additional label declaration for Pasteurized Process Cheese.	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Moisture Content, % Fat Content and % Milk Fat (when the food contains other foodstuffs) for **PASTEURIZED PROCESS CHEESE FOOD** *The product shall conform with the identity, standards for optional ingredients and additional label declaration for Pasteurized Process Cheese Food.	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for % Moisture Content and % Fat	Administrative Order No. 200-A s. 1973	Applicant Company/ Manufacturer/Source/Supplier

	Content for **PASTEURIZED PROCESS CHEESE SPREAD** *The product shall conform with the identity, standards for optional ingredients and additional label declaration for Pasteurized Process Cheese Spread.		
	☑ Valid Certificate of Analysis for Microbiological parameters for **SOFT CHEESE (FROM PASTEURIZED MILK):** Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for **HARD AND SEMI-HARD CHEESE:** Enterobacteriaceae CFU/g, E.coli CFU/g, Salmonella/ 25g, Listeria monocytogenes/ 25g & S. aureus CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for **CREAM CHEESE PRODUCTS:** Coliforms CFU/g or MPN/g or /25g. E. coli CFU/g or MPN/g or /25g and Yeast and Molds CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	☑ Valid Certificate of Analysis for Microbiological parameters for **ALL RAW MILK CHEESE; RAW MILK UN-RIPENED CHEESE W/ MOISTURE > 50%, pH > 5.0:** Campylobacter/25g, Listeria monocytogenes/25g, Salmonella/25g & S. aureus CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **PROCESSED CHEESE SPREAD:** Coliforms CFU/g, S. aureus CFU/g & Aerobic Plate Count CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
A4e - Cheese analogues *"Products that look like cheese, but in which milkfat has been partly or completely replaced by other fats. Includes imitation cheese, imitation cheese mixes, and imitation cheese powders."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=33)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
A4f - Whey protein cheese *"Product containing the protein extracted from the whey component of milk. These products are principally made by coagulation of whey proteins. Example: ricotta cheese."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=34)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
A5 - Dairy-based desserts *"Includes ready-to-eat flavoured dairy dessert products and dessert mixes."*	☑ Valid Certificate of Analysis for % Milk Fat Content by weight; % Milk Solids Non-Fat Content by	Administrative Order No. 132 s. 1970	Applicant Company/ Manufacturer/Source/Supplier

"Includes flavoured yoghurt (a milk product obtained by fermentation of milk and milk products to which flavours and ingredients (e.g., fruit, cocoa, coffee) have been added) that may or may not be heat-treated after fermentation." *Other examples include: "jellied milk, frozen flavoured yoghurt, junket (sweet custard-like dessert made from flavoured milk set with rennet), dulce de leche (cooked milk with sugar and added ingredients such as coconut or chocolate),butterscotch pudding and chocolate mousse. Includes traditional milk-based sweets prepared from milk concentrated partially, from khoa (cow or buffalo milk concentrated by boiling), or chhena (cow or buffalo milk, heat coagulated aided by acids like citric acid, lactic acid, malic acid, etc), sugar or synthetic sweetener, and other ingredients (e.g. maida (refined wheat flour), flavours and colours (e.g. peda, burfee, milk cake, gulab jamun, rasgulla, rasmalai, basundi)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=35)*	weight; Acidity of the product when solid for **YOGURT AND FLAVORED YOGURT**		
	☑ Valid Certificate of Analysis for Microbiological parameters for **YOGURT AND FERMENTED MILK**: S. aureus CFU/mL, Coliforms CFU/mL, Salmonella/25mL & Lactic acid CFU/mL (required minimum level: ≥10^6 CFU/mL) ☑ Valid Certificate of Analysis for Microbiological parameters for **ETHNIC MILK-BASED CONFECTIONERIES (e.g. PASTILLAS and YEMA):** Yeast and Mold Count CFU/g, Salmonella/25, Coliforms MPN/g or CFU/g and Aerobic Plate Count CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
A6a - Liquid whey and whey products *"Whey is the fluid separated from the curd after coagulation of milk, cream, skimmed milk or buttermilk with milk coagulating enzymes during the manufacture of cheese, casein or similar products. Acid whey is obtained after the coagulation of milk, cream, skimmed milk or buttermilk, mainly with acids of the type used for the manufacture of fresh cheese."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=37)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

A6b - Dried whey and whey products *"Whey powders are prepared by spray- or roller-drying whey or acid whey from which the major portion of the milkfat has been removed."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=38)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
A7 - Milk for manufacture	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
A8 - Dairy-based frozen desserts *"Includes frozen dairy confections and novelties, and dairy-based fillings."* *"Other examples include: ice cream (frozen dessert that may contain whole milk, skim milk products, cream or butter, sugar, vegetable oil, egg products, and fruit, cocoa, or coffee), ice milk (product similar to ice cream with reduced whole or skim milk content, or made with nonfat milk)"* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=35)*	☑ Valid Certificate of Analysis for Microbiological parameters for **ICE CREAM & SHERBET (PLAIN AND FLAVORED)**: Coliforms CFU/g, Listeria monocytogenes/25g, Salmonella/25g, Aerobic Plate Count CFU/g & S. aureus CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **ICE CREAM WITH ADDED INGREDIENTS (NUTS, FRUITS, COCOA ETC.)**: Coliforms CFU/g, S. aureus CFU/g, Salmonella/25g, Salmonella/25g CFU/g & Listeria monocytogenes/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
B1 - Dried fruits and vegetable - plain/sun-dried seaweeds, and nuts and seeds *"Products in which the natural water content has been reduced below that critical for growth for microorganisms without affecting the important nutrients. The product may or may not be intended for rehydration prior to consumption. Includes vegetable powders that are obtained from drying the juice, such as tomato powder*	☑ Valid Certificate of Analysis for Microbiological parameters for **SUN DRIED FRUITS**: Mold CFU/g, Osmophilic Yeasts CFU/g & E. coli MPN/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

and beet powder. Examples include: dried potato flakes and dried lentil. Examples of Oriental dried products include: dried sea tangle (kelp; kombu), dried sea tangle with seasoning (shio-kombu), dried seaweed (tororo-kombu), dried gourd strips (kampyo), dried laver (nori), and dried laminariales (wakame)." *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=79)*	**DRIED VEGETABLE:** E. coli MPN/g		
B2 - Vegetable seaweed, and nut and seed - purees, spreads *"Vegetable purees are finely dispersed slurries prepared from the concentration of vegetables, which may have been previously heat-treated (e.g., steamed). The slurries may be filtered prior to packaging. Examples include: tomato puree, peanut butter (a spreadable paste made from roasted and ground peanuts by the addition of peanut oil), other nut butters (e.g., cashew butter), and pumpkin butter."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=82)*	Valid Certificate of Analysis for % Fat Content and % Water Insoluble Inorganic Residue for Peanut Butter *The product shall conform with the identity and label statement for optional ingredients for Peanut Butter.	Administrative Order No. 228 s. 1974	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **PEANUT BUTTER & OTHER NUT BUTTER**S: Salmonella/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
D - Chocolate with nuts	☑ Valid Certificate of Analysis for Microbiological parameters for **CHOCOLATE PRODUCTS:** Molds CFU/g, Salmonella/25g, Coliforms MPN/g or CFU/g & Aerobic Plate Count CFU/g. ☑ Valid Certificate of Analysis for Microbiological parameters for **CHOCOLATE CONFECTIONARIES:** Molds	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	CFU/g, Osmophilic yeast CFU/g, Salmonella/25g, Coliforms MPN/g or CFU/g & Aerobic Plate Count CFU/g		
F1 - Fine bakery products with fillings: meat, milk, poultry, cream, and other perishable foods; icings and coatings *"The term "sweet cracker" or "sweet biscuit" used in this category refers to a cookie-like product that may be eaten as a dessert. Examples include: butter cake, cheesecake, fruit-filled cereal bars, pound cake (including kasutera), moist cake (type of starchy dessert (namagashi)), western cakes, moon cakes, sponge cake, fruit-filled pies (e.g. apple pie), oatmeal cookies, sugar cookies and British "biscuits" (cookies or sweet crackers)."* *(Source URL: https://fao.org/gsfaonline/foods/details.html?id=124)*	☑ Valid Certificate of Analysis for Microbiological parameters for **BAKED GOODS:** Yeast CFU/g, Mold CFU/g, Aerobic Plate Count CFU/g, Coliforms CFU/g & Salmonella/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **COATED OR FILLED, DRIED SHELF-STABLE BISCUITS:** Coliforms MPN/g & Salmonella/25g ☑ Valid Certificate of Analysis for Microbiological parameters for **ETHNIC FLOUR-BASED CONFECTIONERIES e.g. PIAYA):** Yeast and Mold Count CFU/g and Coliforms CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **FROZEN BAKERY PRODUCTS (READY TO EAT) WITH LOW ACID OR HIGH Aw FILLINGS OR TOPPINGS**: S. aureus CFU/g & Salmonella/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	☑ Valid Certificate of Analysis for Microbiological parameters for **FROZEN BAKERY PRODUCTS (TO BE COOKED) WITH LOW ACID OR HIGH Aw FILLINGS OR TOPPINGS**: S. aureus CFU/g & Salmonella/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
F2 - Cookies with nuts	☑ Valid Certificate of Analysis for Microbiological parameters for **BAKED GOODS:** Yeast CFU/g, Mold CFU/g, Aerobic Plate Count CFU/g, Coliforms CFU/g & Salmonella/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
G1a - Heat-treated processed meat, poultry and game products in whole pieces or cuts (canned) *"Includes cooked (including cured and cooked, and dried and cooked), heat-treated (including sterilized) and canned meat cuts. Examples include: cured, cooked ham; cured, cooked pork shoulder; canned chicken meat; and meat pieces boiled in soy sauce (tsukudani)." (Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=136)*	☑ Valid Certificate of Analysis for Microbiological parameters for **MEAT PRODUCTS IN HERMETICALLY SEALED CONTAINERS:** Commercial Sterility ☑ Valid Certificate of Analysis for Microbiological parameters for **PACKAGED COOKED CURED/SALTED MEAT**: S. aureus, CFU/g, Salmonella/25g, Listeria Monocytogenes/25g ☑ Valid Certificate of Analysis for Microbiological parameters for **MARINATED MEAT PRODUCTS**: Salmonella/25g, Listeria	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	monocytogenes/25g, S. aureus, CFU/g		
	☑ Valid Certificate of Analysis for Nitrate or Nitrite Content (if utilized)	Administrative Order No. 154 s. 1971 and Bureau Circular No. 2006-016	Applicant Company/ Manufacturer/Source/Supplier
G1b - Frozen processed meat, poultry and game products in whole pieces or cuts (marinated pork/beef/chicken cuts) *"Includes raw and cooked meat cuts that have been frozen. Examples include: frozen whole chickens, frozen chicken parts, and frozen beef steaks."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=137)*	☑ Valid Certificate of Analysis for Microbiological parameters for **MARINATED MEAT PRODUCTS**: Salmonella/25g, Listeria monocytogenes/25g, S. aureus, CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for **MINCED MEAT AND MEAT PREPARATIONS MADE FROM POULTRY MEAT INTENDED TO BE EATEN COOKED**: Aerobic Plate Count, CFU/g, E.coli, CFU/g, Salmonella/25g ☑ Valid Certificate of Analysis for Microbiological parameters for **MINCED MEAT AND MEAT PREPARATIONS MADE FROM SPECIES OTHER THAN POULTRY INTENDED TO BE EATEN COOKED**: Aerobic Plate Count, CFU/g, E.coli, CFU/g, Salmonella/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	☑ Valid Certificate of Analysis for Microbiological parameters for **FOODS COOKED IMMEDIATELY PRIOR TO SALE OR CONSUMPTION (e.g. Takeaway food, burgers, kebabs, sausages, pizza, ready meals (cook/chill and cook/freeze) after regeneration)**: Aerobic Plate Count CFU/g, Enterobacteriaceae CFU/g, E. coli CFU/g, S. aureus (coagulase +) CFU/g, Salmonella/25g and Listeria monocytogenes/25g ☑ Valid Certificate of Analysis for Microbiological parameters for **COOKED POULTRY MEAT, FROZEN TO BE REHEATED BEFORE EATING**: Aerobic Plate Count, CFU/g, S. aureus, CFU/g, Listeria monocytogenes/25g, Salmonella/25g, Campylobacter Jejuni/25g ☑ Valid Certificate of Analysis for Microbiological parameters for **COLD CUTS, FROZEN & CHILLED HOTDOGS**: E. coli MPN/g or CFU/g or /25g, Salmonella/25g, S. aureus CFU/g,		

	L. monocytogenes/25g & Aerobic Plate Count CFU/g		
G2a - Heat-treated processed comminuted meat, poultry and game products (canned) *"Includes cooked (including cured and cooked, and dried and cooked), heat-treated (including sterilized) and canned comminuted products. Examples include: pre-grilled beef patties; foie gras and pates; brawn and head cheese; cooked, cured chopped meat; chopped meat boiled in soy sauce (tsukudani); canned corned beef; luncheon meats; meat pastes; cooked meat patties; cooked salami-type products; cooked meatballs; saucises de strasbourg; breakfast sausages; brown-and-serve sausages; and terrines (a cooked chopped meat mixture)."* *(Source URL:* https://www.fao.org/gsfaonline/foods/details.html?id=143*)*	☑ Valid Certificate of Analysis for Microbiological parameters for **MEAT PRODUCTS IN HERMETICALLY SEALED CONTAINER**S: Commercial Sterility ☑ Valid Certificate of Analysis for Microbiological parameters for **MARINATED MEAT PRODUCTS:** Salmonella/25g, Listeria monocytogenes/25g, S. aureus, CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for **MINCED MEAT AND MEAT PREPARATIONS MADE FROM POULTRY MEAT INTENDED TO BE EATEN COOKED:** Aerobic Plate Count, CFU/g, E.coli, CFU/g, Salmonella/25g ☑ Valid Certificate of Analysis for Microbiological parameters for **MINCED MEAT AND MEAT PREPARATIONS MADE FROM SPECIES OTHER THAN POULTRY INTENDED TO BE EATEN COOKED:** Aerobic Plate	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	Count, CFU/g, E.coli, CFU/g, Salmonella/25g ☑ **Valid Certificate of Analysis for Microbiological parameters for FOODS COOKED IMMEDIATELY PRIOR TO SALE OR CONSUMPTION** (e.g. Takeaway food, burgers, kebabs, sausages, pizza, ready meals (cook/chill and cook/freeze) after regeneration): Aerobic Plate Count CFU/g, Enterobacteriaceae CFU/g, E. coli CFU/g, S. aureus (coagulase +) CFU/g, Salmonella/25g and Listeria monocytogenes/25g ☑ Valid Certificate of Analysis for Microbiological parameters for **COOKED POULTRY MEAT, FROZEN TO BE REHEATED BEFORE EATING:** Aerobic Plate Count, CFU/g, S. aureus, CFU/g, Listeria monocytogenes/25g, Salmonella/25g, Campylobacter Jejuni/25g ☑ Valid Certificate of Analysis for Microbiological parameters for **COLD CUTS, FROZEN & CHILLED HOTDOGS**: E. coli		

	MPN/g or CFU/g or /25g, Salmonella/25g, S. aureus CFU/g, L. monocytogenes/25g & Aerobic Plate Count CFU/g		
	☑ Valid Certificate of Analysis for Nitrate and Nitrite Content (if utilized)	Administrative Order No. 154 s. 1971 and Bureau Circular No. 2006-016	Applicant Company/ Manufacturer/Source/Supplier
G2b - Frozen processed comminuted meat, poultry and game products (nuggets, patties, dumplings salami, meat loaf, hotdog) *"Includes raw, partially cooked and fully cooked comminuted or mechanically deboned meat products that have been frozen. Examples include: frozen hamburger patties; frozen breaded or battered chicken fingers."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=144)*	☑ Valid Certificate of Analysis for Microbiological parameters for **COLD CUTS, FROZEN & CHILLED HOTDOGS**: E. coli MPN/g or CFU/g or /25g, Salmonella/25g, S. aureus CFU/g, L. monocytogenes/25g & Aerobic Plate Count CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for **COOKED POULTRY MEAT, FROZEN TO BE REHEATED BEFORE EATING (e.g. prepared frozen meals chicken burgers, chicken turkey rolls, chicken nuggets, other breaded poultry meat products):** Aerobic Plate Count CFU/g, S. aureus CFU/g, Listeria monocytogenes/25g, Salmonella/25 and Campylobacter jejuni/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	☑ Valid Certificate of Analysis for Microbiological parameters for **MARINATED MEAT PRODUCTS (e.g. Marinated meat and meat preparations (tapa, sisig, etc.), - Marinated poultry, Dim sum made from meat (siomai)):** Salmonella/25g, Listeria monocytogenes/25g and S. aureus CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for **FOODS COOKED IMMEDIATELY PRIOR TO SALE OR CONSUMPTION (e.g. Takeaway food, burgers, kebabs, sausages, pizza, ready meals (cook/chill and cook/freeze) after regeneration):** Aerobic Plate Count CFU/g, Enterobacteriaceae CFU/g, E. coli CFU/g, S. aureus (coagulase +) CFU/g, Salmonella/25g and Listeria monocytogenes/25g		
	☑ Valid Certificate of Analysis for Microbiological parameters for **MINCED MEAT AND MEAT PREPARATIONS MADE FROM SPECIES OTHER THAN POULTRY INTENDED TO BE**	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	EATEN COOKED: Salmonella/25g, Aerobic Plate Count CFU/g and E. coli CFU/g		
	☑ Valid Certificate of Analysis for Microbiological parameters for **MEAT PASTE & PATE**: Salmonella/25g, Clostridium perfringens CFU/g, S. aureus CFU/g, Coliforms CFU/g & Aerobic Plate Count CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Nitrate and Nitrite Content (if utilized)	Administrative Order No. 154 s. 1971 and Bureau Circular No. 2006-016	Applicant Company/ Manufacturer/Source/Supplier
H1a - Frozen fish, fish fillets and fish products *"Fresh, including partially cooked, fish subjected to freezing or quick-freezing at sea and on land for further processing. Examples include: frozen or deep frozen clams, cod fillets, crab, finfish, haddock, hake, lobster, minced fish, prawns and shrimp; frozen fish roe; frozen surimi; and frozen whale meat."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=151)*	☑ Valid Certificate of Analysis for Microbiological parameters for **FRESH FROZEN FISH**: E. coli MPN/g, S. aureus CFU/g, V. parahaemolyticus MPN/g, Salmonella/25g & Aerobic Plate Count CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **FROZEN RAW CRUSTACEANS**: E. coli MPN/g, S. aureus CFU/g, Salmonella/25g, V. parahaemolyticus MPN/g, Aerobic Plate Count CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **FRESH & FROZEN BIVALVE**	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	MOLLUSCS: E. coli MPN/g, Salmonella/25g, V. parahaemolyticus MPN/g & Aerobic Plate Count CFU/g		
H1b - Frozen battered fish, fish fillets and fish products, including molluscs, crustaceans and echinoderms *"Uncooked product prepared from fish or fish portions, with dressing in eggs and bread crumbs or batter. Examples include: frozen raw breaded or batter-coated shrimp; and frozen or quick-frozen breaded or batter-coated fish fillets, fish portions and fish sticks (fish fingers)."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=152)*	☑ Valid Certificate of Analysis for Microbiological parameters for **FISH AND CRUSTACEAN BASED PROCESSED MEAT (e.g. fish ball, squid ball):** Aerobic Plate Count CFU/g, S. aureus CFU/g, V. parahaemolyticus MPN/g and E. coli MPN/g.	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
H1c - Frozen minced and creamed fish products *"Uncooked product prepared from minced fish pieces in cream-type sauce"* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=153)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
H1di - Cooked fish and fish products *"Cooked products include steamed, boiled or any other cooking method except frying. The fish may be whole, in portions or comminuted. Examples include: fish sausage; cooked fish products boiled down in soy sauce (tsukudani); cooked surimi product (kamaboko); crab-flavoured cooked kamaboko product (kanikama); cooked fish roe; cooked surimi; cooked, tube-shaped surimi product (chikuwa); and cooked fish and lobster paste (surimi-like products."*	☑ Valid Certificate of Analysis for Microbiological parameters for **AQUATIC PRODUCTS:** Salmonella/25g, V. parahaemolyticus MPN/g and S. aureus CFU/g ☑ Valid Certificate of Analysis for Microbiological parameters for	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=155)	**PRE-COOKED BREADED FISH**: E.coli, MPN/g, S. aureus, CFU/g, Aerobic Plate Count, CFU/g		
H1dii - Cooked molluscs, crustaceans and echinoderms *"Cooked products include steamed, boiled or any other cooking method except frying. Examples include: cooked crangon crangon and crangon vulgaris (brown shrimp; cooked shrimp, clams and crabs."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=156)*	☑ Valid Certificate of Analysis for Microbiological parameters for **FROZEN COOKED CRUSTACEANS**: E. coli MPN/g, S. aureus CFU/g, V. parahaemolyticus CFU/g, Salmonella/25g & Aerobic Plate Count CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **COOKED, CHILLED & FROZEN CRABMEAT**: E. coli MPN/g, S. aureus CFU/g, V. parahaemolyticus MPN/g & Aerobic Plate Count CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
H1diii - Fried fish and fish products *"Ready-to-eat products prepared from fish or fish portions, with or without further dressing in eggs and bread crumbs or batter, that are fried, baked, roasted or barbecued, and then packaged or canned with or without sauce or oil. Examples include: ready-to-eat fried surimi, fried calamari, and fried soft-shell crabs."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=157)*	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
H2 - Fully preserved including canned or fermented fish and fish products *"Products with extended shelf life, manufactured by pasteurizing or steam retorting and packaging in*	☑ Valid Certificate of Analysis for Microbiological parameters for **FISH & SHELLFISH PRODUCTS, COOKED**	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

vacuum-sealed air-tight containers to ensure sterility. Products may be packed in their own juice or in added oil or sauce. Examples include: canned tuna, clams, crab, fish roe and sardines; gefilte fish balls; and surimi (heat-pasteurized)." *(Source URL:* https://www.fao.org/gsfaonline/foods/details.html?id=164 *)*	**CRUSTACEANS IN HERMETICALLY SEALED CONTAINERS (THERMALLY PROCESSED) EG. COOKED BAGOONG/SHRIMP PASTE**: Commercial Sterility		
	☑ Valid Certificate of Analysis for Total Solids, Protein and NaCl for **BAGOONG (FISH AND SHRIMP)**	Administrative Order No. 128 s. 1970	Applicant Company/ Manufacturer/Source/Supplier
Ia - Liquid egg products *"The purified whole egg, egg yolk or egg white is pasteurized and chemically preserved (e.g. by addition of salt)."* *(Source URL:* https://www.fao.org/gsfaonline/foods/details.html?id=168 *)*	☑ Valid Certificate of Analysis for Microbiological parameters for **PASTEURIZED EGG PRODUCTS (SMOKED LIQUID, FROZEN, DRIED**): Coliforms CFU/g, Salmonella/25g, Yeast and Mold Count CFU/g **(for dried products)** & SPC/APC CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
Ib - Frozen egg products *"The purified whole egg, egg yolk or egg white is pasteurized and frozen."* *(Source URL:* https://www.fao.org/gsfaonline/foods/details.html?id=169 *)*	☑ Valid Certificate of Analysis for Microbiological parameters for **PASTEURIZED EGG PRODUCTS (SMOKED LIQUID, FROZEN, DRIED**): Coliforms CFU/g, Salmonella/25g, Yeast and Mold Count CFU/g **(for dried products)** & SPC/APC CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
Ic - Dried and/or heat coagulated egg products *"Sugars are removed from the purified whole egg, egg yolk or egg white, which is then pasteurized and dried."* *(Source URL:* https://www.fao.org/gsfaonline/foods/details.html?id=170 *)*	☑ Valid Certificate of Analysis for Microbiological parameters for **PASTEURIZED EGG PRODUCTS (SMOKED LIQUID, FROZEN, DRIED**): Coliforms CFU/g, Salmonella/25g, Yeast	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

	and Mold Count CFU/g **(for dried products)** & SPC/APC CFU/g		
J1 - Infant formula, follow-on formula and formula for special medical purposes for infants **INFANT FORMULA** *"A human milk substitute for infants (aged no more than 12 months) that is specifically formulated to provide the sole source of nutrition during the first months of life up to the introduction of appropriate complementary feeding. Product is in a liquid form, either as a ready-to-eat product, or is reconstituted from a powder."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=225)* **FOLLOW-UP FORMULA** *"Food intended for use as a liquid part of the complementary feeding of infants (aged at least 6 months) and for young children (aged 1-3 years). They may be ready-to-eat or in a powdered form to be reconstituted with water."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=226)* **FORMULA FOR SPECIAL MEDICAL PURPOSES FOR INFANTS** *"Foods for special dietary use that are specially processed or formulated and presented for the dietary management of infants and may be used only under medical supervision. They are intended for the exclusive*	**INFANT FORMULA & FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS**		
	☑ Valid Certificate of Analysis for Energy, Protein, Total Fat, Linolenic Acid, Total Carbohydrates per 100g, Vitamins and Minerals, Trace Minerals and Other Substances, Lauric/Mystiric/Trans Fatty Acids, Optional Ingredients- Taurine, DHA and Contaminants	Codex Stan 72-1981 Rev. 2007	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **POWDERED INFANT FORMULA WITH OR WITHOUT ADDED LACTIC ACID PRODUCING CULTURES (INTENDED FOR 0 TO 6 MONTHS OLD)**: Cronobacter spp./10g, Salmonella/25g, Aerobic Plate Count CFU/g & Enterobacteriaceae/10g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **INFANT FORMULA- LIQUID (UHT/STERILIZED)**: Commercial Sterility	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Clear and complete loose labels or artworks compliant with Department Circular 2008-0006	Department Circular No. 2008-0006	Applicant Company/ Manufacturer/Source/Supplier

or partial feeding of infants with limited or impaired capacity to take, digest, absorb or metabolize ordinary infant formulae or certain nutrients contained therein, or who have other special medically-determined nutrient requirement, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two." *(Source URL:* https://www.fao.org/gsfaonline/foods/details.html?id=227*)*	☑ For FSMP: Scientific Studies indicating safety and benefits of the product for intended medical condition	Codex Stan 72-1981 Rev. 2007 and Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
	FOLLOW-UP FORMULA/MILK SUPPLEMENT		
	☑ Valid Certificate of Analysis for Energy, Protein, Total Fat, Linolenic Acid, Total Carbohydrates per 100g, Vitamins and Minerals, Trace Minerals and Other Substances, Lauric/Mystiric/Trans Fatty Acids, Optional Ingredients- suitable for 6 months onwards and scientifically proven.	Codex Stan 156-1987	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **FOLLOW-UP FORMULA/MILK SUPPLEMENT (FROM 6 MONTHS INFANTS TO 36 MONTHS YOUNG CHILDREN); FORMULA FOR SPECIAL MEDICAL PURPOSES FOR YOUNG CHILDREN**: Salmonella/25g, Aerobic Plate Count CFU/g & Enterobacteriaceae/10g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Clear and complete loose labels or artworks compliant with Department Circular 2008-0006.	Department Circular No. 2008-0006	Applicant Company/ Manufacturer/Source/Supplier
	CEREAL-BASED FOODS FOR INFANTS & YOUNG CHILDREN		

J2 - Complementary foods for infants and young children *"Foods that are intended for infants 6 months of age and older, and for progressive adaptation of infants and children to ordinary food. Products may be ready-to-eat or in powder form to be reconstituted with water, milk, or other suitable liquid. Examples include: cereal-, fruit-, vegetable-, and meat-based "baby foods" for infants, "toddler foods," and "junior foods"; lactea flour, biscuits and rusks for children."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=228)*	☑ Valid Certificate of Analysis for Energy, Protein, Carbohydrates, Lipids, Minerals and Vitamins per 100 kcal or 100 kJ	Codex Stan 074-1981, Rev 1-2006	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **CEREAL-BASED FOODS FOR INFANTS**: Bacillus cereus CFU/g, Clostridium perfringes CFU/g, Aerobic Plate Count CFU/g, Salmonella/25g & Coliforms MPN/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **DRIED AND INSTANT PRODUCTS REQUIRING RECONSTITUTION:** Coliforms MPN/g, Aerobic Plate Count CFU/g, Salmonella/25g & Listeria monocytogenes/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **DRIED PRODUCTS REQUIRING RECONSTITUTION AND BOILING BEFORE CONSUMPTION:** Coliforms MPN/g, Salmonella/25g & Aerobic Plate Count CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Clear and complete loose labels or artworks declaring the statement "Infants six months onwards should be given fresh,	Department Circular No. 2008-0006	Applicant Company/ Manufacturer/Source/Supplier

	indigenous and natural food in combination with continued breastfeeding based on Department Circular 2008-0006.		
	CANNED BABY FOODS		
	☑ Valid Certificate of Analysis to support Nutrition Information	Codex Stan 73-1981 amended 1989	
	☑ Valid Certificate of Analysis for Microbiological parameters for **BABY FOODS IN HERMETICALLY SEALED CONTAINERS**: Commercial Sterility	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Clear and complete loose labels or artworks declaring the statement “Infants six months onwards should be given fresh, indigenous and natural food in combination with continued breastfeeding based on Department Circular 2008-0006.	Department Circular No. 2008-0006	Applicant Company/ Manufacturer/Source/Supplier
J3. Dietetic foods intended for special medical purposes (excluding products under HR Letter J.1.) *"Foods for special dietary use that are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foods or certain nutrients contained therein, or who have other special medically-determined nutrient requirement,*	☑ Scientific Studies indicating safety and benefits of the product for intended medical condition	Codex Stan 180-1991 and Administrative No. Order 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis to support Nutrition Information	Codex Stan 180-1991	Applicant Company/ Manufacturer/Source/Supplier
	☑ Clear and complete loose labels or artworks compliant with Codex Stan 180-1991.	Codex Stan 180-1991	Applicant Company/ Manufacturer/Source/Supplier

whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two." *(Source URL:* *https://www.fao.org/gsfaonline/foods/details.html?id=229* *)*			
J4 - Dietetic formula for slimming purposes and weight reduction *"Formula foods that when presented as "ready-to-eat" or when prepared in conformity with the directions for use are specifically presented as replacements for all or part of the total daily diet. Includes products with reduced caloric content such as those that are low in sugar and/or fat, sugar- or fat-free, or contain sugar- and/or fat-substititues."* *(Source URL:* *https://www.fao.org/gsfaonline/foods/details.html?id=230* *)*	☑ Valid Certificate of Analysis to support Nutrition Information	Codex Stan 181-1991	Applicant Company/ Manufacturer/Source/Supplier
	☑ Clear and complete loose labels or artworks compliant with Codex Stan 181-1991	Codex Stan 181-1991	Applicant Company/ Manufacturer/Source/Supplier
J5 - Dietetic foods (e.g. supplementary foods for dietary use) excluding products under HR Letter J.1 to 4 and Letter K, Food Supplements) *"Products of high nutritional content, in liquid or solid form (e.g. protein bars), to be used by individuals as part of a balanced diet to provide supplemental nutrition. Products are not intended to be used for purposes of weight loss or as part of a medical regimen."* *(Source URL:* *https://www.fao.org/gsfaonline/foods/details.html?id=231* *)*	☑ Scientific Studies indicating safety and suitability of the product to specific disease and disorder to which it is intended	Codex Stan 146-1985 and Administrative No. Order 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis to support Nutrition Information	Codex Stan 146-1985	Applicant Company/ Manufacturer/Source/Supplier
	☑ Clear and complete loose labels or artworks compliant with Codex Stan146-1985	Codex Stan 146-1985	Applicant Company/ Manufacturer/Source/Supplier
J6 - Weaning foods for infants and growing children	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

J7 - Dietetic foods for special medical purpose *"Foods for special dietary use that are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foods or certain nutrients contained therein, or who have other special medically-determined nutrient requirement, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two"* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=229)*	☑ Scientific Studies indicating safety and benefits of the product for intended medical condition	Codex Stan 180-1991 and Administrative No. Order 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis to support Nutrition Information	Codex Stan 180-1991	Applicant Company/ Manufacturer/Source/Supplier
	☑ Clear and complete loose labels or artworks compliant with Codex Stan 180-1991	Codex Stan 180-1991	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate of Analysis for Microbiological parameters for **READY-TO-USE THERAPEUTIC FOODS (RUTF) AND READY-TO-USE-SUPPLEMENTARY FOODS (RUFS), 6-59 MONTHS OF AGE:** Salmonella/25g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
J8 - Dietetic formulas for weight control *"Formula foods that when presented as "ready-to-eat" or when prepared in conformity with the directions for use are specifically presented as replacements for all or part of the total daily diet. Includes products with reduced caloric content such as those that are low in sugar and/or fat, sugar- or fat-free, or contain sugar- and/or fat-substitutes."* *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=230)*	☑ Valid Certificate of Analysis to support Nutrition Information	Codex Stan 181-1991	Applicant Company/ Manufacturer/Source/Supplier
	☑ Clear and complete loose labels or artworks compliant with Codex Stan 181-1991	Codex Stan 181-1991	Applicant Company/ Manufacturer/Source/Supplier
J - Bottled Water *"means water that is placed in a sealed container or packaged and is offered for sale for human consumption as drinking water."*	☑ Valid Certificate of Analysis for Physico-Chemical Properties (Turbidity, Color, Odor, Taste, pH, TDS, Conductivity, Calcium.	Administrative Order No. 18-A s. 1993	Applicant Company/ Manufacturer/Source/Supplier

(Source: AO No. 18-A s. 1993)	Magnesium, Sodium, Potassium, Chloride, Sulfate), Contaminants (Nitrates, Nitrites, Iron, manganese, Copper, Zinc, Aluminum, Fluoride, organic Matter, Surfactants), Toxic Contaminants (Arsenic, Cadmium, Cyanide, Chromium, Lead, Mercury, Selenium, Phenolic Substances), Volatile Organic Compounds (Carbon tetrachloride, Benzene, Trihalomethanes), Pesticides & Related Substances (Carbamates, Organochlorines, Organophosphates, Herbicides, Fungicides, PCB), Radionuclides (Gross Alpha Activity, Gross Beta Activity) and Microbiological Parameters (Coliforms, Fecal Strepcocci, Pseudomonas Aeruginosa, HPC)		
	Clear and complete loose labels or artworks compliant with Administrative Order No. 39 s. 1996 and Administrative Order No. 18-A s. 1993.	Administrative Order No. 39 s. 1996 and Administrative Order No. 18-A s. 1993	Applicant Company/ Manufacturer/Source/Supplier
K1 - Herbs and botanicals and/or Products with other nutritional substances and/or combination as Food Supplement *"Includes vitamin and mineral supplements in unit dose forms such as capsules, tablets, powders, solutions etc.,*	Shelf-life study with stability data containing relevant information on the critical parameters of the finished product, period conducted and conclusion	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier

where national jurisdictions regulate these products as food" *(Source URL: https://www.fao.org/gsfaonline/foods/details.html?id=232)* *"means a processed food product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamin, mineral, herb, or other botanical, amino acid, and dietary substance to increase the total daily intake in amounts conforming to the latest Philippine recommended energy and nutrient intakes or internationally agreed minimum daily requirements. It usually is in the form of capsules, tablets, liquids, gels, powders or pills and not represented for use as a conventional food or as the sole item of a meal or diet or replacement of drugs and medicines."* *(Source URL: https://www.officialgazette.gov.ph/2009/08/18/republic-act-no-9711/)*	Valid Certificate of Analysis of the physico-chemical (Vitamins or Minerals or Amino Acids or Ingredient Assays) and/or microbiological parameters of the finished product (whichever is applicable) *The amount of Vitamins shall conform with the prescribed level of Office Order No. 22 s 1991	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
	Clear and complete loose labels or artworks declaring the term “Food Supplement” and the phrase “NO APPROVED THERAPEUTIC CLAIMS” based on BC 2 S. 1999	Bureau Circular No. 2 s 1999	Applicant Company/ Manufacturer/Source/Supplier
	Sample in actual commercial presentation *for the procedure on submission, please refer to: IV. Guidelines, C. Procedural Guidelines 2. L. ii., Pages 7-8 of FDA Circular 2020-033	Administrative Order No. 2014-0029	Applicant Company/ Manufacturer/Source/Supplier
	For **VIRGIN COCONUT OIL FOOD SUPPLEMENT WITH FLAVOR**: 1) That the raw material (virgin coconut oil) used conforms with the Philippine National Standards for Virgin Coconut Oil;	Bureau Circular 2006-018	Applicant Company/ Manufacturer/Source/Supplier

	2) That the flavoring added should be generally recognized as safe and suitable for human consumption as evidenced by a certification from the supplier. The nature of flavor used (natural, nature-identical, artificial) shall be indicated in the list of ingredients; 3) No other food additive shall be allowed except the flavor; 4) The label shall conform with BC 2 s. 1999; 5) The term “Food Supplement” shall be part of the product name		
	☑ Valid Certificate of Analysis for Microbiological parameters for **VIRGIN COCONUT OIL:** Aerobic Plate Count CFU/ml, Coliform MPN/ml or CFU/ml, Yeast and Mold Count CFU/ml, Salmonella spp. /25ml and E. coli MPN/ml or CFU/ml	FDA Circular No. 2022-012	
	For **GINKGO BILOBA**: 1.) Valid Certificate of Analysis for the Ginkgo Biloba Content; 2.) Clear and complete label declaring the precaution "*It is advised that Ginkgo Biloba should not be taken for 6 months and longer and it should not be used with warfarin and other thrombolytic agents*"	Bureau Circular No. 02 s. 2004	Applicant Company/ Manufacturer/Source/Supplier

	For **TAHEEBO / Pau d'arco / Lapacho**: Clear and complete label declaring the precautions: 1. "This product is not intended to diagnose, treat, cure, and prevent disease" 2. "Maximum daily intake up to 3 cups per day only" 3. "should not be taken with aspirin, ticlopidine, ginkgo biloba, ginseng, warfarin & heparin" 4. "should not be taken by pregnant or breast-feeding mother" 5. "should not be taken at least one week before contemplated operation" 6. Stop intake of this product in the event of nausea, vomiting, diarrhea, skin pallor, bruises and nose bleeding.	Bureau Circular No. 17 s. 2004	Applicant Company/ Manufacturer/Source/Supplier
	For **PROBIOTICS WHICH BACTERIAL STRAINS NOT FOUND IN THE ACCEPTABLE LIST** shall be subject to (1) demonstration of evidence of safe use as food supplement and (2) analysis of the bacterial species found in formulation. Likewise, BFAD shall use as reference: WHO-FAO "Guidelines for the	Bureau Circular No. 16 s. 2004	Applicant Company/ Manufacturer/Source/Supplier

	Evaluation of Probiotics in Food" (2002). A. The BFAD also would like to inform everyone concerned that, for a Probiotic to the effective, the following properties should be demonstrated: a. beneficial effect on the host organism b. should be able to survive in the digestive tract c. should adhere to the mucosal epithelial cells d. should exhibit enhancement and protection of the intestinal ecology e. should remain viable during periods of storage and use. B. For the demonstration of the safety of a Probiotic, the following documents should be submitted: a. Determination of antibiotic resistance patterns b. Assessment of certain metabolic activities (e.g., D-lactate production, bile salt deconjugation) c. Assessment of side-effects during human studies d. Epidemiological surveillance of adverse incidents in consumers (post-market)		

	e. If the strain under evaluation belongs to a species that is a known mammalian toxin producer, it must be tested for toxin production. One possible scheme for testing toxin production has been recommended by the EU Scientific Committee on Animal Nutrition (SCAN, 2000) f. If the strain under evaluation belongs to a species with known hemolytic potential, determination of hemolytic activity is required.		
K2 - Herbs and botanicals and/or Products with other nutritional substances and/or combination as Conventional Food Product e.g. Powdered Juice with marine collagen, coffee powder with barley grass, tongkat ali and royal jelly	☑ Valid Certificate of Analysis for Microbiological parameters for **NON-ALCOHOLIC BEVERAGES (e.g. READY TO DRINK, SOFTDRINKS, ICED TEA, ENERGY DRINKS, JELLY DRINKS)**: Yeast and Mold Count CFU/mL, Coliforms CFU/mL & Aerobic Plate Count CFU/mL	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier
	☑ Valid Certificate for Microbiological parameters for **POWDERED BEVERAGES (e.g. ICED TEA, POWDERED JUICES/MIXES):** Aerobic Plate Count CFU/g, Yeast and Mold Count CFU/g & Coliforms CFU/g	FDA Circular No. 2022-012	Applicant Company/ Manufacturer/Source/Supplier

L. New in the international or local market/Other New Products/Unclassified or Unlisted in A.O. 2014-0029 Annex A	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
FOOD PRODUCTS CONTAINING TRANS-FATTY ACIDS (TFA) FDA Circular 2021-028, FDA Circular No.2021-028-A	☑ technical specifications of raw materials indicating specific oil(s) and/or fat(s) used and the processing it underwent; ☑ recent (within 12 months from date of application) certificate of analysis of the finished product from an accredited laboratory of the FDA and Philippine Accreditation Board/Office (PAB/PAO) or from the country of origin (for imported products), reflecting the TFA content per 100g or ml, validated reference methods of analysis, and the limit of detection for the method used in the analysis of TFA; and ☑ for prepackaged processed food containing naturally-occurring TFA of more than 2g TFA per 100g or ml of the total fat, recent (within 12 months from date of application) certificate of analysis showing that the TFA is naturally-occurring and/or obtained from ruminant animal, from an accredited laboratory of	FDA Circular No. 2021-028 FDA Circular No. 2021-028-A FDA Circular No. 2020-033-B Administrative Order No. 2021-0039	Applicant Company/ Manufacturer/Source/Supplier

	the FDA and Philippine Accreditation Board/Office (PAB/PAO) or from the country of origin, with validated reference method of analysis and the limit of detection for the method used in the analysis.		

FOR AMENDMENT DATA CAPTURE DATA CAPTURE in the modified E-Registration System refers to applications processed in the old E-Registration System (Version 1) or thru manual registration system.		
GENERAL REQUIREMENTS	**BASIS/ISSUANCE**	**WHERE TO SECURE**
☑ Accomplished Application Form as prescribed by FDA regulations e.g. E-Registration System	FDA Circular No. 2020-033 FDA Circular No. 2020-033-A	https://www.fda.gov.ph/
☑ Proof of Payment of Fees as prescribed by current FDA regulations.	Administrative Order No. 50 s. 2001	Systems/Means prescribed by FDA
☑ Scanned Application Letter stating the intended changes (indicate ALL the changes/amendments to be made)	Administrative Order No. 2014-0029 FDA Circular No. 2020-033 FDA Circular No. 2020-033-A	Applicant Company/ Manufacturer/Source/Supplier
☑ VALID AND APPROPRIATE FDA LICENSE TO OPERATE (LTO) (REQUIRED FOR ALL TYPES OF CPR APPLICATION) *The product being applied must be listed in the FDA approved Product Line/Category.	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
☑ Upload ALL INITIAL requirements if previously approved application is in the old E-Registration System (Version 1) or thru manual registration system	FDA Circular No. 2020-033 FDA Circular No. 2020-033-A	Applicant Company/ Manufacturer/Source/Supplier
☑ Additional Requirements per Amendment Type. Please refer to TITLE OF	Administrative Order No. 2014-0029 FDA Circular No. 2020-033 FDA Circular No. 2020-033-A	Applicant Company/ Manufacturer/Source/Supplier

CERTIFICATION/PERMIT: CERTIFICATE OF PRODUCT REGISTRATION (CPR) – AMENDMENT (INITIAL APPLICATION APPROVED FROM MODIFIED E-REGISTRATION (VERSION 2) - III. ADDITIONAL Requirements per Amendment Type.		

FOR RE-APPLICATION DATA CAPTURE DATA CAPTURE in the modified E-Registration System refers to applications processed in the old E-Registration System (Version 1) or thru manual registration system.		
GENERAL REQUIREMENTS	**BASIS/ISSUANCE**	**WHERE TO SECURE**
☑ Accomplished Application Form as prescribed by FDA regulations e.g. E-Registration System	FDA Circular No. 2020-033 FDA Circular No. 2020-033-A	https://www.fda.gov.ph/
☑ Upload ALL INITIAL requirements AND compliance to the deficiencies stated in the previously issued Letter of Denial (LOD) within 6 months upon receipt of LOD.	Administrative Order No. 2014-0029 FDA Circular No. 2020-033 FDA Circular No. 2020-033-A	Applicant Company/ In reference to the previously filed and disapproved INITIAL application
☑ Proof of Payment of Fees as prescribed by current FDA regulations.	Administrative Order No. 50 s. 2001	Systems/Means prescribed by FDA

FOR RENEWAL DATA CAPTURE (REGULAR) DATA CAPTURE in the modified E-Registration System refers to applications processed in the old E-Registration System (Version 1) or thru manual registration system.		
GENERAL REQUIREMENTS	**BASIS/ISSUANCE**	**WHERE TO SECURE**
☑ Accomplished Application Form as prescribed by FDA regulations e.g. E-Registration System	FDA Circular No. 2020-033 FDA Circular No. 2020-033-A	https://www.fda.gov.ph/

☑ VALID AND APPROPRIATE FDA LICENSE TO OPERATE (LTO) (REQUIRED FOR ALL TYPES OF CPR APPLICATION) *The product being applied must be listed in the FDA approved Product Line/Category.	Administrative Order No. 2014-0029 FDA Circular No. 2020-033	Applicant Company/ Manufacturer/Source/Supplier
☑ Upload ALL INITIAL requirements if previously approved application is in the old E-Registration System (Version 1) or thru manual registration system	Administrative Order No. 2014-0029 FDA Circular No. 2020-033 FDA Circular No. 2020-033-A	Applicant Company/ Manufacturer/Source/Supplier
☑ Proof of Payment of Fees as prescribed by current FDA regulations.	Administrative Order No. 50 s. 2001	Systems/Means prescribed by FDA

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1.1. Accomplishes (including uploading of the COMPLETE documentary requirements) the E-Registration System through the E-Portal https://eportal.fda.gov.ph based on the desired type of application in accordance to current FDA regulation/s on the use of the E-Registration Portal/E-Services. 1.2. Forwards the application to **PRE-ASSESSMENT**. A system generated E-mail notification from FDA will be received by the client upon submission of application for Pre-Assessment.	1. Pre-assesses ONLY the completeness of the submitted documents through E-Registration System/E-Portal https://eportal.fda.gov.ph. Result of Pre-assessment will be received by the account holder.		Center for Food Regulation and Research (CFRR) PRE-ASSESSOR (e.g. Food-Drug Regulation Officer (FDRO))

2. (If COMPLETE) Receives the Order of Payment. (If INCOMPLETE) Receives result of Pre-Assessment (Letter of Denial)	2. If found **COMPLETE** Generates Order of Payment through the email of the account holder/client. If found **INCOMPLETE**, Generates result of Pre-Assessment. To refile, the applicant must **start a NEW CASE** and upload initially submitted documentary requirements together with the documents for compliance to the deficiencies mentioned. *For Food Supplement application, the proof of submission of sample can be re-uploaded to the new application.*		CFRR PRE-ASSESSOR (e.g. FDRO)
3. Pays the assessed fee through Systems/Means prescribed by FDA.	3.1. Receives the payment/Official Receipt (OR)/ proof of payment through Systems/Means prescribed by FDA, and then posts the payment. 3.2. Forwards application to CFRR, **once payment is posted**.	***Refer to FDA Cashier 's Citizen Charter***	Administrative and Finance Services (AFS) STAFF
4. Receives Acknowledgement Receipt with the application and pre-assessment details.	4.1. Evaluates the application and ALL the submitted documentary requirements in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, drafts recommendation if the application is for Approval or Disapproval, and then forwards the same to the CHECKER.	8 Working Days	LRD EVALUATOR (e.g. FDRO)

	4.2. Reviews the evaluated application, ALL the submitted documentary requirements, and the drafted recommendation of the EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, drafts recommendation if the application is for Approval or Disapproval, and then forwards the same to the APPROVING AUTHORITY.	7 Working Days	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)
	4.3. Reviews the checked application, ALL the submitted documentary requirements, and the drafted recommendation of the CHECKER, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, and then finalizes the application by issuing **Certificate of Product Registration (CPR) (for APPROVED application)** or **Letter of Denial (LOD) (for DISAPPROVED application)**, through the E-Registration System.	5 Working Days	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
5. If the application is **APPROVED**, receives Certificate of Product Registration (CPR), and other pertinent information. If **DISAPPROVED**, receives an e-mail notification from FDA regarding the issuance of Letter of Denial/Disapproval (LOD), and other pertinent information.	5. Generates electronically signed CPR or LOD.		Information and Communication Technology Management Division (ICTMD) STAFF
		TOTAL: 20 Working Days	
Always refer to the current FDA regulation/s on the use of the E-Registration System/E-Services: https://www.fda.gov.ph/			

1.5. ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) – RE-APPLICATION (INITIAL APPLICATION DISAPPROVED FROM MODIFIED E-REGISTRATION)

'Registration' means the process of approval of an application to register health products prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable, the use, testing, promotion, advertisement, and/or sponsorship of health products. (Republic Act No. 9711)

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Government to Business
Type of Transaction	**:**	Highly Technical
Who May Avail	**:**	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	**:**	In accordance to Administrative Order 50 s. 2001 + Legal Research Fee (LRF). Re-application Fee PhP 200.00 + 1% LRF

GENERAL GUIDELINES

Please refer to:

1) A. General Guidelines, B. Specific Guidelines, and C. Procedural Guidelines, IV. GUIDELINES, pages 2-10 of FDA Circular No. 2020-033 || Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products"; and

2) III. General Guidelines, and IV. Specific Guidelines of FDA Circular No. 2020-033-A || Addendum to FDA Circular No. 2020-033, "Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products" to include Guidelines for Pre-assessment and Reiteration of Pre-Assessment Procedures in Applying for Certificate of Product Registration for Food

CHECKLIST OF REQUIREMENTS FOR ALL TYPES OF FOOD PRODUCTS/FOOD CATEGORIZATION: RAW MATERIALS, LOW RISK, MEDIUM RISK AND HIGH RISK FOOD PRODUCTS

GENERAL REQUIREMENTS	BASIS/ISSUANCE	WHERE TO SECURE
☑ Accomplished Application Form as prescribed by current regulations.	FDA Circular No.2020-033 FDA Circular No.2020-033-A Administrative No. Order 2014-0029	https://www.fda.gov.ph/ 1) For the Certificate of Analysis: a) Applicant Company/

Through the E-Registration System, upload/attach the compliance to the deficiencies stated in the previously issued Letter of Denial (LOD) within 6 months upon receipt of LOD, using the same case number.		Manufacturer/Source/Supplier; or b) Laboratory analysis issued/conducted by FDA accredited laboratories. 2) For other technical document(s): a) Applicant Company/ Manufacturer/Source/Supplier
☑ Proof of payment of fees as prescribed by current FDA regulations.	Administrative Order 50 s. 2001	Systems/Means prescribed by FDA
☑ Valid and appropriate FDA License to Operate (required for all types of CPR application) *The product being applied must be listed in the FDA approved Product Line/Category.	Administrative No. Order 2014-0029 Republic Act No. 9711	FDA Philippines

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1.1. Files using the specific product/CASE NUMBER in the INBOX folder, and then accomplishes (including uploading of the COMPLETE documentary requirements) the E-Registration System through the E-Portal https://eportal.fda.gov.ph based on the desired type of application in accordance to current FDA regulation/s on the use of the E-Registration Portal/E-Services. 1.2. Forwards the application to **PRE-ASSESSMENT**.	1. Pre-assesses ONLY the completeness of the submitted documents through E-Registration System/E-Portal https://eportal.fda.gov.ph. Result of Pre-assessment will be received by the account holder.	Day 0	Center for Food Regulation and Research (CFRR) PRE-ASSESSOR (e.g. Food-Drug Regulation Officer (FDRO))

A system generated E-mail notification from FDA will be received by the client upon submission of application for Pre-Assessment.			
2. (If COMPLETE) Receives the Order of Payment. (If INCOMPLETE) Receives result of Pre-Assessment (Letter of Denial)	2. If found **COMPLETE**, Generates Order of Payment through the email of the account holder/client. If found **INCOMPLETE**, Generates result of Pre-Assessment. To refile, the applicant must **start a NEW CASE** and upload initially submitted documentary requirements together with the documents for compliance to the deficiencies mentioned.	Day 0	CFRR PRE-ASSESSOR (e.g. FDRO)
3. Pays the assessed fee through Systems/Means prescribed by FDA	3.1. Receives the payment/Official Receipt (OR)/ proof of payment through Systems/Means prescribed by FDA, and then post the payment. 3.2. Forwards application to CFRR, **once payment is posted**.	Day 0 ***Refer to FDA Cashier 's Citizen Charter***	Administrative and Finance Services (AFS) STAFF
4. The applicant company receives Acknowledgement Receipt with the application and pre-assessment details.	4. 1. Evaluates the application and ALL the submitted documentary requirements in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, drafts recommendation if the application is for Approval or Disapproval, and then will forward the same to the CHECKER.	Day 0 8 Working Days	LRD EVALUATOR (e.g. FDRO)
	4.2. Reviews the evaluated application, ALL the submitted documentary requirements, and the drafted recommendation of the EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, drafts recommendation if the application is	7 Working Days	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)

	for Approval or Disapproval, and then forwards the same to the APPROVING AUTHORITY.		
	4.3. Reviews the checked application, ALL the submitted documentary requirements, drafted recommendation of the CHECKER, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, and then finalizes the application by issuing **Certificate of Product Registration (CPR) (for APPROVED application)** or **Letter of Denial (LOD) (for DISAPPROVED application)**, through the E-Registration System.	5 Working Days	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
5. If the application is **APPROVED**, Receives an e-mail notification from FDA indicating that the application is approved, and other pertinent information. If **DISAPPROVED**, receives a Letter of Denial/Disapproval (LOD), and other pertinent information.	5. **Generates** electronically signed CPR or LOD.		Information and Communication Technology Management Division (ICTMD) STAFF
		TOTAL: 20 Working Days	
Always refer to the current FDA regulation/s on the use of the E-Registration System/E-Services: https://www.fda.gov.ph/			

2. ISSUANCE OF DIAMOND SANGKAP PINOY SEAL

Diamond Sangkap Pinoy Seal – refer to the seal of good nutrition quality that will be awarded as an incentive to BFAD (FDA) registered staple manufacturer who will fortify their products according to standards. (Administrative Order No. 82 s. 2003)

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Government to Business
Type of Transaction	:	Highly Technical Transaction
Who May Avail	:	All FOOD Manufacturers of Fortified Products
Fees to be Paid	:	P8,000.00 non-refundable fee for the use of the seal (Regular Seal) P500.00 processing fee for every application (Regular Seal or Diamond Seal) + 1% LRF

CHECKLIST OF REQUIREMENTS Submit ONE (1) scanned copy of the required document.	**WHERE TO SECURE**
☑ Basic Requirements based on RA No. 8976 (Food Fortification Law of 2000), RA No. 8172 (ASIN Law), the Sangkap Pinoy Seal Program Manual of Operations (December 2000) and Administrative Order No. 82 s. 2003 (Guidelines on the Granting of Diamond Sangkap Pinoy Seal to Manufacturers of Fortified Products):	https://www.fda.gov.ph/
☑ Duly accomplished application forms	FDA Philippines
☑ Copy of valid and appropriate LTO issued by the FDA	FDA Philippines
☑ Results of product analysis for vitamin A, Iron and Iodine from an FDA recognized laboratory.	For the Certificate of Analysis: Laboratory analysis issued/conducted by FDA accredited laboratories.
☑ Sample label with Diamond Sangkap Pinoy Seal	Applicant Company/ Manufacturer/Source/Supplier
☑ Proof of payment	Systems/Means prescribed by FDA
☑ Inspection report with Certificate of Compliance	FDA Regional Field Office

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
	1. Receives document requirements from FDA Regional Field Office and decks the same to CFRR technical evaluators.	1 Working Day	LICENSING AND REGISTRATION DIVISION (LRD) EVALUATOR (e.g. Food-Drug Regulation Officer (FDRO))
	2.1. Evaluates the application and ALL the submitted documentary requirements in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, drafts recommendation if the application is for Approval or Disapproval, and then forwards the same to the CHECKER.	8 Working Days	LRD EVALUATOR (e.g. Food-Drug Regulation Officer (FDRO))
	2.2. Reviews the evaluated application, ALL the submitted documentary requirements, and the drafted recommendation of the EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, drafts recommendation if the application is for Approval or Disapproval, and then forwards the same to the APPROVING AUTHORITY.	5 Working Days	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)
	2.3. Prints the authorization.	1 Working Day	CFRR ADMINISTRATIVE STAFF
	2.4. Signs the Certification/Authorization.	4 Working Days	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
	3. Forwards the Certificate/Authorization to the Office of Director General, for signature.	1 Working Day	CFRR ADMINISTRATIVE STAFF
		TOTAL: 20 Working Days	

3. ISSUANCE OF E-REGISTRATION PORTAL USER ACCOUNT

The applicant shall be assigned an FDA account to apply through the E-Registration System.

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Government to Business
Type of Transaction	**:**	Simple
Who May Avail	**:**	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters)
Fees to be Paid	**:**	NONE

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
GENERAL GUIDELINES ***Please refer to:*** C. Procedural Guidelines, IV. GUIDELINES, pages 5-6 of FDA Circular No. 2020-033 || Procedure for the Use of the Modified Electronic Registration System for Raw Materials and Prepackaged Processed Food Products Repealing FDA Circular No. 2016-014 "Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products"	https://www.fda.gov.ph/
ISSUANCE OF CFRR E-REGISTRATION USER ACCOUNT	
☑ Send a request for a user account to cfrr@fda.gov.ph **SUBJECT:** CFRR: E-Registration **BODY:** Email Address: Last Name: First Name: Middle Name: Company Name: LTO No.: LTO validity:	Applicant Company

☑ The email must contain an attached scanned copy of notarized authorization letter (please see Annex B of FDA Circular No. 2020-033) from a company with a valid License-to-Operate (LTO).	Applicant Company
CHANGE IN THE APPLICANT COMPANY'S REPRESENTATIVE	Applicant Company
☑ Send a request for change in credentials of the CFRR E-Registration User Account to cfrr@fda.gov.ph **SUBJECT:** CFRR: E-Registration **BODY:** Email Address: Last Name: First Name: Middle Name: Company Name: LTO No.: LTO validity:	Applicant Company
☑ The email must contain an attached scanned copy of notarized Affidavit of Undertaking (please see Annex C of FDA Circular No. 2020-033) from a company with a valid License-to-Operate (LTO).	Applicant Company
RENEWAL OF USER ACCOUNT AT LEAST 90 DAYS PRIOR TO EXPIRATION	Applicant Company
☑ Send a request for renewal of user account to cfrr@fda.gov.ph SUBJECT: CFRR: E-Registration BODY: Email Address: Last Name: First Name: Middle Name: Company Name:	Applicant Company

LTO No.: LTO validity:	
ISSUED USER ACCOUNT BY THE FDAC FOR E-LTO CAN BE REVALIDATED TO ACCESS E-REGISTRATION	Applicant Company
☑ Send a request for revalidation of user account to cfrr@fda.gov.ph SUBJECT: CFRR: E-Registration BODY: Email Address: Last Name: First Name: Middle Name: Company Name: LTO No.: LTO validity:	Applicant Company
RETRIEVAL OF USER NAME AND/OR PASSWORD OF E-REGISTRATION ACCOUNT (IN CASES OF PROBLEMS WITH USER NAME AND/OR PASSWORD)	Applicant Company
☑ Send a request for retrieval of user name and/or password to cfrr@fda.gov.ph SUBJECT: CFRR: E-Registration BODY: Email Address: Last Name: First Name: Middle Name: Company Name: LTO No.:	Applicant Company

LTO validity:	

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits required documents/information to the above-mentioned e-mail address.	1.1. Checks the e-mail request. 1.2. If compliant, user name and password will be issued to the client, via e-mail. Otherwise, the personnel will send an e-mail to the applicant company/authorized representative to request for lacking document(s) or clarify information.	3 Working Days	Food Drug Action Center (FDAC) or Center for Food Regulation and Research (CFRR) STAFF

4. ISSUANCE OF GOOD MANUFACTURING PRACTICES (GMP) CERTIFICATE

Good manufacturing practices refer to a quality assurance system aimed at ensuring that products are consistently manufactured, packed, repacked or held to quality standards appropriate for the intended use. It is thus concerned with both manufacturing and quality control procedure. (Republic Act No. 10611)

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Government to Business
Type of Transaction	:	Highly Technical Transaction
Who May Avail	:	All FOOD Manufacturers (Importer of raw material for own use/Exporters)
Fees to be Paid	:	GMP – Php 500.00 + LRF per year

CHECKLIST OF REQUIREMENTS Submit ONE (1) scanned copy of the required document.	**WHERE TO SECURE**
☑ Inspection report with certificate of Compliance/ Recommendation Letter from RFO	FDA Regional Office
☑ Copy of valid and appropriate LTO issued by the FDA	FDA Philippines
☑ Proof of payment	Systems/Means prescribed by FDA

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
	1. Receives document requirements from FDA Regional Field Office and decks the same to CFRR technical evaluators.	1 Working Day	LICENSING AND REGISTRATION DIVISION (LRD) EVALUATOR (e.g. Food-Drug Regulation Officer (FDRO))
	2.1. Evaluates the application and ALL the submitted documentary requirements in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, drafts recommendation if the application is for Approval or	8 Working Days	LRD EVALUATOR (e.g. Food-Drug Regulation Officer (FDRO))

	Disapproval, and then forwards the same to the CHECKER.		
	2.2. Reviews the evaluated application, ALL the submitted documentary requirements, and the drafted recommendation of the EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, drafts recommendation if the application is for Approval or Disapproval, and then forwards the same to the APPROVING AUTHORITY.	5 Working Days	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)
	2.3. Prints the authorization.	1 Working Day	CFRR ADMINISTRATIVE STAFF
	2.4. Signs the Certification/Authorization.	4 Working Days	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
3. Receives the Certificate/Authorization.	3. Forwards the Certificate/Authorization to Food and Drug Action Center (FDAC) for release of Records Section.	1 Working Day	CFRR ADMINISTRATIVE STAFF
		TOTAL: 20 Working Days	

5. ISSUANCE OF HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) CERTIFICATE

Hazard Analyses at Critical Control Points (HACCP) refer to a science-based system which identities, evaluates and controls hazards which are significant for food safety at critical points during a given stage in the food supply chain. (Republic Act No. 10611)

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Government to Business
Type of Transaction	:	Highly Technical Transaction
Who May Avail	:	All FOOD Manufacturers (Importer of raw material for own use/Exporters)
Fees to be Paid	:	HACCP – Php1,000.00 + LRF per year

CHECKLIST OF REQUIREMENTS Submit ONE (1) scanned copy of the required document.	**WHERE TO SECURE**
☑ Inspection report with certificate of Compliance/ Recommendation Letter from RFO	FDA Regional Office
☑ Copy of valid and appropriate LTO issued by the FDA	FDA Philippines
☑ Proof of payment	Systems/Means prescribed by FDA

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
	1. Receives document requirements from FDA Regional Field Office and decks the same to CFRR technical evaluators.	1 Working Day	LICENSING AND REGISTRATION DIVISION (LRD) EVALUATOR (e.g. Food-Drug Regulation Officer (FDRO))

	2.1. Evaluates the application and ALL the submitted documentary requirements in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, drafts recommendation if the application is for Approval or Disapproval, and then forwards the same to the CHECKER.	8 Working Days	LRD EVALUATOR (e.g. Food-Drug Regulation Officer (FDRO))
	2.2. Reviews the evaluated application, ALL the submitted documentary requirements, and the drafted recommendation of the EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, drafts recommendation if the application is for Approval or Disapproval, and then forwards the same to the APPROVING AUTHORITY.	5 Working Days	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)
	2.3. Prints the authorization.	1 Working Day	CFRR ADMINISTRATIVE STAFF
	2.4. Signs the Certification/Authorization.	4 Working Days	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
3. Receives the Certificate/Authorization.	3. Forwards the Certificate/Authorization to Food and Drug Action Center (FDAC) for release of Records Section.	1 Working Day	CFRR ADMINISTRATIVE STAFF
		TOTAL: 20 Working Days	

6. ISSUANCE OF IMPORT PERMIT

Import permit is the authorization issued by the FDA to an establishment to import a prepackaged processed food, bulk food and raw materials in the Philippines for the purpose of research and development and shall not be intended for market testing purposes and donated food products.

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR)
Classification	**:**	Government to Business
Type of Transaction	**:**	Simple Transaction
Who May Avail	**:**	All FOOD Manufacturers/Traders/Distributors (Importers/ Wholesalers/ Exporters) and Donee/Consignee
Fees to be Paid	**:**	In accordance with Administrative Order No. 50 s. 2001 Import Permit: Php 500.00/invoice + 1% LRF

CHECKLIST OF REQUIREMENTS Submit ONE (1) scanned copy of the required document.	**WHERE TO SECURE**
FOR RELEASE OF SAMPLES:	
☑ Application Letter	No specific format, this document is initiated by applicant company
☑ Notarized Affidavit of Undertaking	See sample template (Annex A)
☑ Certificate of Analysis/ Certificate of Free Sale	Country of Origin or Source of Product to be imported
☑ Pro Forma Invoice	Product Source/company
☑ Packing List	Product Source/company
☑ Bill of Lading/Airway Bill (if available)	Courier or Shipping company
☑ Valid License to Operate	FDA Issued
□ Payment (Php 510.00/inclusive of 1% LRF)	FDA Cashier/Other FDA Authorized Payment Portals or Banks
FOR RELEASE OF DONATED FOOD:	
☑ BIHC Endorsement Letter	BIHC of DOH (The Director)

	* Please refer to DOH Administrative Order 2020-0001) for the requirement to secure BHIC endorsement.
☑ Letter request from Donee	From Donee
☑ Certificate of Quality (should reflect the expiration or last recommended date of consumption) / Certificate of Free Sale	Product Source/Company
☑ Certificate of Donation	From Donor
☑ Deed of Acceptance	From Donee
☑ Invoice Packing List	From product source/company
☑ Bill of Lading/Airway Bill (if available)	Courier or shipping company
☑ Payment (Php 510.00/inclusive of 1% LRF)	FDA Cashier/Other FDA Authorized Payment Portals or Banks

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits documents through email to the Food and Drug Action Center (FDAC).	1. Receives the submitted documents.	Day 0	Food Drug Action Center (FDAC) (e.g. Information Officer I or II)
2. Receives the Document Tracking number as reference for payment.	2. Issues an Acknowledgement Receipt and 14-digit Document Tracking Number (DTN) as reference of the applicant.	Day 0	Food Drug Action Center (FDAC) (e.g. Information Officer I or II)
3. Pays the assessed fee through any FDA Authorized means (e.g. Landbank LinkBiz). (Php 510.00/Invoice).	3. Receives the complete documents and proof of payment through automated transaction.	Day 0	Food Drug Action Center (FDAC) (e.g. Information Officer I or II)
4. Sends the proof of payment to FDAC through email.	4.1. Receives the proof of payment and updates the FDA FIS.	Day 0	Food Drug Action Center (FDAC) (e.g. Information Officer I or II)

	4.2. Verifies and posts the payment through FDA FIS.	Day 0	Administrative and Finance Services (AFS)
	4.3. Forwards the application to CFRR receiving, and also updates the FIS indicating that the application is transmitted to CFRR.	4 Hours	Food Drug Action Center (FDAC) (e.g. Information Officer I or II)
	4.4. Receives application and updates the FIS indicating that the application is forwarded to assigned CFRR evaluator.	4 Hours	Center for Food Regulation and Research (e.g. Administrative Assistant III)
	4.5. Evaluates the correctness of documents and updates the FIS indicating that the application is forwarded to checker for quality assurance.	4 Hours	Center for Food Regulation and Research (e.g. Food-Drug Regulation Officer (FDRO II or III)
	4.6. Checks if the recommendation is appropriate/accurate, and updates the FIS indicating that the application is forwarded to the Center Director.	4 Hours	Center for Food Regulation and Research (e.g. Senior FDRO or Division Chief)
	4.7. Renders the final decision on the recommendation and updates the FIS.	4 Hours	Center for Food Regulation and Research Approving Authority (e.g. Director IV)
5. Receives the IMPORT PERMIT.	5. Forwards the Permit/Authorization to Records section for release and updates the FIS indicating the same.	4 Hours	Center for Food Regulation and Research (e.g. Administrative Aide VI)
		TOTAL: 3 Working Days	

7. ISSUANCE OF LAW ENFORCEMENT AGENCY (LEA) REQUEST FOR PRODUCT/ LICENSE-TO-OPERATE VERIFICATION THROUGH THE REGULATORY ENFORCEMENT UNIT

Verification of the authorization (i.e., License-to-Operate and Certificate of Product Registration) of the establishment and products as requested by the Law Enforcement Agency in line with an ongoing investigation.

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR) – Food Safety Unit (FSU)
Classification	**:**	Government to Government (G2G)
Type of Transaction	**:**	Highly Technical Transaction
Who May Avail	**:**	**FDA** Center - Regulatory Enforcement Unit (REU)
Fees to be Paid	**:**	None

CHECKLIST OF REQUIREMENTS Submit ONE (1) scanned copy of the required document.	**WHERE TO SECURE**
☑ Letter Request for Product Verification/ License-to-Operate Verification/ Food Products from Law Enforcement Agencies	Requesting Party
☑ Output Documents (Verification Report)	Food Safety Technical Staff
☑ Technology (Internet, Printer, Computer)	Office

INTERNAL CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1. Creates referral for the received Product Verification/ License-to-Operate Verification Letter Request from Law Enforcement Agencies (LEAs)		Day 0	Regulatory Enforcement Unit Staff (Requesting Office)

	1.1 Receives, double-checks the completeness of the documents/ samples referred and decks referral.	1 Working Day	Food Safety Unit (FSU) Administrative Staff
	1.2 Verifies the status of License to Operate of the Establishment / Registration of the Food Product and/or Food Supplement.	15 Working Days	FSU Evaluator (e.g. Food-Drug Regulation Officer (FDRO))
	1.3 Reviews the Information and Recommendation of the Evaluator, and forwards the Referral Report to the OIC, Food Safety Unit for Quality assurance.	2 Working Days	FSU Checker (e.g. Senior Food-Drug Regulation Officer)
	1.4 Checks the Referral Report for Quality Assurance, and then forwards the Referral to the CFRR Director.	1 Working Day	FSU, Officer In-Charge (OIC)
	1.5 Checks and signs the Final Referral for release.	1 Working Day	Center for Food Regulation and Research (CFRR) Approving Authority (e.g. DIRECTOR IV)
	1.6 Mails the final referral to the requesting Law Enforcement Agency		CFRR STAFF
		TOTAL: 20 Working Days	

8. ISSUANCE OF SALES PROMO PERMIT (INITIAL AND AMENDMENT APPLICATION)

Authorization issued for activities conducted by the companies which is intended for broad consumer participation which contains promises of gain such as prizes, in cash or in kind, as reward for the purchase of a product, security, service or winning in a contest, game, tournament, and other similar competitions which involves determination of winner/s and which utilize mass media or other widespread means of information. It is also issued for activities purely intended to increase the sales, patronage and/or goodwill of a product.

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Government to Business
Type of Transaction	:	Complex Transaction
Who May Avail	:	Food Manufacturers, Importers, Exporters, Wholesalers/Distributors and Third Party Marketing Agencies
Fees to be Paid	:	In accordance to DTI-DOH JAO NO. 1 s. 2000 **Amount of Prizes: (Fees)** Php 150,000.00- below Php 300,000.00: Php 1,000.00.00 + 1% LRF Php 300, 001.00-Php 500,000.00: Php 2,000.00 + 1% LRF Php 500,001.00- Php 1,000,000.00: Php 3,000.00 + 1% LRF Above Php 1,000.000.00: Php 5,000.00 + 1% LRF **Coverage: (Fees)** NCR only or in several regions in NCR and Nationwide: Php 1,000.00.00 + 1% LRF More than one (1) region in NCR and Nationwide: Php 750.00 + 1% LRF Several provinces/cities/municipalities within a single region: Php 500.00 + 1% LRF Single province/city/municipality: Php 250.00 + 1% LRF **Amendment/Extension:** Php 300.00 + 1% LRF

CHECKLIST OF REQUIREMENTS Submit ONE (1) scanned copy of the required document.	WHERE TO SECURE

INITIAL APPLICATION	
☑ Integrated Application Form	https://www.fda.gov.ph/
☑ Completely and accurately filled-up Information Sheet and Mechanics of Sales Promotion	https://www.fda.gov.ph/
☑ Photocopy of valid Certificate of Product Registration (CPR) and Cosmetic Notification (NN)of the company	FDA Issued
☑ Advertising/Collateral Materials to be used in the promotion, if any	Applicant Company
☑ Proof of Payment of Fees	FDA Cashier/Other FDA Authorized Payment Portals or Banks (where payment was made)
AMENDMENT APPLICATION	
☑ Integrated Application Form	https://www.fda.gov.ph/
☑ Letter of Intent stating the desired changes	Applicant Company
☑ Photocopy of Approved Permit	FDA Issued
☑ Additional Advertising/Collateral Materials to be used in Promotion if any	Applicant Company
☑ Proof of Payment of Fees	FDA Cashier/Other FDA Authorized Payment Portals or Banks (where payment was made)

SALES PROMO PERMIT (INITIAL AND AMENDMENT APPLICATION) PROCESS FLOW based on FDA Circular No.2021-013: Interim Guidelines of the Center for Food Regulation and Research (CFRR) for the Application and Receiving of Sales Promo Permit Applications in Compliance to the Republic Act No. 11032 otherwise known as The Ease of Doing Business and Efficient Government Service Delivery Act Of 2018 or current FDA regulation.

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1. Requests for DTN and schedule of submission for pre-assessment to Food and Drug Action Center (FDAC) through email.	**1.** Provides the DTN and schedule of submission for pre-assessment through email to the client.	Day 0	Food Drug Action Center (FDAC)
2. Submits documents for pre-assessment through email to Center for Food Regulation and Research (CFRR) on their assigned schedule.	**2.** Pre-assesses the completeness and correctness of the submitted documents.	Day 0	CFRR EVALUATOR (e.g. Food-Drug Regulation Officer (FDRO)
3. Receives an email to proceed with the payment and must pay through any FDA Authorized means (e.g. Landbank LinkBiz) or an email stating the deficiency/ies noted on the documents for the client to comply.	3. If complete and correct, Sends an email stating that the company can proceed with the payment will be sent to the email address of the authorized representative. A CFRR pre-assessment slip will also be attached on the email. Otherwise, an email stating the deficiency/ies noted on the documents for the client to comply and they will be advice to secure another DTN and schedule.	Day 0	CFRR STAFF
4. Pays the indicated fee as per Integrated Application Form through any applicable payment system prescribed by FDA.	4.1 Verifies and posts the payment through updating the FDA FIS.	Refer FDA Cashier Citizen's Charter	Administrative and Finance Services (AFS) STAFF

	4.2. Forwards the application to CFRR and updates the FIS indicating the same.	1 Working Day	FDAC STAFF
	4.3. Receives the Sales Promo Permit Application, decks the application to the assigned evaluator, and updates the FIS indicating the same.	1 Working Day	CFRR STAFF
	4.4. Evaluates the consistency of the documents submitted during the pre-assessment stage and the documents received from FDAC, and then forwards the application to the Checker and updates the FIS indicating the same.	1 Working Day	CFRR EVALUATOR (e.g. FDRO)
	4.5. Checks if the recommendation is appropriate and updates the FIS indicating that the application is forwarded to the Center Director.	1 Working Day	CFRR CHECKER (e.g. SENIOR FDRO or DIVISION CHIEF)
	4.6. Renders the final decision on the recommendation and updates the FIS.	1 Working Day	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
	4.7. Forwards the Sales Promotion Permit to FDA Records section for release, and updates the FIS indicating the same	1 Working Day	CFRR STAFF
5. Receives the Certificate/Authorization through courier or pick-up.	5. Updates the status via FIS and release the Certificate/Authorization through courier or pick-up	1 Working Day	Releasing Section Staff
		TOTAL: 7 working days	

9. ISSUANCE OF SANGKAP PINOY SEAL

Sangkap Pinoy Seal Program (SPSP) - a strategy to encourage food manufacturers to fortify processed foods or food products with essential nutrients at levels approved by the DOH. The fundamental concept of the program is to authorize food manufacturers to use the DOH seal of acceptance for processed foods or food products, after these products passed a set of defined criteria. The seal is a guide used by consumers in selecting nutritious foods. (Republic Act No. 8976)

Center/Office/Division	:	Center for Food Regulation and Research (CFRR)
Classification	:	Government to Business
Type of Transaction	:	Highly Technical Transaction
Who May Avail	:	All FOOD Manufacturers of Fortified Products
Fees to be Paid	:	P8,000.00 non-refundable fee for the use of the seal (Regular Seal) P500.00 processing fee for every application (Regular Seal or Diamond Seal) + 1% LRF

CHECKLIST OF REQUIREMENTS Submit ONE (1) scanned copy of the required document.	**WHERE TO SECURE**
☑ Basic Requirements based on RA No. 8976 (Food Fortification Law of 2000), RA No. 8172 (ASIN Law), the Sangkap Pinoy Seal Program Manual of Operations (December 2000) and Administrative Order No. 82 s. 2003 (Guidelines on the Granting of Diamond Sangkap Pinoy Seal to Manufacturers of Fortified Products):	https://www.fda.gov.ph/
☑ Duly accomplished application forms	FDA Philippines
☑ Copy of valid and appropriate LTO issued by the FDA	FDA Philippines
☑ Results of product analysis for vitamin A, Iron and Iodine from an FDA recognized laboratory.	For the Certificate of Analysis: Laboratory analysis issued/conducted by FDA accredited laboratories.
☑ Sample label with Sangkap Pinoy Seal	Applicant Company/ Manufacturer/Source/Supplier
☑ Proof of payment	Systems/Means prescribed by FDA
☑ Inspection report with Certificate of Compliance	FDA Regional Field Office

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
	1. Receives document requirements from FDA Regional Field Office and decks the same to CFRR technical evaluators.	1 Working Day	LICENSING AND REGISTRATION DIVISION (LRD) EVALUATOR (e.g. Food-Drug Regulation Officer (FDRO))
	2.1. Evaluates the application and ALL the submitted documentary requirements in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, drafts recommendation if the application is for Approval or Disapproval, and then forwards the same to the CHECKER.	8 Working Days	LRD EVALUATOR (e.g. Food-Drug Regulation Officer (FDRO))
	2.2. Reviews the evaluated application, ALL the submitted documentary requirements, and the drafted recommendation of the EVALUATOR, in accordance to existing FDA regulation/s and Quality Work/Standard Procedures, drafts recommendation if the application is for Approval or Disapproval, and then forwards the same to the APPROVING AUTHORITY.	5 Working Days	LRD CHECKER (e.g. SENIOR FDRO or SUPERVISOR or DIVISION CHIEF)
	2.3. Prints the authorization.	1 Working Day	CFRR ADMINISTRATIVE STAFF
	2.4. Signs the Certification/Authorization.	4 Working Days	CFRR APPROVING AUTHORITY (e.g. DIRECTOR IV)
	3. Forwards the Certificate/Authorization to the Office of Director General, for signature.	1 Working Day	CFRR ADMINISTRATIVE STAFF
		TOTAL: 20 Working Days	

COMMON SERVICES LABORATORY
EXTERNAL

1.ACCREDITATION OF PRIVATE TESTING LABORATORY

The Republic Act No. 9711, otherwise known as the “The Food and Drug Administration Act of 2009,” empowers the FDA to accredit private testing laboratories to increase the testing laboratories that may conduct testing, calibration, assay and examination of samples of health products. This application for laboratory accreditation for private testing laboratories follows the rules and regulations stipulated in the FDA Order No. 2012-001.

Center/Office/Division:	Common Services Laboratory (CSL) – Office of the Director, Receiving and Releasing Unit, Laboratory Accreditation Team FDA Cashier
Classification:	Highly Technical Transaction
Type of Transaction:	G2B - Government to Business
Who May Avail:	Private Testing Laboratory
Fees to be Paid:	1) Audit of Testing Laboratory (per visit) Within Metro Manila - PHP 10,000.00 + transportation cost Outside Metro Manila - PHP 10,000.00 + per diem/per auditor + transportation cost 2) Accreditation of Testing Laboratory Fee (per year) – PHP 20,000.00 3) Legal Research Fee (LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Duly Notarized Accomplished Petition Form (FDA Order No. 2012-001 Annex A)	FDA Website (www.fda.gov.ph)
Copy of valid ISO 17025 Certificate of Accreditation with defined scope of accreditation issued by Philippine Accreditation Bureau (PAB) within the last six months prior to date of application with FDA (1 scanned or photocopy)	Applicant
Copy of Laboratory Quality Manual and List of SOPs (1 scanned or photocopy)	Applicant
List of PAB Approved Signatories for the particular test or types of test covered by the Scope of Accreditation (1 scanned or photocopy)	Applicant
Location Map of the Laboratory (1 scanned or photocopy)	Applicant

Copy of latest PAB assessment findings with corresponding corrective action (1 scanned or photocopy)	Applicant
Floor layout with appropriate scale reflecting laboratory areas (1 scanned or photocopy)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submits scanned copy of requirements to info@fda.gov.ph with the email subject: ***CSL_Accreditation of Testing Laboratory [space] Name of Laboratory*** *Note:* Printed copies of the requirements may be forwarded to FDA Central Office, Alabang, Muntinlupa City, through courier.	Receives and acknowledges receipt of the email inquiry and forwards to the CSL.	None	Refer to FDAC Citizen's Charter	*Information Officer II* FDAC
	Receives application requirements and provides Document Track Number (DTN). Pre-evaluates submitted documents as to completeness: If found non-compliant, application is rejected and Applicant is informed of the noted discrepancies on the submitted documents. If found compliant, a tentative date for audit will be scheduled.	None	–	*Laboratory Accreditation Secretariat* CSL – Laboratory Accreditation Team
	Sends Notice of Audit to the Applicant through email.	None	1 Working Day	
	Reviews submitted document as pre-audit assessment.	None		*Laboratory Accreditation Member*

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
				CSL – Laboratory Accreditation Team
Confirms the proposed date of audit within seven (7) working days after receipt of Notice of Audit. *Note:* Non-receipt of confirmation to the scheduled assessment within the stipulated timeline shall mean forfeiture of application.	Conducts audit (remote or on-site) and provides audit report with findings and recommendations.	None	3 Working Days	*Laboratory Accreditation Member* CSL – Laboratory Accreditation Team
Submits signed first corrective action plan through email or courier.	Receives documents sent through courier and forwards to assigned auditors.	None	6 Working Days	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Evaluates first corrective action plan and sends prepared report to the Applicant.	None		*Laboratory Accreditation Member* CSL – Laboratory Accreditation Team
Submits second and/or third corrective action plan through email or courier.	Receives documents sent through courier and forwards to assigned auditors	None	8 Working Days	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Evaluates second and/or third corrective action plan and sends prepared report to the Applicant.	None		*Laboratory Accreditation Member* CSL – Laboratory Accreditation Team
	Provides Final Evaluation Report and notifies Applicant that accreditation is granted or denied.	None		

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Issues assessment slip to the Applicant.	None		*Laboratory Technician* CSL – Receiving and Releasing Unit
Proceeds to their preferred payment option; submits clear copy of proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to csl@fda.gov.ph.	Posting of payment.	PHP 10,000 (x no. of visit) + PHP 20,000 (x year) + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
	Upon confirmation of payment from FDA Cashier, prepares Certificate of Accreditation and Scope and prints on security paper and plain A4 paper with the official receipt no./reference number.	None	2 Working Days	*Laboratory Accreditation Member* CSL – Laboratory Accreditation Team
	Signs Certificate of Accreditation and Scope.	None		*Director II* CSL
	Releases signed Certificate of Accreditation and Scope to the Applicant.	None		*Laboratory Accreditation Member* CSL – Laboratory Accreditation Team
	TOTAL		**20 Working Days**	

2.ISSUANCE OF LOT RELEASE CERTIFICATION FOR VACCINES AND BIOLOGICAL PRODUCTS

The Certificate of Lot or Batch Release or Lot or Batch Release Certificate is a document for each lot or batch of a vaccine or biologic product issued by the NRA of the exporting country or the country of origin. It is part and parcel of a Summary Lot or Batch Protocol, and is accompanied by the following: a) a label of the final container approved by the NRA of the exporting country or country of origin, and b) an instruction leaflet or product insert for users approved by the NRA of the exporting country or country of origin. Issuance of Lot Release Certificate (LRC) for Vaccine and Biological Products to Marketing Authorization Holder (MAH)

Center/Office/Division:	Common Services Laboratory (CSL) – Office of the Director, Receiving and Releasing Unit, Vaccines and Biologicals Unit FDA Cashier FDA Records
Classification:	Complex Transaction
Type of Transaction:	G2B - Government to Business
Who May Avail:	All FDA-Licensed Vaccines and Biologicals Marketing Authorization Holder (Importers and Distributors)
Fees to be Paid:	PHP 1,000.00 + Legal Research Fee (LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Duly notarized accomplished Lot Release Application Form with declaration and undertaking	FDA website (www.fda.gov.ph)
Self-Assessment Checklist for Lot Release Certification.	FDA website (www.fda.gov.ph)
Certificate of Product Registration (CPR) complete with its annexes (Certificate of Variation, if any) and valid at the time of application (1 original scanned copy)	Applicant
Valid License to Operate (LTO) of the: Manufacturer (if applicable) Distributor Importer	Applicant
Certificate of Analysis (CoA) for the Final/ Finished Product (and for the diluent as necessary)	Applicant

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Three (3) final containers of representative product samples in their final packaging representation in proper storage condition as per approved specification. *(Note: For products with multiple final containers in one (1) box, only three (3) final containers are required but will still be submitted inside the box)*	Applicant
SOP for Sampling Method from the license holder	Applicant
Complete Summary Lot Protocol (SLP)	Applicant
Manufacturing Process Flow Diagram	Applicant
. Batch Numbering System	Applicant
. For imported products, Lot Release Certificate (or equivalent National Regulatory Authority (NRA) certification) from the country of origin of the product	Applicant
. One (1) set of final packaging materials as seen on the actual samples (including primary and secondary packaging/labels that of the diluent, and package insert)	Applicant
. Generic Labelling Exemption (if applicable)	Applicant
. Pro forma invoice, packing list, shipping invoice or any document indicating the lot number and actual number of doses/units delivered/shipped in the Philippines (for imported products)	Applicant
. Temperature monitoring data during shipment (Cold Chain Documents)	Applicant
Additional Requirements	
For government-procured products (Expanded Program on Immunization (EPI's) and non-EPI's): Purchase Order and Notice of Award from the Department of Health	Department of Health
For donated vaccines/ biological products: Identification of Medical Officer who will be responsible for prompt reporting Adverse Drug Reaction (ADR)/ Adverse Event Following Immunization (AEFI), among others to FDA and/or Report/ Recommendation of the Field Regulatory Operations Office (FROO) on the inspection of the actual shipment	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submits application for pre-assessment to cslvbu@fda.gov.ph. All submissions shall contain all the specified documentary requirements for National Lot Release in PDF format. *Note:* If a file to be provided is too large to be an email attachment, link to a cloud storage (e.g., Google Drive, Microsoft OneDrive, etc.) may be allowed, provided that all files have download privileges.	1. Pre-assess the application as to the completeness of requirements. If found to be non-compliant, Applicant will be informed via email indicating the deficiencies and/or discrepancies noted and will be advised to submit necessary documents prior to acceptance. If found to be compliant, Applicant will be informed via email and will be issued with Document Tracking Number (DTN) and an assessment slip.	None	–	*Food-Drug Regulation Officer* CSL – Vaccine and Biological Unit
Proceeds to their preferred payment channel.	Posting of payment.	PHP 1,000/ application + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
Sends documentary requirements via csl@fda.gov.ph with the subject: ***National Lot Release Initial Application_DTN(14-digit number)*** Filled out Excel copy of the application form; Scanned copy of proof of acceptance in PDF format; Accomplished assessment slip; and Official receipt or machine-validated Landbank ONCOLL payment slip.	Reviews and checks submitted documentary requirements, and performs the following steps: Assigns LRV No. Fills out the necessary information in the Excel copy of the application form. Records information to CSL-Receiving and Releasing Unit Database.	None	1 Hour	*Laboratory Technician* CSL – Receiving and Releasing Unit

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Inform CSL-Vaccine and Biological Unit and the Applicant on the receipt of the application. Forwards the documentary requirements via email to cslvbu@fda.gov.ph.			
Submits the representative sample/s and notarized application form at the FDA Central Office, Alabang, Muntinlupa City.	1 Checks the application requirements and representative sample/s.	None	2 Hours	*Food-Drug Regulation Officer* CSL – Vaccine and Biological Unit
	2 Receives and reviews documentary requirements, and decks the application for evaluation.	None	2 Hours	
	Evaluates the application and prepare the corresponding worksheet/s. Performs visual examination of samples, updating Section Database, and wrapping and tagging of samples.	None	5 Working Days	
	Review of Worksheet and Preparation of Lot Release Certificate or Letter of Denial (as applicable, indicating noted findings as to why safety and quality could not be established).	None	4 Hours	*Food-Drug Regulation Officer/Laboratory Technician* CSL – Vaccine and Biological Unit
	Reviews and approves Lot Release Certification or Letter of Denial (as applicable).	None	30 Minutes	*Food-Drug Regulation Officer*

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
				CSL – Vaccine and Biological Unit
	Signs the Lot Release Certificate or Letter of Denial (as applicable).	None	10 Minutes	*Director II* CSL
	Forwards signed Lot Release Certificate or Letter of Denial (as applicable) to FDA Records.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Scans and releases Lot Release Certificate or Letter of Denial (as applicable) to the Applicant.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**7 Working Days**	

3.CONDUCT OF ROUTINE LABORATORY ANALYSIS

Conduct of Routine Laboratory Analysis, including testing through Accredited Third Party Laboratory

Laboratory testing involves the physico-chemical and microbiological analysis of health products to determine compliance with the standards of safety, efficacy, purity and quality. Samples received by the Common Services Laboratory are categorized as:

a. Complaints – These are alleging deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a health product after release from distribution. High-risk complaints shall be processed for seven (7) working days.
b. Government Deliveries – These are health products submitted by government agencies like the Department of Health, Local Government Units and government hospitals. Government deliveries for anti-tuberculosis drugs (DOH-LMD) shall be processed for fifteen (15) working days.
c. Donations – Samples coming from government and private institutions intended for donations.
d. Referrals – These are health products referred by the FDA Centers or Offices (CDRR, CFRR, CCHUHSRR, CDRRHR, Regulatory Enforcement Unit, FDA Satellite laboratories)
e. Post Market Surveillance (PMS) – These are health products sampled/collected by the FDA Inspectorates and Regulatory Enforcement Officers, as part of monitoring the safety, effectiveness, efficiency and performance after it has been released on the market. This includes Annual Post-Marketing Surveillance (APMSP) and *motu propio*, among others. PMS is an important part of FDA's advocacy in health/pharmacovigilance.

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Duly Accomplished Request for Analysis (RFA) Form	FDA website (https://www.fda.gov.ph/downloadables/)
Actual Sample/s Quantity should be in accordance with FDA Circular No. 2014-014 "Minimum Number of Samples Units required for Each Test Analysis"	Applicant/Requesting Party https://www.fda.gov.ph/wp-content/uploads/2021/06/FC2014-014-Minimun-Numbers-of-Samples-Units-Required-for-Each-Test-Analysis.pdf
With expiration date at least three (3) months prior to request for analysis	
Actual sample per request should bear the same batch or lot	
Properly handled	
Additional Requirements	
If purpose of collection is **scheduled/planned PMS** - compliance to the current approved APMSP.	
For Complaint Samples	

- Copy of Medical certificate or any document that will serve as a guide to the laboratory on the analyte that has to be checked - Copy of Report on the interview conducted, if any - Endorsement from the concerned FDA Center, if applicable - For food-borne illness outbreak-related samples, information on the onset of symptoms, time of consumption, and other food consumed must be provided. *e:* Sample that will be submitted to the CSL for analysis should be from the same batch or lot number as the subject product of the complaint.	

Center/Office/Division:	Common Services Laboratory (CSL) – Office of the Director, Receiving and Releasing Unit, Laboratory Sections FDA Cashier FDA Records
Classification:	Highly Technical Transaction
Type of Transaction:	G2G - Government to Government; G2C - Government to Client (G2C)
Who May Avail:	Government Agencies, FDA Centers and Offices
Fees to be Paid:	DOH Administrative Order No. 50 s. 2001 (Refer to Table 11.1) + Legal Research Fee (LRF)

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Sends Request for Analysis (RFA) per request through email: For Alabang Testing and Quality Assurance Laboratory: atqal.rfa@fda.gov.ph For Cebu Testing and Quality Assurance Laboratory: ctqal.rfa@fda.gov.ph For Davao Testing and Quality Assurance Laboratory: dtqal.rfa@fda.gov.ph	Pre-assessment and evaluation of the RFA based on the following requirements: If the above requirements are not met, the Customer shall be informed by email response and/or by telephone communication, indicating that the request is rejected. Consequently, RFA will be	None	–	*Food-Drug Regulation Officer/Health Program Officer/Laboratory Technician* CSL – Receiving and Releasing Unit

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
For Internal Customers (FDA Centers/Offices), email subject shall be: ***Purpose of Collection [space] Center/Region*** For External Customers (other Government Agencies), email subject shall be: ***Name of Agency [space] RFA*** *Note:* For requests for analysis related to food-borne illness outbreak, pre-assessment and evaluation of RFA will be conducted in-person. For requests for analysis from Regulatory Enforcement Unit (REU), pre-assessment and evaluation of RFA will be conducted through videoconferencing.	returned, for appropriate actions. Revised RFA shall be submitted for pre-assessment prior to acceptance. If the above requirements are met, the request is accepted. *Note:* For External Customers, a reference number will be issued during pre-assessment.			
Submits the required number of samples for laboratory analysis, as well as the printed and signed copies of pre-assessed RFA.	Receives and assesses accuracy of information indicated in the RFA vis-a-vis the actual sample. Likewise, checks if compliant with the required handling conditions. If found acceptable, issues Laboratory Number.	None	15 Minutes	*Food-Drug Regulation Officer/Health Program Officer/Laboratory Technician* CSL – Receiving and Releasing Unit

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	If found unacceptable, rejects the RFA and issues Letter for Returned Sample.			
	2 Encodes RFA in CSL database.	None	5 Minutes	*Food-Drug Regulation Officer/Laboratory Technician* CSL – Receiving and Releasing Unit
	3 Forwards the following to the concerned Section: RFA Sample Transmittal Sheet	None	5 Minutes	*Food-Drug Regulation Officer/Laboratory Technician* CSL – Receiving and Releasing Unit
	Receives and updates the FDA Inventory System (FIS), as well as the Database: RFA Sample Transmittal Sheet	None	10 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL– Laboratory Section/s
	Records received samples in respective Section's Database and schedules decking of samples for testing.	None	10 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL– Laboratory Section/s
	Handles and stores samples for testing in designated location.	None	5 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL–

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
				Laboratory Section/s
	Pre-evaluates received samples as per label and/or test required.	None	10 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL–Laboratory Section/s
	Conducts laboratory testing with corresponding processing timelines: **A. Complaints** High risk Low-medium risk **B. Government deliveries** Anti-tuberculosis (TB) drugs (DOH-LMD) DOH-LMD, other than TB drugs Other government agencies (LGUs, etc.) **C. Donations** **D. Post-marketing Surveillance** **E. Referrals** **F. Microbiological Tests *(see notes)*** Sterility testing Commercial sterility Evaluation of antimicrobial protection	None	**(A)** 5 Working Days 18 Working Days **(B)** 13 Working Days 18 Working Days 18 Working Days **(C)** 18 Working Days **(D)** 18 Working Days **(E)** 18 Working Days	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
			(F) 18 Working Days 23 Working Days 42 Working Days (note: with pending request to ARTA)	
	Records and compute data gathered from laboratory testing.	None	1 Working Day	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s
	Evaluates data and results from laboratory testing.	None	4 Hours	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s
	Prepares Test Reports	None	1 Hour	*Laboratory Technician/ Administrative Aide* Concerned CSL–Laboratory Section/s
	Signs all test reports	None	10 Minutes	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s
	Signs non-conforming test reports	None	10 Minutes	*Director II* CSL

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Issues assessment slip and/or order of payment for fees for the tests/ parameters conducted.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
Proceeds to their preferred payment channel; submits clear copy of the proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to concerned laboratory email: Alabang (atqal.rfa@fda.gov.ph); Cebu (ctqal.rfa@fda.gov.ph); or Davao (dtqal.rfa@fda.gov.ph).	Posting of payment.	Fee for Test/ Parameters Conducted (refer to Table 11.1) + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
	Upon confirmation of payment, forwards the Test Report with assessment slip and/or order of payment to FDA Records.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Releasing of Test Reports to External Customer.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**20 Working Days except** **(A) High Risk** **7 Working Days** **(B) TB Drugs 15 Working Days**	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
			(F) Antimicrobial Protection **44 Working Days**	

NOTES:

- Samples subject for **Sterility Testing** requires a total number of **twenty-eight (28) calendar days** (equivalent to **twenty (20) working days**), which includes: (1) 1-day media preparation; (2) 2-days preparation of reference culture; (3) 5 days Growth Promotion Test and Method Suitability Test; (4) 14 days Incubation period; (5) 4 days Confirmatory Test and (6) a total of 2 days for receiving, data recording and computation, evaluation, reporting and releasing to RRU. *(Reference: United States Pharmacopeia and the National Formulary USP/NF <71> Sterility Test)*
- Samples subject for **Commercial sterility** of thermally processed foods in hermetically sealed containers requires approximately **thirty-three (33) calendar days** (equivalent to **twenty-three (23) working days**), which includes: (1) 1-day media preparation; (2) 10-days sample pre-incubation; (3) 5-days sample culturing; (4) 15-days (as needed) Sub-culturing, morphological characterization and Confirmatory tests; (5) a total of 2 days for receiving, data recording and computation, evaluation, reporting and releasing to RRU. *(Reference: Bacteriological Analytical Manual (BAM) Chapter 21A: Examination of Canned Foods 8th Edition by AOAC International)*
- Samples subject for **Evaluation of the Antimicrobial Protection** of a Cosmetic Product requires a total number of **sixty (62) calendar days** (equivalent to **forty-four (44) working days**), which includes: (1) 1 day media preparation; (2) 16 days preparation of inoculate; (3) 5 days of demonstration of the neutralizer efficacy, additional 5 days for modification of the neutralizer (if necessary); (4) 33 days of determination of the Preservation Efficacy of the Formulation; and (6) a total of 2 days for receiving, data recording and computation, evaluation, reporting and releasing to RRU. *(Reference: ASEAN Cosmetic Method: Evaluation of the Antimicrobial Protection of a Cosmetic Product ACM No. 008; ISO 11930:2019 – Evaluation of the Antimicrobial Protection of a Cosmetic Product)*

TABLE 11.1. SCHEDULE OF FEES BASED ON DOH ADMINISTRATIVE ORDER NO. 50 s. 2001

CLASSIFICATION	FEES (PHP)
Physico-chemical Analysis	
Drugs and Antibiotics	
Visual Examination	300.00
Assay/Potency (single component)	1,500.00
Assay/Potency (multi-component)	2,000.00
Dissolution Test	2,000.00
Disintegration Test	350.00
Hardness Test	350.00
Identification Test	500.00
Purity Test / Related Substances	500.00
Moisture Content	300.00
Loss on Drying	300.00
pH	300.00
Vitamins	
Vitamin A	1,000.00
Vitamin B1, B2, B6	2,000.00
Vitamin C (Ascorbic Acid)	500.00
Vitamin E	500.00
Other Vitamins	500.00
Minerals	800.00
in vitro Diagnostic Reagents	1,000.00
Medical Devices	1,500.00
Cosmetics	
Assay	1,200.00
Identification Test	500.00
Volatile/Non-volatile Matters	500.00
Food Products	
Moisture	300.00

CLASSIFICATION	FEES (PHP)
Protein	1,000.00
Fat/Oil	500.00
Starch	500.00
Glucose	500.00
Sucrose	500.00
Lactose	500.00
Crude Fibers	500.00
Dietary Fibers	2,000.00
Total Solids	300.00
Soluble Solids	300.00
Water-Insoluble Solids	300.00
Ash	300.00
Acid-insoluble Ash	500.00
Saponification Number	500.00
Viscosity	300.00
Refractive Index	300.00
Peroxide Value	500.00
Free Fatty Acids	500.00
Permanganate Oxidation Number (PON)	500.00
Total Acidity	300.00
Water Activity	500.00
Vacuum	300.00
Minerals	1,000.00
Amino Acids (LC)	2,000.00
Proline	500.00
Additives	
Nitrate	500.00
Nitrite	500.00
Sodium Benzoate	500.00

CLASSIFICATION	FEES (PHP)
Sorbic Acid	500.00
Food Color	300.00 per color
Sodium metabisulfite	500.00
Bromates	500.00
BHT	500.00
BHA	500.00
Aspartame	500.00
Saccharin	500.00
Monosodium Glutamate	500.00
Micronutrients	
Vitamin A	1,000.00
Vitamin E	1,000.00
Beta Carotene	1,000.00
Vitamin C	500.00
Vitamin B1, B6	1,000.00
Vitamin B1, B6, Niacin	1,000.00
Iodine	500.00
Iron	500.00
Contaminants	
Borax	300.00
Aflatoxin	2,000.00
Total heavy metals	500.00
Lead	500.00
Cadmium	300.00
Chromium	300.00
Arsenic	300.00
Mercury	300.00
Tin	300.00
Cyanide	300.00
Histamine	1,500.00

CLASSIFICATION	FEES (PHP)
Filth	500.00
Formalin	500.00
Pesticide residue	2,000.00
Alcohol content	1,000.00
Gas volume	300.00
Total Soluble Solids (Brix)	300.00
pH	300.00
Caffeine	500.00
Food Supplements	4,000.00
Beverages	
Alcohol Content	1,000.00
Gas Volume	300.00
Total Soluble Solids (Brix)	300.00
pH	300.00
Caffeine	500.00
Bottled Water	2,000.00
Food Chemicals/Additives	
Direct	1,000.00
Indirect	500.00
Containers/Wrappers	
Migratable Substances	1,000.00
Plastic Additives	500.00
Cellulosic Materials for Pesticide Residue	1,500.00
Materials Testing	500.00
Microbiological Assay	
Potency of Antibiotics	2,500.00
Sterility Tests	
Injectables, Medical Devices, and Large Volume Parenterals	2,500.00
Microbial Limit Tests	

CLASSIFICATION	FEES (PHP)
Aerobic Plate Count	500.00
Aerobic Halophilic Count	500.00
Aerobic Thermophilic Count	500.00
Coliform Plate Count	500.00
Coliform / *Escherichia coli* (MPN)	500.00
Fecal Streptococci	600.00
Yeast and Mold Count	500.00
Halophilic Yeast Count	500.00
Staphylococcus aureus Count	600.00
Pseudomonas aeruginosa	600.00
Identification of Microorganisms (*Salmonella* sp.)	
Presumptive Test	600.00
Confirmatory Test (complete biochemical reaction)	2,000.00 per organism
Commercial sterility of thermally processed foods in hermetically sealed containers	1,000.00
Bioassay Tests	
Bacterial endotoxin test (LAL)	4,000.00

4.ISSUANCE OF EXPORT CERTIFICATE FOR ACACIA WOODENWARES (VOLUNTARY)

Voluntary application for Issuance of Export Certificate for Acacia Woodenwares.

Center/Office/Division:	Common Services Laboratory (CSL) – Receiving and Releasing Unit, Cosmetic-Toxicology Section Food and Drug Action Center (FDAC) FDA Cashier FDA Records
Classification:	Complex Transaction
Type of Transaction:	G2B - Government to Business
Who May Avail:	Acacia Woodenwares' Exporting Companies
Fees to be Paid:	PHP 500.00 + Legal Research Fee (LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Request Letter stating the intended use of the product (1 signed scan copy)	Applicant
Product Information (1 scanned copy of each, with the product name as the filename) Technical Specification Intended use (State if direct or indirect contact with food) Overview of the production process Packing List including Net and Gross Weight	Applicant
Certificate of Analysis wherein Batch/Lot No. and Production date are indicated (1 original scanned copy, with the product name as the filename)	Applicant
Health and Safety Information / Safety Data Sheet for finished product and raw materials (1 original scanned copy, with the product name as the filename	Applicant

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Formulation/Composition indicating the specific chemical names and corresponding CAS numbers of all raw materials used (including lacquers, colorants and additives, if any (1 original scanned copy, with the product name as the filename)	Applicant
Report of Analysis based on finished article/product being applied for evaluation from an FDA-accredited laboratory. The Batch/Lot No. must be indicated in the Test Report (1 original scanned copy, with product name as the filename)	FDA-accredited Laboratory
Clear photos of the product capturing all parts i.e., inner and outer parts (photos should be in .jpeg, .png, or .pdf file, with product name as the filename)	Applicant
Proof of payment e.g., Official Receipt, LandBank ONCOLL Machine-Validated Payment (1 original scanned copy)	LandBank/Online Banking

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submits the scanned copy of the requirements to info@fda.gov.ph with the email subject: ***CSL_Voluntary Application for Certification of Acacia Wooden Wares***	Receives application and forwards to CSL	None	Refer to FDAC Citizen's Charter	*Information Officer II* FDAC
	Pre-assesses the application as to the completeness of requirements and assigns Document Tracking Number (DTN). If found non-compliant, informs the Applicant via email for	None	–	*Food-Drug Regulation Officer / Health Program Officer / Laboratory Technician* CSL – Receiving and Releasing Unit

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	submission of necessary documents. If found compliant, issues an assessment slip and advise the Applicant to make the necessary payment through acceptable payment channels			
Proceeds to their preferred payment channel; submits a clear copy of the proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to csl@fda.gov.ph.	Verifies, validates, and posting of payment.	PHP 500/ application + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
	Forwards the application to the Cosmetic-Toxicology Section upon receipt of payment confirmation from FDA Cashier.	None	5 Minutes	*Food-Drug Regulation Officer / Health Program Officer / Laboratory Technician* CSL – Receiving and Releasing Unit
	Receives and prints forwarded application/s, records in Section Database, and decks the application for evaluation.	None	30 Minutes	*Food-Drug Regulation Officer / Administrative Assistant* CSL – Cosmetic-Toxicology Section
	Conducts food suitability evaluation.	None	6 Working Days	
	Forwards the result of evaluation and Export Certificate to the CSL-Receiving and Releasing Unit.	None	10 Minutes	*Administrative Assistant* CSL – Cosmetic-Toxicology Section

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Emails the scanned copy of the result of evaluation and Export Certificate to the Applicant.	None	2 Minutes	*Food-Drug Regulation Officer / Health Program Officer / Laboratory Technician* CSL – Receiving and Releasing Unit
	Forwards the result of evaluation and Export Certificate (original printed copy) to the FDA Records Section for release.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Releases the result of evaluation and Export Certificate to Applicant.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**7 Working Days**	

NOTES:

1. Failure to submit the mandatory documentary requirements, and submission of documents that do not substantiate the suitability and safety of the product for its intended use shall be grounds for denial/disapproval of the application. Once denied/disapproved, re-application may opt to be done considering the noted observations on the initial application. Re-application entails payment of the required fee.

5.ISSUANCE OF FOOD EXPORT CERTIFICATE AND FOOD COMMODITY CLEARANCE

Pursuant to Section 3 of Presidential Decree No. 930 otherwise known as Export simplification Decree, the FDA, then BFAD, issued a guidelines through the Administrative Order No. 15-a s. 1981 for the simplified export procedures for the information and guidance of all exporters. The issuance of food export certificate and food commodity clearance applies to all FDA-licensed food establishments.

Center/Office/Division:	Common Services Laboratory (CSL) – Office of the Director, Receiving and Releasing Unit, Food Section FDA Records
Classification:	Simple Transaction
Type of Transaction:	G2B - Government to Business
Who May Avail:	All FDA-Licensed Food Establishments (Manufacturers, Traders, and Exporters)
Fees to be Paid:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Scanned copy of the completely filled-out Application Form in two (2) copies	FDA website (https://www.fda.gov.ph/downloadables/)
Scanned copy of valid License to Operate (as manufacturer/trader/ exporter, whichever is applicable)	Applicant
Scanned copy of a valid Certificate of Product Registration of the product for export	Applicant
Scanned copy of the signed Packing List or Sales Invoice (System generated/electronically signed is also accepted)	Applicant
Excel copy of the filled-out templates of the draft Certificates and database	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Downloads the Application Form, draft template of the Certificate, and database from the FDA website.	Checks email requests lodged at cslexport@fda.gov.ph.	None	30 Minutes	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Applicant to fill-out the required information and submit an email request with attached soft copies of the forms to cslexport@fda.gov.ph.				*Food-Drug Regulation Officer / Laboratory Technician* CSL – Food Section
	Reviews application for completeness of requirements and correctness of Application Form.	None	1 Hour	
	If found non-compliant, the application is returned to the Applicant stating the reason for rejection.	None	30 Minutes	
	If found compliant, a Reference Number is issued for each application received.	None	30 Minute	
	Edits draft Certificate submitted to reflect Reference Number (FE for Food Export and FCO for Food Commodity Clearance).	None	1 Hour	
	Shares the prepared Certificate and/or Clearance at the network with the issued Reference Number as the label.	None	1 Hour	
	Reviews the prepared Certificate and/or Clearance.	None	30 Minutes	
	Prints the final copy of the Certificate and/or Clearance and submits to the CSL Director for signature.	None	30 Minutes	
	Signs the Certificate and/or Clearance.	None	30 Minutes	*Director II* CSL

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Seals the approved and signed Certificates and/or Clearances.	None	30 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Updates the CSL Main Database.	None	30 Minutes	
	Prints the transmittal slip in two (2) copies	None	30 Minutes	
	Forwards Certificates and Clearances and transmittal slip to FDA Records for release.	None	30 Minutes	
	Releases the Certificates and/or Clearances to the Applicant.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**1 Working Day**	

NOTES:

1. Failure to submit the mandatory documentary requirements and submission of incorrect and misleading information shall be grounds for denial of the application. Once denied, another email request together with the required documents should be sent to cslexport@fda.gov.ph.

6.ISSUANCE OF ONLINE BATCH NOTIFICATION FOR ANTIBIOTIC PRODUCTS

Batch Notification refers to the filing by a manufacturer, trader or distributor/importer of a notice to the Department of Health, through the Food and Drug Administration, concerning the manufactured or imported batch or batches of antibiotic drug product/s prior to release for sale, offer for sale, distribution, transfer, donation, or offer as Physician Samples of such particular batch or batches of drug product/s. Issuance of Batch Notification for antibiotic products is done online following the FDA Circular No. 2017-011.

Center/Office/Division:	Common Services Laboratory (CSL) – Antibiotic Section FDA Cashier
Classification:	Simple Transaction
Type of Transaction:	G2B - Government to Business
Who May Avail:	All FDA-Licensed Pharmaceutical Establishment (Manufacturer, Importer, Distributor, and Trader)
Fees to be Paid:	PHP 5,000.00 + Legal Research Fee (LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Pre-Evaluation	
Clear scanned copy of the Online Batch Notification Application Form in A4 size page, completely and correctly filled out and signed by the current company pharmacist	E-mailed by the cslbn@fda.gov.ph
Electronic copy (Excel format) of the Online Batch Notification Application Form	E-mailed by the cslbn@fda.gov.ph
Commitment Letter for submission	Applicant
Clear scanned copy of valid License to Operate (as manufacturer/trader/exporter, whichever is applicable)	Applicant
Clear scanned copy of valid Certificate of Product Registration (CPR) and/or Certificate for Variation (COV) application	Applicant

<table>
<tr><th>CHECKLIST OF REQUIREMENTS</th><th>WHERE TO SECURE</th></tr>
<tr><td>Clear scanned / electronic copy of valid Certificate of Analysis of the finished product reflecting similar batch/lot number with the sample submitted, batch size, theoretical and actual yield</td><td>Applicant</td></tr>
<tr><td>For imported products (1) Clear scanned / electronic copy of commercial invoice and/or packing list reflecting the expiry date and batch/lot number of the product or any document to prove the actual volume of importation; and (2) Transport Documents (Bill of Lading / Airway Bill / Seaway Bill) for the particular shipment. The volume of importation must be the same in the application form</td><td>Applicant</td></tr>
<tr><td>Clear scanned / electronic copy of Notice of Minor Variation/s (if applicable)</td><td>Applicant</td></tr>
<tr><td>Clear scanned / electronic copy of updated Document Tracking Number or status of the request (if applicable)</td><td>Applicant</td></tr>
<tr><td>. Image of the representative sample (as illustrated below) including the product insert and box in commercial presentation bearing the Principal Label, Batch/Lot No., Company Address, Registration No., Manufacturing and Expiration Date.
<table>
<tr><th>SAMPLE TYPE</th><th>QUANTITY REQUIRED</th></tr>
<tr><td>Tablet or capsule</td><td>1 blister pack or foil strip</td></tr>
<tr><td>Oral Suspension</td><td>1 bottle per presentation</td></tr>
<tr><td>Granules or Powder for Suspension</td><td>1 bottle</td></tr>
<tr><td>Cream or Ointment</td><td>1 tube per presentation</td></tr>
<tr><td>Ophthalmic, Otic, Nasal Drops</td><td>1 bottle per presentation</td></tr>
<tr><td>Injectables
Liquid Preparations</td><td>1 ampoule or vial per presentation</td></tr>
<tr><td>Solid Preparations</td><td>1 vial</td></tr>
</table></td><td>Applicant</td></tr>
<tr><td>Post-Evaluation</td><td></td></tr>
</table>

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Clear scanned copy / electronic copy of the Proof of Payment	LandBank / Online Banking
Two (2) sets of NOTARIZED APPROVED BATCH NOTIFICATION APPLICATION ON-LINE FORM with the company pharmacist's original signature on Page 3. 1.1. Applicants that submitted Notarized BN Application Form must submit it, together with the APPROVED BN FORM (with or without the notarial requirements for the latter) with the company pharmacist's original signature on Page 3. 1.2. Post-submission for nonnotarized BN application/s must follow the guidelines of the notarial requirements of the FDA Circular No.2017-011 - Batch Notification under II. SPECIFIC INSTRUCTIONS 2.e.: "...dates should be within the week of actual submission of the BN Form." or within 5 working days from the date of notarization. Submission of antedated application/s will not be accepted.	Applicant
Other required documents	Applicant
Commitment Letter	Applicant
Representative Sample	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Download, accomplish, print, and scan the Online Batch Notification Application Form; take a clear image of the representative sample and its packaging; and submit an email request with the link of the compressed/zipped documents or attached electronic and scanned copies of the requirements to cslbn@fda.gov.ph.	Checks email requests lodged at cslbn@fda.gov.ph.	None	30 Minutes	*Food-Drug Regulation Officer / Laboratory Technician* CSL-Antibiotic Section
	Reviews the application for completeness of requirements and	None	30 Minutes	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	correctness of the Application Form and the actual sample submitted.			
	If found non-compliant, the application is returned, and the Applicant will be informed of the reason/s for rejection. Note: Applicant is advised to re-submit all documents the next working day.	None	30 Minutes	
	If found compliant, the following steps are performed: Assigns BN Number and initials of the evaluator; and Issues payment details for each application received.	None	2 Hours	
. Proceeds to their preferred payment option; submits a clear copy of the proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to cslbn@fda.gov.ph.	Verifies, validates, and posting of payment.	PHP 5,000/ application + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
	Reviews e-mailed proof of payment and completes the portion of Payment Information on the online BN application form.	None	1 Hour	*Food-Drug Regulation Officer / Laboratory Technician* CSL-Antibiotic Section

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Stamps the name and electronic signature of the approving personnel on the online BN application form.	None	1 Hour	
	Sends approved and signed Online BN application form	None	30 Minutes	
. Submits the hard copies of the notarized approved online BN application and representative sample to the FDA Central Office.	Checks for the correctness and completeness of the documents.	None	1 Hour	
	Records the BN Number to the Releasing Logbook and releases the signed BN form to the applicant.	None	1 Hour	
	TOTAL		**1 Working Day**	

NOTES:

1. The approved BN shall be paid within 5 working days, any late payment will invalidate your application. Any payment before the approval of your application shall be voided.
2. Walk-in post-submission of online applications will be accepted every Wednesday from 9:00 AM to 4:00 PM only, except during holidays and suspension of work. All post-submission beyond the set schedule shall not be accommodated. Only those post-submission requirements forwarded via courier, dispatch riders, or other forwarding services with no definite arrival time shall be accepted by the on-duty guard, which shall be subjected to further evaluation and shall not guarantee acceptance by the CSL.
3. Submit only one (1) hard copy of the NOTARIZED APPROVED BATCH NOTIFICATION APPLICATION ONLINE FORM, with the company pharmacist's signature (Page 3 of BN Form) together with the required documents and the representative sample within twenty (20) working days. Failure to submit requirements and samples within the required timeline will be subject to termination of the application and non-refundable payment.

7.ONLINE APPLICATION FOR FOOD SUITABILITY CERTIFICATION OF FOOD CONTACT ARTICLES (VOLUNTARY)

Regulation of Food Contact Articles (FCA) is specified in Republic Act No. 10611, also known as the Food Safety Act of 2013, which states that food is adulterated if it is in a container having in whole or in part any poisonous or deleterious substance. As such, any food packaging material which results or may reasonably be expected to result, or indirectly in it becoming a component or otherwise affecting the characteristics of any food is considered a food additive according to the Bureau Circular No. 2006-016 or the Updated List of Food Additives. This service shall cover both locally manufactured and imported food contact articles, in finished or final form, with or without applied adhesives and/or printing inks limited to direct food contact articles for pre-packaged processed food products and articles with incidental contact to processed food products as indicated in the FDA Circular No. 2022-011 or the Guidelines on the Application and Issuance of Voluntary Certification of Food Contact Articles (FCA) Used for Prepackaged Processed Food Products.

Center/Office/Division:	Common Services Laboratory (CSL) – Receiving and Releasing Unit, Cosmetic-Toxicology Section Food and Drug Action Center (FDAC) FDA Cashier FDA Records
Classification:	Highly Technical Transaction
Type of Transaction:	G2B - Government to Business
Who May Avail:	All Food Contact Articles Manufacturers and Distributors
Fees to be Paid:	PHP 500.00 + Legal Research Fee (LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Request Letter stating the product and its intended use (1 signed scan copy)	Applicant
Product Information (1 scanned copy of each, with the product name as the filename) Technical Specification Intended use (state if to be used as primary or secondary packaging/ if to have direct or indirect contact with food) Overview of the production process	Applicant

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
For products wherein part of its component is recycled material, additional requirements must be submitted as well: Recycling process Source of starting material or major material that will be recycled	
Certificate of Analysis wherein Batch/Lot No. and Production date are indicated (1 original scanned copy, with the product name as the filename)	Applicant
Health and Safety Information / Safety Data Sheet for finished product and raw materials (1 original scanned copy, with the product name as the filename)	Applicant
Formulation/Composition indicating the specific chemical names and corresponding CAS numbers of all raw materials used (including colorants and additives, if any (1 original scanned copy, with the product name as the filename) *Note:* For products made from metals and alloy, the specific alloy should be indicated along with its elemental composition. For products wherein part of its component is recycled materials, all the chemicals used in the recycling process must be reflected.	Applicant
Report of Analysis based on finished article/product being applied for evaluation from an FDA-accredited laboratory. The Batch/Lot No. must be indicated in the Test Report (1 original scanned copy, with product name as the filename)	Applicant
Clear photos of the product capturing all parts i.e., inner and outer parts (photos should be in .jpeg, .png, or .pdf file, with product name as the filename)	Applicant
Proof of payment e.g., Official Receipt, LandBank ONCOLL Machine-Validated Payment (1 original scanned copy)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submits the scanned copy of the requirements to info@fda.gov.ph with the email subject:	Receives and acknowledges receipt of the copy of requirements and forwards to CSL.	None	Refer to FDAC Citizen's Charter	*Information Officer II* FDAC

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
CSL_Voluntary Application for Certification of Food Contact Articles				
	Pre-assesses the submitted requirements as to their completeness and assigns Document Tracking Number (DTN). If found non-compliant, the Client will be informed via email for submission of necessary documents. If found compliant, issues an assessment slip and advise the Client to make the necessary payment through acceptable payment channels.	None	–	*Food-Drug Regulation Officer / Health Program Officer / Laboratory Technician* CSL – Receiving and Releasing Unit
Proceeds to their preferred payment channel; submits a clear copy of the proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to csl@fda.gov.ph.	Verifies, validates, and posting of payment.	PHP 500/ application + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
	Forwards the application to the Cosmetic-Toxicology Section upon receipt of payment confirmation from FDA Cashier.	None	5 Minutes	*Food-Drug Regulation Officer / Health Program Officer / Laboratory Technician*

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
				CSL – Receiving and Releasing Unit
	Receives and prints forwarded application/s, records in Section Database, and decks the application for evaluation.	None	30 Minutes	*Food-Drug Regulation Officer / Administrative Assistant* CSL – Cosmetic-Toxicology Section
	Conducts food suitability evaluation.	None	11 Working Days	
	Forwards the result of evaluation to the CSL-Receiving and Releasing Unit.	None	10 Minutes	*Administrative Assistant* CSL – Cosmetic-Toxicology Section
	Emails the scanned copy of the result of the evaluation to the Client.	None	2 Minutes	*Food-Drug Regulation Officer / Health Program Officer / Laboratory Technician* CSL – Receiving and Releasing Unit
	Forwards the result of the evaluation (original printed copy) to the FDA Records.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Releases the reply letter to the Client.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**12 Working Days**	

NOTES:

1. Failure to submit the mandatory documentary requirements, and submission of documents that do not substantiate the suitability and safety of the product for its intended use shall be grounds for denial/disapproval of the application. Once denied/disapproved, re-application may opt to be done considering the noted observations on the initial application. Re-application entails payment of the required fee.

8.ONLINE PRE-APPLICATION QUERY FOR FOOD SUITABILITY EVALUATION OF FOOD CONTACT ARTICLES (VOLUNTARY)

Regulation of Food Contact Articles (FCA) is specified in Republic Act No. 10611, also known as the Food Safety Act of 2013, which states that food is adulterated if it is in a container having in whole or in part any poisonous or deleterious substance. As such, any food packaging material which results or may reasonably be expected to result, or indirectly in it becoming a component or otherwise affecting the characteristics of any food is considered a food additive according to the Bureau Circular No. 2006-016 or the Updated List of Food Additives. This service shall cover both locally manufactured and imported food contact articles, in finished or final form, with or without applied adhesives and/or printing inks limited to direct food contact articles for pre-packaged processed food products and articles with incidental contact to processed food products as indicated in the FDA Circular No. 2022-011 or the Guidelines on the Application and Issuance of Voluntary Certification of Food Contact Articles (FCA) Used for Prepackaged Processed Food Products.

Center/Office/Division:	Common Services Laboratory (CSL) – Receiving and Releasing Unit, Cosmetic-Toxicology Section Food and Drug Action Center (FDAC) FDA Records
Classification:	Complex Transaction
Type of Transaction:	G2B - Government to Business
Who May Avail:	All Food Contact Articles Manufacturers and Distributors
Fees to be Paid:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Email inquiry to be sent to info@fda.gov.ph containing the following information, at a minimum: Product/Article that will be applied for evaluation Composition/Formulation of the product/article Intended use of the product/article Specific condition of use and the food that it will be in contact with the product/article	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Sends email inquiry to info@fda.gov.ph with the email subject: ***CSL_Pre-application Query for Food Contact Articles***	Receives and acknowledges receipt of the email inquiry and forwards to the CSL.	None	Refer to FDAC Citizen's Charter	*Information Officer II* FDAC
	Receives the email and checks the completeness of necessary information. If found incomplete, responds to the Applicant requesting additional necessary information.	None	5 Minutes	*Food-Drug Regulation Officer / Health Program Officer / Laboratory Technician* CSL – Receiving and Releasing Unit
	Forwards email inquiry to CSL-Cosmetic-Toxicology Section once all necessary information is received from the Applicant.	None	5 Minutes	
	Receives and prints forwarded application/s, records in Section Database, and decks the application for evaluation.	None	30 Minutes	*Food-Drug Regulation Officer / Administrative Assistant* CSL – Cosmetic-Toxicology Section
	Drafts and finalizes reply letter to the query.	None	6 Working Days	
	Forwards the reply letter to the CSL – Receiving and Releasing Unit.	None	10 Minutes	*Administrative Assistant* CSL – Cosmetic-Toxicology Section

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Emails the scanned reply letter to the Applicant.	None	2 Minutes	*Food-Drug Regulation Officer / Health Program Officer / Laboratory Technician* CSL – Receiving and Releasing Unit
	Forwards the reply letter (original printed copy) to the FDA Records.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Releases the reply letter to the Applicant.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**7 Working Days**	

9.REQUEST FOR CONDUCT OF CALIBRATION OF RADIOTHERAPY DOSIMETER

Conduct of Calibration of Radiotherapy Dosimeter.

Center/Office/Division:	Common Services Laboratory (CSL) - Physics Laboratory Support Division (PLSD), Secondary Standard Dosimetry Laboratory (SSDL) FDA Cashier
Classification:	Highly Technical
Type of Transaction:	G2G – Government to Government, G2B – Government to Business
Who May Avail:	Government (DOH, LGUs) hospitals, private hospitals and clinics
Fees to be Paid:	PHP 1,600.00/equipment assembly* + Legal Research Fee (LRF) **Equipment assembly includes the electrometer with power cable, farmer type ionization chamber, and ionization chamber extension cable only.*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Schedule of calibration of radiotherapy dosimeter (RTDM) *Note:* The PLSD personnel assigned in SSDL informs the Radiation Oncology Medical Physicist (ROMP) thru email regarding the annual calibration schedule of their radiotherapy dosimeters. The schedule is preferably set during dry months. Request forms are collected for scheduling purposes.	PLSD Personnel in SSDL

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submits scheduled equipment for calibration at the SSDL located in DOH Office, Tayuman, Manila City.	1. Pre-assesses the submitted requirements, as well as the	None	–	*Health Physicists* CSL – Physics Laboratory Support

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Note: Applicant's entrance is at the gate of the new Dr. Jose Fabella Memorial Hospital in Tayuman Street, Manila City.	completeness of equipment and accessories submitted. If found non-compliant, the Client will be informed via email for submission of necessary documents. If found compliant, issues Document Tracking Number (DTN) and Order of Payment, and advise the Client to make the necessary payment through acceptable payment channels.			Division, Secondary Standard Dosimetry Laboratory
Proceeds to their preferred payment channel; submits a clear copy of the proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to csl-plsd@fda.gov.ph.	Posting of payment.	PHP 1,600/ equipment assembly + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
	Upon confirmation of payment from FDA Cashier, confirms schedule date for equipment calibration.	None	1 Working Day	*Health Physicists* CSL – Physics Laboratory Support Division, Secondary Standard Dosimetry Laboratory
	Conducts performance test and calibration of radiotherapy dosimeter.	None	5 Working Days	
	Prepares and reviews performance test repot and	None	6 Working Days	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	calibration certificate of radiotherapy dosimeter.			
	Signs performance test report and calibration certificate.	None	3 Working Days	*Laboratory Division Chief* CSL – Physics Laboratory Support Division
	Notifies ROMP on the schedule of releasing of radiotherapy dosimeter.	None	1 Working Day	*Health Physicists* CSL – Physics Laboratory Support Division, Secondary Standard Dosimetry Laboratory
	Releases equipment, performance test report, and calibration certificate, and scans signed receiving copy of released equipment and documents for filing.	None	3 Working Days	
	TOTAL		**20 Working Days**	

10.REQUEST FOR CONDUCT OF QUALITY AUDIT OF MEDICAL LINAC IN RADIOTHERAPY FACILITY

Conduct of Quality Audit of Radiotherapy Facility.

Center/Office/Division:	Common Services Laboratory (CSL) – Office of the Director, Receiving and Releasing Unit, Physics Laboratory Support Division (PLSD) FDA Cashier FDA Records
Classification:	Highly Technical
Type of Transaction:	G2G – Government to Government, G2B – Government to Business
Who May Avail:	Government (DOH, local) hospitals, private hospitals and clinics
Fees to be Paid:	PHP 7,920.00/radiologic equipment + Legal Research Fee (LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Request for Quality Audit of Radiotherapy Facility (Request for Performance Testing RPT Form)	FDA website (www.fda.gov.ph)

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submit accomplished and signed Performance Testing of Radiological Equipment Request form through email at csl-plsd@fda.gov.ph.	1. Receives and evaluates submitted request form. If found non-compliant, request will be rejected. If found compliant, issues Document Track Number (DTN), Order of Payment, and PLSD code.	None	–	*Administrative Aide* CSL – Physics Laboratory Support Division

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Proceeds to their preferred payment channel; submits a clear copy of the proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to csl-plsd@fda.gov.ph.	Posting of payment.	PHP 7,920/ radiologic equipment + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
	Upon confirmation of payment from FDA Cashier, provides a tentative schedule date to the Applicant for the performance testing.	None	1 Working Day	*Administrative Aide* CSL – Physics Laboratory Support Division
	Determines the availability of the Health Physicists/ Radiologic Technologists and endorses the accomplished request form submitted by Applicant.	None	2 Working Days	*Administrative Aide* CSL – Physics Laboratory Support Division
Confirms the readiness of the facility, functionality of the Co-60 and/or LINAC, availability of medical physicist/s in-charge, and travel arrangements for Health Physicist/Radiologic Technologist.	Evaluates documents and information submitted and communicates the proposed date of performance testing.	None	3 Working Days	*Health Physicist/ Radiologic Technologist* CSL – Physics Laboratory Support Division
	Prepares travel documents, gate pass for performance testing equipment, test forms, and test protocols, and recommends approval of travel to the CSL Director.	None	3 Working Days	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Conducts quality audit of facility and functionality of radiologic equipment[1] and prepares initial test report to be received by the representative of the facility.	None	3 Working Days	
	Drafts performance test report and submits final performance test report for review and approval.	None	5 Working Days	
	Reviews and attests performance test report.	None	1 Working Day	*Laboratory Division Chief* CSL – Physics Laboratory Support Division
	Forwards signed performance test reports and endorsement letter for signature.	None		*Administrative Aide* CSL – Physics Laboratory Support Division
	Signs endorsement letter to be attached to the performance test report.	None		*Director II* CSL
	Forwards signed endorsement letter and attached performance test report for releasing.	None		*Laboratory Technician* CSL – Receiving and Releasing Unit
	Releases performance test report: Forwards one (1) copy of the signed performance test report to FDA Records for mailing to the Applicant.	None	1 Working Day	*Administrative Aide* CSL – Physics Laboratory Support Division

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Scans the signed copy of performance test report and sends as an email attachment to the Radiation Regulation Division (RRD) of the Center for Device Regulation, Radiation Health and Research (CDRRHR) and to the Applicant.			
	.Releases the endorsement letter with attached performance test report to the Applicant.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**20 Working Days**	

[1]Conduct of performance testing may be prolonged depending on the type of radiological equipment and the location of the facility.

11.REQUEST FOR PERFORMANCE TESTING OF RADIOLOGIC EQUIPMENT

Request for Performance Testing of Radiological Equipment.

Center/Office/Division:	Common Services Laboratory (CSL) – Office of the Director, Receiving and Releasing Unit, Physics Laboratory Support Division (PLSD) FDA Cashier FDA Records
Classification:	Highly Technical
Type of Transaction:	G2G – Government to Government, G2B – Government to Business
Who May Avail:	Government (DOH, Local) hospitals, private hospitals and clinics
Fees to be Paid:	PHP 7,920.00/radiologic equipment + Legal Research Fund (LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Request for Performance Testing of Radiologic Equipment (Request for Performance Testing RPT Form)	FDA website (www.fda.gov.ph)

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submit accomplished and signed Performance Testing of Radiological Equipment Request form through email at csl-plsd@fda.gov.ph.	Receives and evaluates submitted request form: If found non-compliant, request will be rejected. If found compliant, issues Document Track Number (DTN), Order of Payment, and PLSD code.	None	–	*Administrative Aide* CSL – Physics Laboratory Support Division

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Proceeds to their preferred payment channel; submits a clear copy of the proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to csl-plsd@fda.gov.ph.	Posting of payment.	PHP 7,920/ radiologic equipment + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
	Upon confirmation of payment from FDA Cashier, provides a tentative schedule date to the Applicant for the performance testing.	None	1 Working Day	*Administrative Aide* CSL – Physics Laboratory Support Division
	Determines the availability of the Health Physicists/ Radiologic Technologists and endorses the accomplished request form submitted by Applicant.	None	2 Working Days	
Confirms the readiness of the facility, functionality of the radiologic equipment to be tested, availability of service engineer, and travel arrangements for Health Physicist/Radiologic Technologist.	Evaluates documents and information submitted and communicates the proposed date of performance testing.	None	3 Working Days	*Health Physicist/ Radiologic Technologist* CSL – Physics Laboratory Support Division
	Prepares travel documents, gate pass for performance testing equipment, test forms, and test protocols, and recommends approval of travel to the CSL Director.	None	3 Working Days	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Conducts on-site performance testing[1] of radiologic equipment and prepares initial test report to be received by the representative of the facility.	None	3 Working Days	
	Drafts performance test report and submits final performance test report for review and approval.	None	5 Working Days	
	Reviews and attests performance test report.	None	1 Working Day	*Laboratory Division Chief* CSL – Physics Laboratory Support Division
	Forwards signed performance test reports and endorsement letter for signature.	None		*Administrative Aide* CSL – Physics Laboratory Support Division
	Signs endorsement letter to be attached to the performance test report.	None		*Director II* CSL
	Forwards signed endorsement letter and attached performance test report for releasing.	None		*Laboratory Technician* CSL – Receiving and Releasing Unit
	Releases performance test report: Forwards one (1) copy of the signed performance test report to FDA Records for mailing to the Applicant.	None	1 Working Day	*Administrative Aide* CSL – Physics Laboratory Support Division

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Scans the signed copy of performance test report and sends as an email attachment to the Radiation Regulation Division (RRD) of the Center for Device Regulation, Radiation Health and Research (CDRRHR) and to the Applicant.			
	Releases the endorsement letter with attached performance test report to the Applicant.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**20 Working Days**	

[1]Conduct of performance testing may be prolonged depending on the type of radiological equipment and the location of the facility.

COMMON SERVICES LABORATORY
INTERNAL SERVICES

1.CONDUCT OF ROUTINE LABORATORY ANALYSIS

Conduct of Routine Laboratory Analysis, including testing through Accredited Third Party Laboratory

Laboratory testing involves the physico-chemical and microbiological analysis of health products to determine compliance with the standards of safety, efficacy, purity and quality. Samples received by the Common Services Laboratory are categorized as:

Complaints – These are alleging deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a health product after release from distribution. High-risk complaints shall be processed for seven (7) working days.

Government Deliveries – These are health products submitted by government agencies like the Department of Health, Local Government Units and government hospitals. Government deliveries for anti-tuberculosis drugs (DOH-LMD) shall be processed for fifteen (15) working days.

Donations – Samples coming from government and private institutions intended for donations.

Referrals – These are health products referred by the FDA Centers or Offices (CDRR, CFRR, CCHUHSRR, CDRRHR, Regulatory Enforcement Unit, FDA Satellite laboratories)

Post Market Surveillance (PMS) – These are health products sampled/collected by the FDA Inspectorates and Regulatory Enforcement Officers, as part of monitoring the safety, effectiveness, efficiency and performance after it has been released on the market. This includes Annual Post-Marketing Surveillance (APMSP) and *motu propio*, among others. PMS is an important part of FDA's advocacy in health/pharmacovigilance.

Center/Office/Division:	Common Services Laboratory (CSL) – Office of the Director, Receiving and Releasing Unit, Laboratory Sections FDA Cashier FDA Records
Classification:	Highly Technical Transaction
Type of Transaction:	G2G - Government to Government
Who May Avail:	FDA Centers and Offices
Fees to be Paid:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Duly Accomplished Request for Analysis (RFA) Form	FDA website (https://www.fda.gov.ph/downloadables/)

Actual Sample/s Quantity should be in accordance with FDA Circular No. 2014-014 "Minimum Number of Samples Units required for Each Test Analysis"	Applicant/Requesting Party https://www.fda.gov.ph/wp-content/uploads/2021/06/FC2014-014-Minimun-Numbers-of-Samples-Units-Required-for-Each-Test-Analysis.pdf
With expiration date at least three (3) months prior to request for analysis	
Actual sample per request should bear the same batch or lot	
Properly handled	
Additional Requirements	
If purpose of collection is **scheduled/planned PMS** - compliance to the current approved APMSP.	
For Complaint Samples - Copy of Medical certificate or any document that will serve as a guide to the laboratory on the analyte that has to be checked - Copy of Report on the interview conducted, if any - Endorsement from the concerned FDA Center, if applicable - For food-borne illness outbreak-related samples, information on the onset of symptoms, time of consumption, and other food consumed must be provided. *e:* Sample that will be submitted to the CSL for analysis should be from the same batch or lot number as the subject product of the complaint.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Sends Request for Analysis (RFA) per request through email: For Alabang Testing and Quality Assurance Laboratory: atqal.rfa@fda.gov.ph For Cebu Testing and Quality Assurance Laboratory: ctqal.rfa@fda.gov.ph	Pre-assessment and evaluation of the RFA based on the following requirements: If the above requirements are not met, the Customer shall be informed by email response and/or by telephone communication,	None	–	*Food-Drug Regulation Officer/Health Program Officer/Laboratory Technician* CSL – Receiving and Releasing Unit

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
For Davao Testing and Quality Assurance Laboratory: dtqal.rfa@fda.gov.ph For Internal Customers (FDA Centers/Offices), email subject shall be: ***Purpose of Collection [space] Center/Region*** For External Customers (other Government Agencies), email subject shall be: ***Name of Agency [space] RFA*** *Note:* For requests for analysis related to food-borne illness outbreak, pre-assessment and evaluation of RFA will be conducted in-person. For requests for analysis from Regulatory Enforcement Unit (REU), pre-assessment and evaluation of RFA will be conducted through videoconferencing.	indicating that the request is rejected. Consequently, RFA will be returned, for appropriate actions. Revised RFA shall be submitted for pre-assessment prior to acceptance. If the above requirements are met, the request is accepted. *Note:* For External Customers, a reference number will be issued during pre-assessment.			
Submits the required number of samples for laboratory analysis, as well as the printed and signed copies of pre-assessed RFA.	1 Receives and assesses accuracy of information indicated in the RFA vis-a-vis the actual sample. Likewise, checks if compliant with the required handling conditions. If found acceptable, issues Laboratory Number.	None	15 Minutes	*Food-Drug Regulation Officer/Health Program Officer/Laboratory Technician* CSL – Receiving and Releasing Unit

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	If found unacceptable, rejects the RFA and issues Letter for Returned Sample.			
	2 Encodes RFA in CSL database.	None	5 Minutes	*Food-Drug Regulation Officer/Laboratory Technician* CSL – Receiving and Releasing Unit
	3 Forwards the following to the concerned Section: RFA Sample Transmittal Sheet	None	5 Minutes	*Food-Drug Regulation Officer/Laboratory Technician* CSL – Receiving and Releasing Unit
	Receives and updates the FDA Inventory System (FIS), as well as the Database: RFA Sample Transmittal Sheet	None	10 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL– Laboratory Section/s
	Records received samples in respective Section's Database and schedules decking of samples for testing.	None	10 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL– Laboratory Section/s
	Handles and stores samples for testing in designated location.	None	5 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL–

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
				Laboratory Section/s
	Pre-evaluates received samples as per label and/or test required.	None	10 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL–Laboratory Section/s
	Conducts laboratory testing with corresponding processing timelines: **A. Complaints** High risk Low-medium risk **B. Donations** **C. Post-marketing Surveillance** **D. Referrals** **E. Microbiological Tests *(see notes)*** Sterility testing Commercial sterility Evaluation of antimicrobial protection	None	**(A)** 5 Working Days 18 Working Days **(B)** 18 Working Days **(C)** 18 Working Days **(D)** 18 Working Days **(E)** 18 Working Days 23 Working Days 42 Working Days (note: with pending request to ARTA)	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Records and compute data gathered from laboratory testing.	None	1 Working Day	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s
	Evaluates data and results from laboratory testing.	None	4 Hours	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s
	Prepares Test Reports	None	1 Hour	*Laboratory Technician/ Administrative Aide* Concerned CSL–Laboratory Section/s
	Signs all test reports	None	10 Minutes	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s
	Signs non-conforming test reports	None	10 Minutes	*Director II* CSL
	Forwards signed Test Reports to concerned Office/Center.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Forwards the Test Report to FDA Records for Test Reports to Regional Field Offices.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Releasing of Test Reports to Internal Customer.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**20 Working Days except** **<u>(A) High Risk</u>** **7 Working Days** **<u>(E) Antimicrobial Protection</u>** **44 Working Days**	

<u>NOTES:</u>

- Samples subject for **Sterility Testing** requires a total number of **twenty-eight (28) calendar days** (equivalent to **twenty (20) working days**), which includes: (1) 1-day media preparation; (2) 2-days preparation of reference culture; (3) 5 days Growth Promotion Test and Method Suitability Test; (4) 14 days Incubation period; (5) 4 days Confirmatory Test and (6) a total of 2 days for receiving, data recording and computation, evaluation, reporting and releasing to RRU. *(Reference: United States Pharmacopeia and the National Formulary USP/NF <71> Sterility Test)*
- Samples subject for **Commercial sterility** of thermally processed foods in hermetically sealed containers requires approximately **thirty-three (33) calendar days** (equivalent to **twenty-three (23) working days**), which includes: (1) 1-day media preparation; (2) 10-days sample pre-incubation; (3) 5-days sample culturing; (4) 15-days (as needed) Sub-culturing, morphological characterization and Confirmatory tests; (5) a total of 2 days for receiving, data recording and computation, evaluation, reporting and releasing to RRU. *(Reference: Bacteriological Analytical Manual (BAM) Chapter 21A: Examination of Canned Foods 8th Edition by AOAC International)*
- Samples subject for **Evaluation of the Antimicrobial Protection** of a Cosmetic Product requires a total number of **sixty (62) calendar days** (equivalent to **forty-four (44) working days**), which includes: (1) 1 day media preparation; (2) 16 days preparation of inoculate; (3) 5 days of demonstration of the neutralizer efficacy, additional 5 days for modification of the neutralizer (if necessary); (4) 33 days of determination of the

Preservation Efficacy of the Formulation; and (6) a total of 2 days for receiving, data recording and computation, evaluation, reporting and releasing to RRU. *(Reference: ASEAN Cosmetic Method: Evaluation of the Antimicrobial Protection of a Cosmetic Product ACM No. 008; ISO 11930:2019 – Evaluation of the Antimicrobial Protection of a Cosmetic Product)*

FOOD AND DRUG ACTION CENTER
EXTERNAL SERVICES

1. PROCEDURE IN CALL HANDLING AT THE FOOD AND DRUG ACTION CENTER (FDAC)

This encompasses all telephone calls received by the FDAC seeking assistance for complaints, follow-ups, and requests for information relative to the mandate of the agency.

Center/Office/Division	**:**	Food and Drug Action Center/Telephone Operators Team
Classification	**:**	Simple
Type of Transaction	**:**	Government to Business - G2B ; Government to Government
Who May Avail	**:**	All Stakeholders (Internal and External)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Details of inquiries, complaints, follow-ups, and request	Must be provided by the client

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Calls the FDAC Hotline numbers: (02) 8857-1900 Local 1000 (02) 8842-5635	1.1 Answers phone calls. Identification and probing of concern	None	Minimum of 1 minute Maximum of 3 minutes	Information Officer II
	1.2 Checks resources & tools (e.g. CDS, EPortal EServices, DTS)	None	5 minutes	Information Officer II
	1.3 Provides appropriate response/resolution Escalates concern to proper Center/Office if technical concern	None	5 minutes	Information Officer II
	1.4 Provides closing spiels	None	1 minute	Information Officer II
	5. Documents call/s received at the database	None	1 minute	Information Officer II
TOTAL:		**None**	**15 minutes**	

2. RECEIVING OF LETTERS, MAILS, PARCELS, PRODUCT SAMPLES, AND OTHER DOCUMENTS SENT VIA COURIER/POSTAL SERVICE BY FDAC

This service is for the receiving of letters, mails, parcels, product samples, and other documents sent by internal (FDA Field Inspectors) and external stakeholders of the FDA through courier/postal service and other delivery services.

Center/Office/Division	:	Food and Drug Action Center/Courier Team
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B, Government to Government – G2G
Who May Avail	:	All Stakeholders (External and Internal)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Signed Letters, Mails and Other Documents 2. Properly labeled parcels and health product samples	FDA website (www.fda.gov.ph) – Citizen's Charter portion

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends letters, mails, parcels, health product samples (for verification or laboratory analysis), and other documents through courier/ postal service and other delivery services available	1.1 Checks received letters, parcels, health product samples, and other documents for details needed in recording including attachments and enclosures	None	5 minutes	Food and Drug Action Center Information Officer II
	1.2 Records the details of sender to FDAC Courier Database and FIS-Document Tracking System (DTS)	None	3 minutes	Food and Drug Action Center Information Officer II

	1.3 Issues Acknowledgment Receipt (A.R) and sends it to the sender via email. Updates FIS-DTS if documents are from FDA \ Regional Offices.		2 minutes	Food and Drug Action Center Information Officer II
	1.4 Prepares daily summary of documents received and prints Transmittal Slip	None	5 minutes	Food and Drug Action Center Information Officer II
	1.5 Endorses received documents/parcels/samples to the prope Center/ Office	None	5 minutes	Food and Drug Action Center Information Officer II
	TOTAL:	**None**	**20 minutes**	

FDAC Courier Team transmits the following documents with urgency: all documents from Malacañang (Office of the President), DOH, DOJ, Supreme Court, Regional/Municipal Trial Court, House of Representatives, Senate, ARTA, and Presidential Complaint Center

3. RECEIVING OF COMPLAINTS

3.1 RECEIVING OF COMPLAINTS VIA EMAIL

This service is for the receiving and handling of complaints involving health products and establishments, services and FDA personnel submitted via ereport@fda.gov.ph.

Center/Office/Division	**:**	FDAC/eReport Team
Classification	**:**	Simple
Type of Transaction	**:**	Government to Business - G2B, Government to Citizen- G2C, or Government to Government - G2G
Who May Avail	**:**	All Stakeholders

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Details of complaints	Website Food and Drug Action Center
Evidence of such complaint and other supporting documents if applicable.	

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends complaint with detailed information to ereport@fda.gov.ph	1.1 Checks the adequacy & quality of information. If complete: acknowledges the concern/complaint; encodes the details in the FIS-Document Tracking System (DTS) and generates a 14-digit Document Tracking System (DTS) ; and records the information in the e-Report Database for tracking and monitoring.	None	5 minutes	Food and Drug Action Center Information Officer I

	If Incomplete, sends an email to the client requesting additional information.			
	1.2 Sends email to the client with attached copy of the generated Document Tracking Log.	None	3 minutes	Food and Drug Action Center Information Officer I
	1.3 Forwards the client's email to the concerned FDA Center/Office for information and appropriate action.	None	3 minutes	Food and Drug Action Center Information Officer I
	TOTAL:	**None**	**16 minutes**	

3.2 RECEIVING OF COMPLAINTS FROM WALK-IN CLIENTS

This service is for the receiving and handling of complaints involving health products and establishments, services and FDA personnel submitted onsite.

Center/Office/Division	**:**	FDAC/eReport Team
Classification	**:**	Simple
Type of Transaction	**:**	Government to Business - G2B, Citizen G2C, or Government G2G
Who May Avail	**:**	All Stakeholders

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Duly Signed letter of Intent	Food and Drug Action Center
Evidence of such complaint and other supporting documents if applicable.	

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits a duly signed letter addressed to the FDA Director General	1.1 Checks the completeness of information provided by the client including supporting documents. If the information/documents provided by the client is sufficient: a. receives the concern and encodes the details in the FIS-Document Tracking System b. generates 14-digit Document Tracking Number (DTN); and records the details in the e-Report Database for tracking and monitoring.	None	10 minutes	Food and Drug Action Center Information Officer I

	If the information/document provided by the client is insufficient, request additional documents.			
	1.2 Issues Acknowledgment Receipt with Document Tracking Number (DTN) to the client.	None	3 minutes	Food and Drug Action Center Information Officer I
	1.3 Prepares Transmittal Slip	None	3 minutes	Food and Drug Action Center Information Officer I
	1.4 Endorses the documents including product sample (if applicable) to the concerned Center/Office for information and appropriate action.	None	5 minutes	Food and Drug Action Center Information Officer I
	TOTAL:	**None**	**21** minutes	

4. ISSUANCE OF APPOINTMENT SCHEDULE AND DOCUMENT TRACKING NUMBER

This procedure covers the provision of 14-digit Document Tracking Number (DTN) and schedule of submission for pharmaceutical and household urban pesticide registration applications (initial, renewal, variations, and re-applications) via email to the Food and Drug Action Center (FDAC). This also applies to the submission of applications for other authorizations such as Sales and Promo Permit, Generic Labeling Exemption (GLE), Certificate of Pharmaceutical Product (CoPP), Certificate of Free Sale (CFS), Export Certificate, and re-issuance of authorizations processed using the Integrated Application Form (IAF).

Center/Office/Division	**:**	Food and Drug Action Center/Accounts and Schedulers Team
Classification	**:**	Simple
Type of Transaction	**:**	Government to Business - G2B
Who May Avail	**:**	Marketing Authorization Holders (MAH) of pharmaceutical products and household urban pesticides and company applicants of Sales and Promo Permits

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Accomplished Integrated Application Form (IAF) 2. Email request with the generated syntax (contained in the email worksheet of the accomplished IAF)	**FDA Circular No. 2014-003 -** Filing and Receiving of Registration, Licensing and Other Application Using the Integrated Form

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an email request to fdac@fda.gov.ph following FDA Circular No. 2014-003	1.1 Checks the received email based on the requirements stipulated in FDA Circular No. 2014-003 If compliant, proceed with the procedure in the issuance of schedule and Document Tracking Number (DTN)	None	3 minutes	Food and Drug Action Center Information Officer II

	If not compliant, FDAC Officer sends an email to the requesting party for clarificatio or correction of the request			
	1.2 Issues Document Tracking Log (DTL) bearing the schedule of submission and DTN	None	5 minutes	Food and Drug Action Center Information Officer II
Receives Document Tracking Log (DTL)	2. Sends email to requesting party with DTL as an attachment and other reminders for guidance of the client	None	2 minutes	Food and Drug Action Center Information Officer II
	TOTAL:	**None**	**10 minutes**	

5. ISSUANCE OF USER ACCOUNT (USER NAME AND PASSWORD) FOR THE ELECTRONIC PORTAL SYSTEM (E-PORTAL)

This service covers the issuance of a User Account (User Name and Password) for clients engaged in the manufacture of pharmaceuticals, processed food products, cosmetics, and medical devices applying for License To Operate (LTO) at the EPortal System.

Center/Office/Division	:	Food and Drug Action Center/Account and Schedulers Team
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B
Who May Avail	:	Manufacturers of Pharmaceuticals, Processed Food Products, Cosmetics and Medical Devices

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Email request with signed and notarized Authorization Letter as an attachment (Annex B of FDA Circular No. 2016-004)	**FDA Circular No. 2016-004 -** Procedure on the Use of The New Application Form for the License To Operate (LTO) through the Food and Drug Administration (FDA) Electronic Portal (E-portal)

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an email request to fdac@fda.gov.ph following the format specified in FDA Circular No. 2016-004 with a signed and notarized Authorization Letter	1. Checks the received email based on the requirements stipulated in FDA Circular No.2016-004 If compliant: Proceed with the procedure in the issuance of the User Account If not compliant: FDAC Information Officer sends an email to the	None	7 minutes	Food and Drug Action Center Information Officer II

	requesting party for clarification or correction of the request.			
2. Receives User Account via email	2. Issues User Account to the requesting party	None	3 minutes	Food and Drug Action Center Information Officer II
	TOTAL:	**None**	**10 minutes**	

6. RECEIVING OF DRUG CPR MINOR VARIATION NOTIFICATION AND FOREIGN GMP WITH REQUIRED PRE-ASSESSMENT BY CDRR AT THE FOOD AND DRUG ACTION CENTER (FDAC) LETTERS SECTION

This service covers acknowledgement of Minor Variation Notification and Foreign GMP applications, endorsement to CDRR's Pre assesssement Team and issuance of pre-assessment result to client and receiving of proof of payment.

Center/Office/Division	:	Food and Drug Action Center (Letters Section)
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B
Who May Avail	:	Marketing Authorization Holder (MAH) applying for Drug CPR Minor Variation Notification and Foreign GMP

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Signed Letter of Intent 2. Required documents specified in the application guidelines. 2.1 https://www.fda.gov.ph/wp-content/uploads/2021/05/Minor-Variation-Notification.pdf 2.2 https://www.fda.gov.ph/wp-content/uploads/2020/07/Philippine-Variation-Guidelines-V.1.0-with-fees-and-charges.pdf 2.3 https://www.fda.gov.ph/wp-content/uploads/2021/03/List-of-Requirements-for-Foreign-GMP-Clearance.pdf	**FDA Circular No. 2020-026-** Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA) and Its Related Issuances

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits application/request through fdac.letters.cdrr@fda.gov.ph	1.1 Checks the completeness of the submission For application with complete submission: Receives the application	None	10 Minutes	Food and Drug Action Center Information Officer I and Information Officer II

	For application/request with incomplete submission: Notifies the client that submissio was rejected (state reason of rejection) and advises client to re-submit			
	1.2 Issues Acknowledgement Receipt containing Document Tracking Number (DTN)	None	5 Minutes	Food and Drug Action Center Information Officer I and Information Officer II
	1.3 Prepares and prints summary of documents received and endorses Transmittal Slip to CDRR for pre-assessment	None	5 Minutes	Food and Drug Action Center Information Officer I and Information Officer II
	1.4 Uploads the e-copy of documents to the shared network folder and updates FIS-Document Tracking System (DTS)	None	60 Minutes	Food and Drug Action Center Information Officer I and Information Officer II
	1.5 Receives transmittal slip with pre-assessment result (Accepted/Not Accepted) from CDRR and releases result to the client via email **For Acceptable Result**: informs client of the result of pre-assessment and advises to pay the required fees **For Not Acceptable Result**: informs client o the result of pre-assessment and advises client to resubmit the documents for issuance of a new DTN	None	5 minutes	Food and Drug Action Center Information Officer I and Information Officer II

2. Submits proof of payment	2.1 Receives proof of payment and updates status in the DTS and FDAC Letters Database	Based on AO 50 s. 2001	5 Minutes	Food and Drug Action Center Information Officer I and Information Officer II
	2.2 Prepares transmittal and uploads the softcopies via shared OneDrive	None	25 Minutes	Food and Drug Action Center Information Officer I and Information Officer II
	2.3 Endorses the Transmittal Slip to CDRR		5 Minutes	Food and Drug Action Center Information Officer I and Information Officer II
	TOTAL:	**None**	**2 Hours**	

**Application/request emailed after 5:00pm will be treated as a submission for the next working day.*
**Received applications are transmitted on the next working day.*

7. RECEIVING OF APPLICATION AND OTHER DOCUMENTS BY THE FDAC LETTERS TEAM

This service includes acknowledging email requests, letter notifications and applications, as well as receiving proof of payment where applicable.

Center/Office/Division	:	Food and Drug Action Center (Letters Section)
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B
Who May Avail	:	Stakeholders applying for Import Permit Clearance, Special Permit, Medical Device CPR Renewal and Amendment, CMDL, Donations, HACCP, Sangkap Pinoy Seal, Local GMP, IAC application, and other letter request

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Signed Letter of Intent 2. Other required documents specified in the application guidelines https://www.fda.gov.ph/downloadables/ **CFS MEDICAL DEVICE** https://www.fda.gov.ph/wp-content/uploads/2022/05/Checklist-Requirements-CFS.pdf **CDRRHR CPR VARIATION** https://www.fda.gov.ph/wp-content/uploads/2022/05/Checklist-Requirements-Variation.pdf **CPR RENEWAL FORMS** https://www.fda.gov.ph/wp-content/uploads/2022/05/Application-Form-Renewal-IVD.pdf https://www.fda.gov.ph/wp-content/uploads/2021/05/Administrative-Order-No.-2018-002.pdf **CMDL** https://www.fda.gov.ph/wp-content/uploads/2022/05/LRD-13-Annex-02-Application-FormCMDL.pdf	**FDA Circular No. 2020-026-** Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA) and its related issuances

SPECIAL PERMIT COVID TEST KIT https://www.fda.gov.ph/wp-content/uploads/2021/04/FDA-Advisory-No.2021-0684.pdf https://www.fda.gov.ph/wp-content/uploads/2021/03/FDA-Memorandum-No.-2021-009.pdf **SANGKAP PINOY SEAL** https://www.fda.gov.ph/wp-content/uploads/2021/05/Administrative-Order-No.-2018-002.pdf https://www.fda.gov.ph/wp-content/uploads/2021/05/Administrative-Order-No.-4-A-s.-1995.pdf **Diamond Sangkap Pinoy Form** https://www.fda.gov.ph/wp-content/uploads/2021/03/Application-Form-Diamond-Sangkap-Pinoy-Seal.pdf **Sangkap Pinoy Form** https://www.fda.gov.ph/wp-content/uploads/2021/03/Application-Form-Diamond-Sangkap-Pinoy-Seal.pdf https://www.fda.gov.ph/wp-content/uploads/2021/05/Administrative-Order-No.-4-A-s.-1995.pdf **IAC Application** https://www.fda.gov.ph/fda-advisory-no-2023-1544-schedule-of-receiving-of-inter-agency-committee-on-executive-order-no-51-milk-code-applications/ **Import permit**	

https://www.fda.gov.ph/wp-content/uploads/2021/03/Requirements-for-Release-of-Food-Samples.pdf **Donations** https://www.fda.gov.ph/wp-content/uploads/2021/03/Requirements-for-Release-of-Food-Donations.pdf	

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits application/request through fdac.letters@fda.gov.ph or fdac.letters.cdrr@fda.gov.ph (if document is for the CDRR)	1.1 Checks the application or request as indicated in the body of the email and its attachment. For application/request with complete submission: Receives the application For application/request with incomplete submission: Notifies the client that submission was rejected (state reason of rejection) and advises to submit a new application.	None	10 Minutes	Food and Drug Action Center Information Officer I and Information Officer II
	1.2 Issues Acknowledgement Receipt containing Document Tracking Number (DTN) For letter notification, application and request that do not require payment: issues Document Tracking Number	None	10 minutes	Food and Drug Action Center Information Officer I and Information Officer II

	For application/request that requires payment: issues Document Tracking Number with required application fee and payment instruction			
2. Submits proof of payment	2.1 Receives proof of payment and requirements and updates status in the Document Tracking System (DTS) and FDAC Letters Database	Based on AO 50 s. 2001	10 minutes	Food and Drug Action Center Information Officer I and Information Officer II
	2.2 Prepares summary of documents received and prints Transmittal Slip.		20 minutes	Food and Drug Action Center Information Officer I and Information Officer II
	2.3 Uploads the e-copy of documents to the shared network folder and updates FIS DTS		60 minutes	Food and Drug Action Center Information Officer I and Information Officer II
	2.4 Endorses the Transmittal Slip o concerned Center/Offices		10 minutes	Food and Drug Action Center Information Officer I and Information Officer II
	TOTAL:	**None**	**2 Hours**	

**Application/request emailed after 5:00pm will be treated as a submission for the next working day.*

8. RECEIVING OF PRE-ASSESSED APPLICATIONS BY PACD TEAM

8.1 RECEIVING OF APPLICATIONS FOR CERTIFICATE OF PRODUCT REGISTRATION AND OTHER AUTHORIZATIONS FOR CENTER FOR DRUG REGULATION AND RESEARCH (CDRR)

This service covers the acknowledgement of application, issuance of pre-assessment result, and endorsement to the Center for Drug Regulation and Research for further processing.

Center/Office/Division	**:**	FDAC/Public Assistance and Complaints' Desk (PACD)
Classification	**:**	Simple
Type of Transaction	**:**	Government to Business - G2B
Who May Avail	**:**	Marketing Authorization Holders (MAH) of pharmaceutical products and company applicants of Sales and Promo Permits for Pharmaceutical Products.

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Integrated Application Form (IAF)	FDA Website FDA Circular No. 2020-026- Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA) and its related issuances
2. Other required documents specified in the application guidelines https://www.fda.gov.ph/downloadables/	

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an email to fdac.pacd.cdrr@fda.gov.ph on the assigned date with all the necessary requirements	1.1 Checks the received email. ompliant, receives application pre- assessment. on-compliant, sends an email to client advising them to request another schedule of submission.	None	20 minutes	Food and Drug Action Center Information Officer II

	1.2 Forwards the application via email to the Center Pre-Assessment Unit and updates the status on FIS/Document Tracking System and FDAC PACD Database.	None	5 minutes	Food and Drug Action Center Information Officer II
	1.3 Prepares transmittal for the acknowledged applications for pre-assessment and updates the status on FIS/Document Tracking System.	None	20 minutes	Food and Drug Action Center Information Officer II
	1.4 Endorses the Transmittal Slip to Center Pre-assessment Unit.	None	5 minutes	Food and Drug Action Center Information Officer II
	1.5 Issues pre-assessment result to client **If acceptable**, notifies the client via email to proceed with payment and updates the status on FIS-Document Tracking System and FDAC-PACD Database **If not acceptable**, notifies the client via email with advice to request for new DTN and updates the status on FIS-Document Tracking System and FDAC PACD Database	None	20 minutes	Food and Drug Action Center Information Officer II

2. Submits the proof of payment to FDAC in the same email thread	Upon receiving proof of payment, downloads the pre-assessed documents along with a copy of the pre-assessment result, and updates the status on FIS-Document Tracking System and FDAC PACD Database.	Based on AO 50 s. 2001	60 minutes	Food and Drug Action Center Information Officer II
	Prepares transmittal and uploads the electronically received documents to the FDAC OneDrive link shared with the Center Receiving–Releasing Personnel.		60 minutes	Food and Drug Action Center Information Officer II
	2.3 Endorses the Transmittal Slip to Center Receiving–Releasing Personnel.		5 minutes	Food and Drug Action Center Information Officer II
	TOTAL:	**None**	**3 hours and 15 minutes**	

**Application emailed after 5:00pm will be treated as a submission for the next working day.*

8.2 RECEIVING OF CERTIFICATE OF PRODUCT REGISTRATION (CPR) APPLICATIONS FOR HOUSEHOLD URBAN PESTICIDE

This service covers the acknowledgement of application, issuance of result, and endorsement to the Center for Cosmetics and Household Urban Hazardous Substances Regulation and Research for further processing.

Center/Office/Division	**:**	FDAC - Public Assistance and Complaints' Desk (PACD)
Classification	**:**	Simple
Type of Transaction	**:**	Government to Business - G2B
Who May Avail	**:**	Marketing Authorization Holders (MAH) of Household Urban Pesticide

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Integrated Application Form	FDA Website FDA Circular No. 2020-026- Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA) and its related issuances
2. Other required documents specified in the application guidelines https://www.fda.gov.ph/wp-content/uploads/2021/05/Administrative-Order-No.-2019-0008.pdf	

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an email to fdac.pacd@fda.gov.ph on the assigned date from 8:00AM to 12:00NN with all the necessary requirements	1.1 Checks the received email submission. If compliant, receipt of the application shall be acknowledged and notifies the client via email. If not compliant, sends email to the client w advice to request another schedule.	None	5 minutes	Food and Drug Action Center Information Officer II

	1.2 Forwards the application to the center pre-assessment unit from 1:00PM to 2:00PM and updates the status on FIS/Document Tracking System and FDAC PACD Database.	None	5 minutes	Food and Drug Action Center Information Officer II
	1.3 Issues pre-assessment result to client. **If acceptable**, notifies the client via email to proceed with payment and updates the status on FIS/Document Tracking System and FDAC-PACD Database **If not acceptable**, notifies the client via email with advice to request for rescheduling and updates the status on FIS/Document Tracking System and FDAC PACD Database	None	5 minutes	Food and Drug Action Center Information Officer II
2. Submits the proof of payment to FDAC in the same email thread.	2.1 Upon receiving proof of payment, downloads the pre-assessed documents along with a copy of the pre-assessment result, and updates the status on FIS/Document Tracking System and FDAC PACD Database.	AO 50 s. 2001	10 minutes	Food and Drug Action Center Information Officer II

	2.3 Prepares transmittal and uploads the electronically received documents to the FDAC OneDrive link shared with the Center Receiving–Releasing Personnel.	None	45 minutes	Food and Drug Action Center Information Officer II
	2.4 Endorses the Transmittal Slip to Center Receiving–Releasing Personnel.		5 minutes	Food and Drug Action Center Information Officer II
	TOTAL:	**None**	**1 hour and 10 minutes**	

**Application emailed after 12:00pm will be acknowledged and will be endorsed on the next HUP day.*

8.3 RECEIVING OF CFRR PRE-ASSESSED PROMO APPLICATIONS VIA EMAIL BY THE FDAC - PUBLIC ASSISTANCE AND COMPLAINTS' DESK (PACD)

This service covers the receiving of acceptable promo applications pre-assessed by the Center for Food Regulation and Research submitted to Food and Drug Action Center via email.

Center/Office/Division	**:**	FDAC - Public Assistance and Complaints' Desk (PACD)
Classification	**:**	Simple
Type of Transaction	**:**	Government to Business - G2B
Who May Avail	**:**	Food Manufacturers, Importers, Exporters, Wholesalers/Distributors and Third-Party Marketing Agencies

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Proof of Payment	FDA Website FDA Circular No.2021-013 || Interim Guidelines of the Center for Food Regulation and Research (CFRR) for the Application and Receiving of Sales Promo Permit Applications in Compliance to the Republic Act No. 11032 otherwise known as The Ease of Doing Business and Efficient Government Service Delivery Act Of 2018
2. Pre-assessment Result Form	

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an email to fdac.pacd@fda.gov.ph with proof of payment and copy of pre-assessment result.	1.1 Checks status of application. If payment is already posted, receipt of the application shall be acknowledged and notifies the client via email. If payment is not posted yet, notifies the client that submission is pending for posting of payment and updates FIS/Document Tracking System	AO 50 s. 2001	5 minutes	Food and Drug Action Center Information Officer II

	1.2 Downloads proof of payment along with a copy of the pre-assessment result, and updates the status on FIS/Document Tracking System and FDAC PACD Database.	none	5 minutes	Food and Drug Action Center Information Officer II
	1.3 Prepares transmittal and uploads the electronically received documents to the FDAC OneDrive link shared with the Center Receiving–Releasing Personnel.		45 minutes	Food and Drug Action Center Information Officer II
	1.4 Endorses the Transmittal Slip to Center Receiving–Releasing Personnel.		5 minutes	Food and Drug Action Center Information Officer II
	TOTAL:	**None**	**60 minutes**	

9. RECEIVING OF PAID APPLICATIONS FOR OTHER AUTHORIZATIONS (CERTIFICATE OF FREE SALE, SALES PROMO PERMIT, LICENSE TO OPERATE – ONE STOP SHOP) AND REAPPLICATION FOR MEDICAL DEVICES AND PHARMACEUTICAL PRODUCTS

This service covers the submission of applications with proof of payment for reapplication and other authorizations submitted to FDAC via email and endorsement of the complete documents to the concerned Center for further processing.

Center/Office/Division	:	FDAC/Public Assistance and Complaints' Desk (PACD)
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B
Who May Avail	:	Marketing Authorization Holders (MAH) of pharmaceutical products, cosmetics and medical devices

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Integrated Application Form	FDA Website FDA Circular No. 2020-026- Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA) and its related issuances
2. Other required documents specified in the application guidelines https://www.fda.gov.ph/downloadables/	

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an email to fdac.pacd@fda.gov.ph or fdac.pacd.cdrr@fda.gov.ph on the assigned date with all the necessary requirements	1.1 Checks the received email If compliant, receipt of the application shall be acknowledged and notifies the client via email. If non-compliant, sends an email to the client with advice to provide the lacking documents within the given timeframe.	Based on AO 50 s.2001	5 minutes	Food and Drug Action Center Information Officer II

	1.2 Downloads the documents and updates the status on FIS-Document Tracking System and FDAC PACD Database	None	5 minutes	Food and Drug Action Center Information Officer II
	1.3 Prepares transmittal and uploads the electronically received documents to the FDAC OneDrive link shared with the Center Receiving–Releasing Personnel.	None	20 minutes	Food and Drug Action Center Information Officer II
	1.4 Endorses applications to the concerned Center for evaluation.	None	5 minutes	Food and Drug Action Center Information Officer II
	TOTAL:	**None**	**35 minutes**	

10. RECEIVING OF COMPLIANCES FOR REGIONAL FIELD OFFICES AND CENTER FOR DEVICE, RADIATION REGULATION AND HEALTH RESEARCH AND ADDITIONAL DOCUMENTS FOR CENTER FOR DRUGS REGULATION RESEARCH

This service covers the submission of compliances and additonal documents submitted to FDAC via email and endorsement to the concerned Center for further processing.

Center/Office/Division	:	FDAC/Public Assistance and Complaints' Desk (PACD)
Classification	:	Simple
Type of Transaction	:	Government to Business - G2B
Who May Avail	:	Marketing Authorization Holders (MAH) of pharmaceutical products, cosmetics, processed and prepacked food and medical devices

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of Intent	FDA Website FDA Circular No. 2020-026- Food and Drug Action Center (FDAC) New Normal Operational Guidelines of the Food and Drug Administration (FDA) and its related issuances
2. Other required documents specified in the application guidelines https://www.fda.gov.ph/downloadables/	

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends an email to fdac.pacd@fda.gov.ph or fdac.pacd.cdrr@fda.gov.ph on the assigned date with all the necessary requirements	1.1 Checks the received email If compliant, receipt of the application shall be acknowledged and notifies the client via email. If non-compliant, sends an email to the client with advice to provide the lacking documents within the given timeframe.	None	5 minutes	Food and Drug Action Center Information Officer II

	1.2 Downloads the documents and updates the status on FIS-Document Tracking System and FDAC PACD Database	None	10 minutes	Food and Drug Action Center Information Officer II
	1.3 Prepares transmittal and uploads the electronically received documents to the FDAC OneDrive link shared with the Center Receiving–Releasing Personnel.	None	20 minutes	Food and Drug Action Center Information Officer II
	1.4 Endorses applications to the concerned Center for evaluation.	None	5 minutes	Food and Drug Action Center Information Officer II
	TOTAL:	**None**	**40 minutes**	

11. RECEIVING AND PROCESSING OF REQUEST FOR PERMIT TO MAIL/HAND CARRY HEALTH PRODUCTS FOR NON-COMMERCIAL USE

This service covers the receipt and processing of request for Permit to Mail/Hand Carry Health Products for Non-Commercial Use/Personal Use.

Center/Office/Division	**:**	FDAC/Public Assistance and Complaints' Desk (PACD)
Classification	**:**	Simple
Type of Transaction	**:**	Government to Citizen G2C
Who May Avail	**:**	All Stakeholders (Internal and External)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Email request	Food and Drug Action Center
2. Duly accomplished online application form	

CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Sends email request to fdac.permittomail@fda.gov.ph	1. Checks the nature of request. If health products subject of the request for Permit to Mail/Hand Carry is for non-commercial use (for personal consumption), sends online application form to the client. If not, notifies the client that request shall not be granted.	None	5 minutes	Food and Drug Action Center Information Officer II

2. Fills-out the online application form	2.1 Checks the sender's address. If from NCR, conducts verification of valid product registration in coordination with concerned FDA Center. If outside the NCR, endorses application via email to the respective FDA Regional Field Offices for further processing and notifies the client.	None	30 minutes	Information Officer II
	2.2 Encodes the details of request in the FIS-Document Tracking System and generates Document Tracking Number	None	5 minutes	Information Officer II
	2.3 Issues Order of Payment to the client via email with advice to proceed with payment	None	3 minutes	Information Officer II
3. Submits proof of payment to fdac.permittomail@fda.gov.ph .	3.1 Receives proof of payment and prepares the draft for FDAC OIC's final approval and signature	Php 50 + LRF (AO 50s 2001)	15 minutes	Information Officer II
	3.2 Sends soft copy of the electronically signed permit to the client.	None	2 minutes	Information Officer II
	TOTAL:	**None**	**60 minutes**	

INFORMATION AND COMMUNICATION TECHNOLOGY DIVISION
RECORDS SECTION

1.REISSUANCE OF MANUAL FDA AUTHORIZATIONS

Covers all FDA Authorizations from different Centers / Offices that requires reissuance.

Center/Office/Division	**:**	ODG -Information and Communication Technology Management Division (ICTMD) – Records Section
Classification	**:**	*Simple*
Type of Transaction	**:**	*G2B, G2G*
Who May Avail	**:**	FDA Stakeholders
Fees to be Paid	**:**	₱ 510.00 / document

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Tracking log	FDAC
Proof of payment	
Filled out Integrated applications form	Downloadable at FDA website
Scanned copy of applications to be re-issued	FDA

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1. Submit the complete requirements through email at releasing.schedule@fda.gov.ph	1. Receives the Request thru email re: re-issuance of manual FDA authorizations	5 minutes per email	Records Section Information Officer I
	1.2. Encodes to the database of the received request for re-issuance	5 minutes per document	Records Section Information Officer II
	1.3. Checks and verifies the request for re-issuance	5 minutes per document	Records Section Information Officer II
	1.4. Retrieves the scanned copy of FDA manual Authorizations	5 minutes per document	Records Section Information Officer II
	1.5. Approves and prints of the Re-issuance	5 minutes per document	Records Section Officer-`in-Charge
	1.6. Sends an email schedule of pick - up	5 minutes per document	Records Section Information Officer II

2. Pick up the requested re-issuance with required proper identification and documents	2.Releases of FDA Authorization requested for reissuance	5 minutes per document	Records -Releasing unit
	TOTAL:	**35 minutes**	

2.RELEASING OF ALL FDA AUTHORIZATIONS

Covers all FDA Authorizations from different Centers / Offices

Center/Office/Division	**:**	Information and Communication Technology Management Division (ICTMD) – Records Section
Classification	**:**	*Simple*
Type of Transaction	**:**	*G2B, G2G*
Who May Avail	**:**	FDA Stakeholders
Fees to be Paid	**:**	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
An electronic copy of the confirmation email, sent from our records section- releasing unit to the Registered Owner/Authorized Company Representative electronically (either print-out or soft copy)	The Records Section-Releasing Unit will promptly send the client an email schedule of pick-up
If the Claimant is not the company Owner, they must furnish an authorization letter from the actual owner for verification purposes.	
Photocopy of the Owner's valid identification with Signature, preferably the company-issued identification card	
Photocopy of the company ID of the Authorized Personnel with Signature (Original ID must be presented for validation)	

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
	1.1 Receiving of FDA Authorizations (LTO, CPR & other Authorizations)	5 minutes per document	ICTMD Receiving – Admin Assistant II
	1.2 Comprehensive encoding and updating of all received FDA authorizations into the database and the FDA Inventory System (FIS).	5 minutes per document	Records Personnel Admin Assistant I

	1.3 Efficiently scan and transmit scanned copies to the client's official email, with the exception of the following: •CDRRHR application •CSL applications, such as Test Report, Export/Commodity Clearance, and Evaluation.	5 minutes per document	Records Personnel Admin Assistant III
	1.4 Barcoding and uploading of manual authorizations to FIS such as: CFRR-LTO, GMP CCRR-LTO, CPR & GMP CDRRHR-LTO X-RAY, Medical Devices CPR & Health related Certificates	5 minutes per document	Records Personnel Admin Assistant I
	1.5 Emailing Client's Official Schedule for Pickup	5 minutes per document	Records Personnel Admin Assistant I
2. Pick up the requested re-issuance with required proper identification and documents	2.1 Releasing of FDA Authorizations to the client	5 minutes per document	Records Personnel Admin Assistant I
	TOTAL:	**30 minutes**	

FIELD REGULATORY OPERATIONS OFFICE (FROO)
REGIONAL FIELD OFFICE (RFO)
EXTERNAL SERVICE

1.ISSUANCE OF CERTIFICATE OF COMPLIANCE (COC), RECOMMENDATION FOR DISAPPROVAL (RFD) AND RECOMMENDATION LETTER (RL)

The Certificate of Compliance (COC), Recommendation for Disapproval (RFD), and Recommendation Letter (RL) is the output on the evaluation of documents and/or inspection stating the recommendation of the Regional Field Offices. These will be forwarded to FDA Centers/Offices for processing of the application.

Center/Office/Division	:	Field Regulatory Operations Office (FROO)
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	Manufacturers, Traders, Distributors (Importers, Exporters, Wholesalers) of health products, drug outlets or retailers and retail outlet for non-prescription drugs, as determined by the FDA
Fees to be paid	:	AO No. 50, s. 2001* + 1% Legal Research Fee (LRF), AO No.18-A, s. 1993 and Republic Act 8172

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
The following requirements shall be presented to the FDA Inspector for examination and review, when required, based on Administrative Order No. 2020-0017:	
Risk Management Plan (RMP) Required for medium and large food manufacturers, and all drug, cosmetics, household urban hazardous substances (HUHS), including household/urban pesticides (HUP) and toys and childcare articles (TCCA), medical device manufacturers, traders and distributors (importer, exporter and/or wholesaler), among others.	Applicant Establishment/ Qualified Person
Site Master File (SMF) Required for drug, cosmetic, HUHS, including HUP and TCCA, medical device and large and medium food manufacturers, among others	Applicant Establishment/ Qualified Person
Refer to the FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection.	Applicant Establishment/ Qualified Person

1.1.THROUGH EPORTAL:

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Receives electronic application via FDA e-Portal System or Manual application through FDA-Document Tracking System (FIS-DTS)	None	1 working day	Data Controller/ Assigned Personnel Regional Field Office
	Generates Document Tracking Number (DTN) thru DTS and Encodes in the Internal Database (IDB)	None		Data Controller/ Assigned Personnel Regional Field Office
	Decks and forwards application to Licensing Officer/ Designated Officer	None		Licensing Team Leader Regional Field Office
	Receives application via FDA e-Portal System or thru FIS-DTS	None	2 working days	Licensing Officer/ Assigned Personnel Regional Field Office
If with minor deficiencies,	Evaluates application: If compliant and inspection is not needed, proceed to Step 12 (for RL) If with major deficiencies, proceed to Step 12 (for RFD) If with minor deficiencies, notify applicant thru e-mail/ declared contact no. to comply within 5 working days ***STOP CLOCK***	None		Licensing Officer/ Assigned Personnel Regional Field Office

the applicant needs to submit documents, or records to comply with the deficiencies.	Receives and evaluates compliance: (Follow step 5.1, 5.2 or 5. 4) Note: Non-compliance within the 5 working days grace period shall be treated as major deficiency and shall be a ground for disapproval of application. 5.4 If compliant and inspection is needed, forwards application to Inspection Section			
	Receives Electronic and Manual application thru FIS-DTS and decks to Inspectors	None	2 working days	Inspection Section Team Leader Regional Field Office
	Pre -inspection activities: 7.1 Receives application thru FIS-DTS 7.2 Schedules Inspection 7.3 Reviews Company File 7.4 Prepares Itinerary of Inspection, Attendance Sheet, Inspection Agenda, Inspection Plan 7.5 Forwards prepared documents to the Team Leader (TL)/Supervisor for approval 7.6 Prepare Notice of Inspection (when necessary)	None		FDA Inspectors Regional Field Office

9. If the establishment is non-compliant, the applicant needs to submit documents, or records to comply with the deficiencies.	Conducts inspection as per approved itinerary: If non-compliant, the establishment is given maximum of 15 working days to submit Corrective Action and Preventive Action Plan (CAPA Plan) *****STOP CLOCK***.** The applicant is required to comply with all the deficiencies in 6 months and can be allowed for an extension of 3 months subject for approval.	None	5 working days	FDA Inspectors Regional Field Office
	Post -inspection activities: 9.1 Classifies Deficiencies 9.2 Prepares Risk Assessment 9.3 Submits Inspection Report 9.4 Updates FIS-DTS 9.5 Conducts deliberation for Panel Approval (when applicable) 9.6 Submits to Team Leader 9.7 Evaluates CAPA and/or objective evidence (when applicable) 9.7.1 Submits inspection report with recommendation to TL *Note: If the establishment has not performed any corrective measures within the specified grace period or if the corrective measures made are not acceptable, the inspector recommends disapproval of the application*	None	5 working days	FDA Inspectors Regional Field Office
	Reviews Inspection Report	None	2 working days	Inspection Section Team Leader

	10.1 Updates FIS-DTS and Inspection Database			Regional Field Office
	Forwards Inspection Report to Licensing Section	None		
	Prepares Certificate of Compliance (COC) / Recommendation for Disapproval (RFD) / Recommendation Letter (RL) whichever is applicable 12.1 Updates FIS-DTS 12.2 Forwards to Licensing TL/Supervisor	None	2 working days	Licensing Officer/Assigned Personnel Regional Field Office
	Checks and affixes initials to COC / RFD / RL	None		Licensing Team Leader/ Supervisor Regional Field Office
	Approves/signs COC/RL/ RFD	None		Director/Supervisor Regional Field Office
	Updates Database	None		Data Controller/Assigned Personnel Regional Field Office
	Releases COC/ RFD/RL 16.1 Updates FIS-DTS 16.2 Forwards COC / RFD / RL to Centers	None	1 working day	Data Controller/ Assigned Personnel Regional Field Office
TOTAL:		**None**	**20 working days**	

1.2.THROUGH ESERVICES:

CLIENT STEPS	AGENCY ACTION	Fees to be Paid	PROCESSING TIME	PERSON RESPONSIBLE
	Receives electronic LTO application via FDA e-Services Portal and Generates Document Tracking Number (DTN) thru Document Tracking System (FIS-DTS)	None	1 working day	Data Controller/ Assigned Personnel Regional Field Office
	Encodes received application in the Internal Database (IDB)	None		Data Controller/ Assigned personnel Regional Field Office
	Decks and forwards application to Licensing Section (for application not requiring inspection) or to the Inspection and Compliance Section (for application requiring inspection	None		Licensing Team Leader or assigned personnel Regional Field Office
	Licensing Section: Receives application via FDA e-Services System	None	2 working days	Licensing Officer or assigned personnel Regional Field Office

If with minor deficiencies, the applicant needs to submit documents, or records to comply with the deficiencies.	Evaluates application: If compliant and inspection is not needed, proceed to Step 12 (for issuance of Recommendation Letter) If with major deficiencies, proceed to Step 12 (for issuance of Recommendation for Disapproval) If with minor deficiencies, notify applicant thru e-mail/ declared contact no. to comply within 5 working days ***__STOP CLOCK__*** Receives and evaluates compliance: (Follow step 5.1, 5.2 or 5.4) Note: Non -compliance within the 5 working days grace period shall be treated as major deficiency and shall be a ground for disapproval of application 5.4 If compliant and inspection is needed, forwards application to Inspection and Compliance Section	None		Licensing Officer or assigned personnel Regional Field Office
	Inspection and Compliance Section: Receives electronic application thru FIS-DTS and decks to Inspectors	None	2 working days	Inspection Section Team Leader/Supervisor Regional Field Office
	Pre -inspection activities: 7.1 Receives application thru FIS-DTS and claims application through FDA e-Services Portal 7.2 Schedules Inspection 7.3 Reviews Company File 7.4 Prepares Itinerary of Inspection, Attendance Sheet, Inspection Plan and Inspection Agenda	None		FDA Inspectors Regional Field Office

If the establishment is non-compliant, the applicant needs to submit documents, or records to comply with the deficiencies.	Conducts inspection as per approved itinerary: If non -compliant, the establishment is given maximum of 15 working days to submit Corrective Action and Preventive Action (CAPA) Plan *****STOP CLOCK***** The applicant is required to comply with all the deficiencies in 6 months and can be allowed for an extension of 3 months subject for approval.	None	5 working days	FDA Inspectors Regional Field Office
	Post -inspection activities: 9.1 Classifies Deficiencies 9.2 Prepares Risk Assessment 9.3 Submits Inspection Report 9.4 Updates FIS-DTS 9.5 Conducts deliberation for Panel Approval (when applicable) 9.6 Submits to Team Leader 9.7 Evaluates CAPA and/or objective evidence (when applicable) 9.7.1 Submits inspection report with recommendation to TL *Note: If the establishment has not performed any corrective measures within the specified grace period or if the corrective measures made are not acceptable, the inspector recommends disapproval of the application*	None	5 working days	FDA Inspectors Regional Field Office
	Reviews Inspection Report 10.1 Reviews and updates FIS-DTS and Inspection Database	None	2 working days	Inspection Team Leader/Supervisor

	Forwards Inspection Report to Licensing Section	None		Regional Field Office
	Prepares Certificate of Compliance (COC) / Recommendation for Disapproval (RFD) / Recommendation Letter (RL) whichever is applicable 12.1 Updates FIS-DTS 12.2 Forwards to Supervisor	None	1 working day	Licensing Officer or assigned personnel Regional Field Office
	For COC / RL: Approves/signs COC/RL for routing to centers For RFD: Reviews and recommend final decision for routing to Director	None		Supervisor Regional Field Office
	Vets RFD for routing to centers	None	2 working days	Director Regional Field Office
TOTAL:		**None**	**20 working days**	

References:

AO. No. 2014-0029- *Rules and Regulation on the Licensing of Food Establishments and Registration of Processed Foods, and Other Food Products, and for Other Purposes.*

AO No. 2014-0034- *Rules and Regulations on the Licensing of Establishments Engaged in the Manufacture, Conduct of Clinical Trial, Distribution, Importation, Exportation, and Retailing of Drug Products, and Issuance of Other Related Authorization*

AO No. 2014-0038- *Rules and Regulation Governing Household / Urban Pesticides Licensing of Establishment and Operators, Registration of Their Products and for Other Purpose***.**

FDA Circular 2014-025- *Guidelines on Implementation of New Rules and Regulation on Licensing of Drugstore / Pharmacy / Botica and Similar Outlets following Administrative Order No. 2014-0034, dated 13 October 2014*

FDA Circular 2014-026- *Guidelines on the Implementation of New Rules and Regulations on the Licensing of Drug Distributors following Administrative Order No. 2014-0034, dated 13 October 2014*

FDA Circular 2014 -027 *Guidelines on the Implementation of New Rules and Regulations on the Licensing of Drug Manufacturer following Administrative Order No. 2014-0034, dated 13 October 2014*

FDA Circular2014 -028 *Guidelines on the Implementation of New rules and regulation I the licensing of Retail outlet for Non-Prescription Drugs (RONPDs) following Administrative Order No. 2014-0034, dated 13 October 2014*

Amendment to FDA Circular No. 2013-002 *Revised Guidelines in Licensing of Cosmetic Establishments*

Amendment to FDA Circular No. 2013-009 *Revised Guidelines in Licensing of Household Hazardous Substances (HHS) Establishments*

FDA Memorandum Circular No. 2020-001 Interim *Guidelines for the Issuance of Provisional License to Operate (LTO) and Certificate of Product Notification (CPN) for Manufacturers of Rubbing Alcohol Products Under the Center for Cosmetics Regulation and Research*

FDA Circular No. 2020-025 *Implementing Guidelines for Administrative Order No. 2019-0019, "Reinstatement of Requirements of Licensing as Importers, Exporters, Manufacturers, Toll Manufacturers, Wholesalers, Distributors, Retailers, or Re-Packers of Those Engaged in Certain Household/Urban Hazardous Substances, and from the Requirement of Prior Registration and/or Notification of Said Products"*

FDA Advisory No. 2020-1599 Implementation *of FDA Circular No. 2020-0025, entitled "Implementing Guidelines for Administrative Order No. 2019-0019, "Reinstatement of Requirements of Licensing as Importers, Exporters, Manufacturers, Toll Manufacturers, Wholesalers, Distributors, Retailers, or Re-Packers of Those Engaged in Certain Household/Urban Hazardous Substances, and from the Requirement of Prior Registration and/or Notification of Said Products"*

FDA Advisory No. 2020-2035 *"Update on the Implementation of FDA Circular No. 2020-0025, entitled "Implementing Guidelines for Administrative Order No. 2019-0019, "Reinstatement of Requirements of Licensing as Importers, Exporters, Manufacturers, Toll Manufacturers, Wholesalers, Distributors, Retailers, or Re-Packers of Those Engaged in Certain Household/Urban Hazardous Substances, and from the Requirement of Prior Registration and/or Notification of Said Products"*

Administrative Order No. 2019-0019 *"Reinstatement of Requirements of Licensing as Importers, Exporters, Manufacturers, Toll Manufacturers, Wholesalers, Distributors, Retailers or Re-Packers of Those Engaged in Certain Household/Urban Hazardous Substances, and from the Requirements of Prior Registration and/or Notification of Said Products"*

FDA Circular 2017-003 "Strict Implementation of the Mandatory Requirement to Secure a License to Operate (LTO), Certificate of Product Registration (CPR) or Any Authorization from FDA Prior to Engaging in the Manufacture, Importation, Exportation, Sale, Offering for Sale, Distribution, Transfer, Promotion, Advertisement and/or Sponsorship of Medical Devices

FIELD REGULATORY OPERATIONS OFFICE INSPECTION AGENDA

Bureau of Customs – For Donation

Certification	Classification[1]	Type of Transaction[2]	Processing Time[3]	List of Requirements
Inspection Report with recommendation for release (Upon validation/inspection of the products)	Simple	Government-to-Business (G2B)	3 days upon receipt of request for inspection from the consignee	FDA Clearance issued by Centers

Legend:
[1] Classify if Simple, Complex, or Highly Technical Transaction
[2] Classify if Government-to- Citizens (G2C), Government-to-Business (G2B), and Government-to-Government (G2G)
[3] Based on Current Citizen's Charter Timeline

Bureau of Customs – For Personal Use

Certification	Classification[1]	Type of Transaction[2]	Processing Time[3]	List of Requirements
E-mail Reply (citing Joint Circular No.1)	Simple	Government-to-Business (G2B)	1 day upon receipt of request from the consignee	E-mail Request request (payment, specific information/ complete details needed, photo of product)

Legend:
[1] Classify if Simple, Complex, or Highly Technical Transaction
[2] Classify if Government-to- Citizens (G2C), Government-to-Business (G2B), and Government-to-Government (G2G)

[3] Based on Current Citizen's Charter Timeline

INSPECTION AGENDA FOR HEALTH PRODUCTS HELD AT THE BUREAU OF CUSTOMS/CONSIGNEE'S WAREHOUSE FOR VERIFICATION AND FINAL DISPOSITION

Inspection Activity
Inspection [SITE/LOCATION OF CARGO /SHIPMENT] **Opening Meeting** [BOC Examiner and Consignee/ Consignee's authorized representative] **Actual inspection of the cargo/shipment** 3.1 temperature storage condition 3.2 physical examination of the products [appearance and label] Verification/ validation of the following Documentary Requirements as applicable and necessary vs. actual cargo/shipment **For donations** 4.1 Affidavit/Deed of Undertaking 4.2 *Airway Bill/ Bill of Lading 4.3 *Packing List 4.4 *Proforma Invoice / Commercial Invoice 4.5 *Certificate of Free Sale (CFS) or its equivalent 4.6 Deed of Acceptance 4.7 Deed of Donation **For public auction / products with safety issues /alert** Valid FDA License to Operate [LTO]

Valid Certificate of Product Registration [CPR)]

*applicable documents mentioned above
Certificate of Analysis and other pertinent documents [as applicable and necessary]

Collection of product samples [as applicable and necessary]
Report Writing (Observation and findings/recommendation/directives)
Exit Meeting (discussion observation and findings/recommendation/directives)

INSPECTION AGENDA – FOOD DISTRIBUTOR

Inspection Activity
Opening Meeting
Document Review
-Verification of submitted licensing documentary requirements
2.1 Organization, Management & Personnel
Organizational Chart /Job Description/ Duties and responsibilities
Training Plan/ Records/ Competency evaluation
2.2 QMS & Documentation
Authorization (LTO & CPR)
Risk Management Plan (RMP)
Standard Operating Procedures

Records (Importation/Distribution/Deliveries, complain, recall)

2.3 Contract activities
Quality Agreement with suppliers/sources
GMP Certificate/Free Sale /Phytosanitary Certificate and other equivalent documents
Franchise agreement (if applicable)

III. Walk-through Inspection

3.1 Warehouse facilities (Dry & Cold)
Premises (Sanitation: Sanitation Program/Pest Control /housekeeping/ventilation/Lighting etc.)
Storage fixtures (pallets, steel racks/cabinet)
Storage equipment (Temperature monitors)
Storage area/segregated areas for recalled/damaged/expired/returned products
Storage condition (Stock Rotation and arrangement)
Records (temperature and RH, calibration, Stock Reconciliation/ Inventory, Dispatch)

3.2

Pro

ducts (physical examination / Collection of samples)

3.3

Tra

nsport & Dispatch of products
Vehicle Maintenance, Personnel, Compliance to Storage Requirements

IV. Report Writing (Consolidation of findings)

Exit Meeting (Discussion of findings**)**

INSPECTION AGENDA – FOOD TRADER

Inspection Activity
OPENING MEETING (including Presentation of Inspection Agenda) **DOCUMENTATION REVIEW** License to Operate (if applicable) DTI Certificate / SEC Registration with Articles of Incorporation / Cert. Of Cooperative Development Authority (if Cooperative) Mayor's Business Permit / Brgy. Clearance (if the business name and/or address is different from the registered name and/or address in the DTI / SEC) Notarized Proof of Occupancy / Lease Contract / Transfer Certificate of Title (Office/Warehouse/Stock Room) List of Products and copy of valid Certificate of Product Registration (for LTO renewal/PLI) List of Suppliers / Sources (foreign/local) Franchise agreement (if applicable) Suppliers Documents For Local Supplier Copy of valid LTO of Toll Manufacturer / Repacker Notarized Toll Packing / Food Manufacturing / Repacking Agreement (including warehousing & logistics services) For Importer of Raw Material for own use: Foreign Agency Agreement (Distributorship Agreement / Proforma Invoice / Commercial Invoice / Certificate/Letter of Appointment; Status of Manufacturer (GMP Certificate / Certificate of Free Sale / HACCP Certificate / Phytosanitary Certificate – issued and attested by Health Regulatory Authority / Recognized Association (duly authenticated by the Philippine Consulate from the country of origin)

Distribution Records/Sales Invoice Standard Operating Procedures for: Handling Product Recall, Complaints and Returns Pest Control including Service Records / Contract Stock Management Control Dispatching & Transporting of Products Cleaning & Sanitation Equipment Maintenance including Calibration Records of Temperature Devices (if applicable) Duties and Responsibilities / Trainings of the warehouse personnel Other pertinent documents **Walk Through Inspection** (Office/Warehouse/Stock Room) **REPORT WRITING** **EXIT MEETING**
GDP FOOD INSPECTION AGENDA

Inspection Activity
Ocular Inspection [declared office address] **Premise** [accessibility, suitability, display of FDA License to Operate (LTO)] **Opening Meeting** [Introduction/ Stating Purpose of Inspection/, Presentation of Inspection Agenda, Accomplishment of Attendance Sheet] **Document Review** **Note:** presentation/provision of the following documents will depend or based on the findings noted during inspection [as applicable and necessary] **GENERAL DOCUMENTS**

Proof of payment for renewal and variation/amendment of LTO and CPR in case of change of location/activity/supplier/manufacturer /formulation/label etc.
Organizational Chart
Credentials of the Qualified Person/Compliance Safety Officer
Job Description [JD] / Duties and responsibilities, Training Plan/Training Records/Competency Profile of the Key Personnel involved in the operation
Valid Proof of Business Name Registration / Business Permit
Valid Proof of Occupancy [Office and Warehouse Facility]
Affidavit of Undertaking with the corresponding list of clients [name and complete address of client/s if no warehouse facility is declared
Valid Certificate of Product Registration
Product List indicating the product name, supplier/ manufacturer, registration number and validity, status of registration for new products (initial), renewal, and or amendment
Copy of FDA approved product label; Letter of exhaustion for old labels used
Distribution Records [Proforma/Commercial Invoice/Bill of Lading/ Airway Bill/ Packing List/ Sales Invoice/Delivery Receipt]
Standard Operating Procedures [product recall, complaint, return /damaged/ expired products, disposal/ destruction, compliance to Good Storage and Distribution Practices (GDSP): Sanitation Program, Pest Control Program, Stock Management Control, Dispatch and Transport] etc.]

SPECIFIC DOCUMENTS

For Distributor-Importer

Proforma Invoice /Valid Foreign Agency Agreement/ Appointment/Distributorship Agreement/ Letter of Appointment
Compliance to CGMP [GMP Certificate or its equivalent]
Appropriate Test Result or Certificate of Analysis routinely conducted in country of origin or source that would indicate or show safety of the product

For Distributor-Exporter

Valid notarized Distributorship Agreement or Letter of Appointment between FDA-licensed manufacturer and exporter
Valid CPR

For Distributor -Wholesaler
Valid notarized Distributorship Agreement or Letter of Appointment between the
applicant and FDA-licensed source

For product under Food Fortification and Asin Law
Notarized Affidavit of Undertaking for salt used as industrial
LTO and MOA with the manufacturer for salt and staple food - intended for iodization/re-iodization and fortification/re-fortification
Certificate of Analysis for Vitamin A and /or Iron, Iodine

Ocular inspection of warehouse/s depot [Dry and Cold storage facility/ies following compliance to Good Storage and Distribution Practices (GDSP) within the area of jurisdiction:

Premises [suitability, access/security, sanitation, ventilation, Lighting etc.]
Storage Fixtures Storage fixtures [palettes, steel racks/cabinet]
Storage equipment/s [Temperature monitoring System: Monitoring Device]
Storage area/s for various products
Segregated areas for recalled/damaged/expired/returned products
Stock Management and Control
Physical examination of the product/s
Conformance to Mandatory labeling requirements (pre-packed foods)
Conformance to Mandatory labeling requirements for specific products based on standards [food supplement/s, bottled water, staple products, iodized salt]
Collection of samples when necessary

Ocular inspection of Transport Vehicle

Report Writing (Observation and findings/recommendation/directives) **Exit Meeting** (discussion observation and findings/recommendation/Accomplishment of Attendance Sheet)

INSPECTION AGENDA – DRUG & MEDICAL DEVICE DISTRIBUTOR

Inspection Activity
I. Opening Meeting Introductions Inspection scope Confirmation of Confidentiality Attendance record **Document Review** ***2.1 Organization, Management & Personnel*** Organizational Chart Job Description / Duties and responsibilities of personnel involved in supply chain Training Plan Training Records Competency evaluation of personnel Qualified Person (for medical device) Pharmacist Credentials (for drugs) Pharmacovigilance Officer (for ADRs) ***2.2 QMS & Documentation*** License to Operate Risk Management Plan (RMP)

SOPs
Franchise agreement (if applicable)

Records
Distribution Records

Importation documents

Receipts from suppliers

Receipts issued to customers

Product complaints

Product recall

Product returns

Adverse Drug Reaction (ADR)Reports

Certificates of Product Registration & Notification (for medical device)

Batch Notifications (for antibiotics)

Lot Release Certificates (for vaccines)
List of products per supplier with CPR number and its validities
MDRP (EO 821 & EO 104 / IEC materials) / GMAP / EDPMS
Self-inspection (Internal audit)

2.3 Contract activities

Distribution agreements with suppliers (quality agreements)
With FDA Licenses (for local suppliers) / GMP Certificates / ISO 13485 QMS Certificates (for medical device)-(for foreign suppliers)

Agreement with third party (TP) logistics or carrier (when applicable)

III. Walk-through Inspection

3.1 Warehouse facilities

Restrictions to entry
Adequate/ sufficient and labeled or identified areas for products:
Commercial stocks
Rejects /Returns/Recalled
Quarantined
Facilities & equipment
Pallets /Racks

Calibrated Temperature /RH Monitoring Device

Storage conditions (must be in compliance with the recommendations of manufacturer or instructions on the label)
Warehouse fixture, equipment, and temperature monitors

Arrangement of stocks (to avoid mix-ups)
Stock Rotation ((first expiry/first out (FEFO) system must be observed)

3.2 Records

Sanitation /Pest Control Records
Recorded temperature and relative humidity (RH) monitoring data

Calibration records of temperature/RH monitors
Stock Reconciliation/ Inventory
Dispatch Records

3.3

Pro

ducts
Labeling requirements
Registration / Notification (for medical device)

3.4 Transport & Dispatch of products
Vehicle Maintenance
Personnel in-charge for transport of products (must be knowledgeable on handling ie. Compliance to Storage requirement for products)
3.6 Other Additional Requirements for TTSPPs

For Temperature-controlled rooms, cold rooms and freezer rooms:
Uninterrupted power supply (UPS)
Calibrated continuous temperature monitoring system
Continuous humidity monitoring devices with sensors located at points representing humidity extremes
Preventive maintenance on all temperature controlled rooms or equipment
Temperature-controlled road vehicles equipped with calibrated temperature monitoring devices
shipping containers
Stabilizing medium: dry ice, ice or gel packs, cool water packs or warm packs, bubble wrap
V. Report Writing
Consolidation of findings

VI. Exit Meeting
Attendance record

Discussion of findings /Signing of Inspection Report

INSPECTION AGENDA – DRUGSTORE

Inspection Activity

I. Opening Meeting

· Introductions
· Inspection scope
· Confirmation of confidentiality
· Attendance record

II. Ocular inspection of Premises / Storage facilities and Products

· Storage and sanitary conditions
· Segregated area for expired, damaged, recalled or returned products
· Equipment – Bioref / dedicated refrigerator, generator Set (if selling TTSPPs)
· Dispensing apparatus including ice packs for dispensing of TTSPPs
· Product compliance to registration and labeling requirements – may collect product

III. Document and Records Review

· License to Operate
· Pharmacist's credentials
· Organizational structure with duties and responsibilities of personnel
· Records of training, competency evaluation of personnel · Attendance to FDA licensing seminar
· Risk Management Plan
· Standard Operating Procedures (SOPs)
· Invoices issued by suppliers (lot #, exp. Date and transport temp requirement)
· Stock reconciliation records
· Prescription book – both full and partially filled prescriptions must be recorded in Rx book
· Senior Citizens and PWD records · Generic menu cards

· Temperature Monitoring records (bioref/ refrigerator if with TTSPPs and room) · Calibration Certificates of temperature monitoring device/s and/or bioref **IV. Report Writing** · Consolidation of findings; Notice of Violation when necessary **Exit Meeting** · Attendance record /Discussion of findings or deficiencies /violation

INSPECTION AGENDA - RETAIL OUTLET FOR NON-PRESCRIPTION DRUGS (RONPD)

Inspection Activity
I. Opening Meeting Introductions Inspection scope Confirmation of Confidentiality Attendance record **II. Ocular inspection of Premises / Storage facilities and Products** Storage and sanitary conditions Segregated area for expired, damaged, recalled or returned products Product compliance to registration and labeling requirements – may collect product (All pharmaceutical products must be OTC) **III. Document and Records Review** License to Operate Pharmacist's credentials List of all RONPDs supervised by the pharmacist with corresponding schedule Attendance to FDA licensing seminar Risk Management Plan

Standard Operating Procedures (SOPs)
Invoices issued by suppliers (lot #, exp. Date and transport temp requirement)
Franchise agreement (if applicable)

IV. Report Writing
Consolidation of findings; Notice of Violation when necessary
V. Exit Meeting
Attendance record /Discussion of findings or deficiencies /violation

INSPECTION AGENDA – COSMETICS & HOUSEHOLD URBAN PESTICIDES DISTRIBUTOR

Inspection Activity
Opening Meeting Introductions Inspection scope Attendance record **Document Review** **Organization, Management & Personnel** Organizational Chart Job Description / Duties and responsibilities of personnel involved in supply chain Training Plan Training Records and/or Competency evaluation of personnel **QMS & Documentation** License to Operate Proof of Business Registration (DTI / SEC and Business / Mayor's Permit)

Standard Operating Procedures
Franchise agreement (if applicable)
Records
Distribution Records
Importation documents
Receipts from suppliers
Receipts issued to customers
Product complaints
Product recall
Summary list with status of notification
Recorded temperature and relative humidity (RH) monitoring data (where applicable)
Calibration records of temperature/RH monitors (where applicable)
Stock Reconciliation/ Inventory

Contract activities

Distribution agreements with suppliers (quality agreements)
FDA Licenses (for local suppliers) / GMP Certificates or other equivalent document (for foreign suppliers)
Agreement with third party (TP) logistics or carrier (when applicable)

III. Walk-through Inspection

Warehouse facilities

Adequate/ sufficient and labeled or identified areas for products:
Commercial stocks/Rejects /Returns/Recalled
Facilities & equipment (PPEs for HUPs)
Storage conditions (must be in compliance with the recommendations of manufacturer or instructions on the label)
Temperature monitors
Sanitation /Pest Control Records
Stock Rotation ((first expiry/first out (FEFO) system must be observed)

Products

Labeling compliance
Status of Notification/ Product registration
Sample collection (as necessary)
Other Requirements
Product Information File for Cosmetic Products
Part I Administrative Documents & product Summary
Part II Quality Data of Raw Materials
Part III Quality Data of Finished Product
Part IV Safety & Efficacy Data

Report Writing
Consolidation and discussion of findings
Exit Meeting
Attendance record
Presentation/ discussion of findings
Signing of Inspection Report

INSPECTION AGENDA – HOSPITAL PHARMACY

Inspection Activity
I. Opening Meeting
Introductions
Inspection scope
Confirmation of Confidentiality
Attendance record
II. Ocular inspection of Premises / Storage facilities and Products
Pharmacy signage
Storage and sanitary conditions
Segregated area for expired, damaged, recalled or returned products

Equipment – Bioref / dedicated refrigerator, generator Set (if selling TTSPPs)
Dispensing apparatus including ice packs for dispensing of TTSPPs
Product compliance to registration and labeling requirements – may collect product (different areas – CSR, OR, DR, ER, Nurse stations/e-carts, others)

III. Document and Records Review

License to Operate
Pharmacist's credentials
Organizational structure with duties and responsibilities of personnel
Records of training, competency evaluation of personnel
Attendance to FDA licensing seminar
Risk Management Plan
Standard Operating Procedures (SOPs)
Invoices issued by suppliers (lot #, exp. Date and transport temp requirement)
Stock reconciliation records
Prescription book – both full and partially filled prescriptions must be recorded in Rx book
Senior Citizens and PWD records
MDRP (EO 821 & EO 104 / IEC materials) /GMAP / EDPMS / Hospital Formulary
Temperature Monitoring records (bioref/ refrigerator if with TTSPPs and room)
Calibration Certificates of temperature monitoring device/s and/or bioref

IV. Report Writing

Consolidation of findings; Notice of Violation when necessary

V. Exit Meeting

Attendance record /Discussion of findings or deficiencies /violation

INSPECTION AGENDA – FOOD MANUFACTURER/ REPACKER/ BOTTLED WATER MANUFACTURER

Inspection Activity
OPENING MEETING
Presentation of inspection agenda, attendance sheet
Company presentation (plant layout, process flow, HACCP Plan, *if any*)
INSPECTION PROPER
Storage/Warehouse facilities (raw materials, packaging materials and finished products)
Premises (Sanitation: Sanitation Program/Pest Control /housekeeping/ventilation/Lighting etc.)
Storage fixtures (pallets, steel racks/cabinet)
Storage equipment (Temperature monitors)
Storage area/segregated areas for recalled/damaged/expired/returned products
Storage condition (Stock Rotation and arrangement)
Records (temperature and RH, calibration, Stock Reconciliation/ Inventory, Dispatch)
Processing area
Laboratory facility *(**If provided;** mandatory to bottled **water processor**)*
Sanitary facilities (**such as but not limited to** gowning area, hand washing, toilet facilities)
Products (physical examination / Collection of samples)
Transport & Dispatch of products
Vehicle Maintenance, Personnel, Compliance to Storage Requirements
DOCUMENTATION REVIEW
Quality Control Procedures/Quality Manual, GMP Manual and/or HACCP Manual
Standard Operating Procedures
Cleaning and Sanitation (production area, equipment, premises)
Rejection/Returns/Disposal
Product Recall
Retention Sample
QC Methods and Procedures / Sanitation & Hygiene Records / Preventive Maintenance Records:

In-house and third-party laboratory analysis (water, finished products) Production Record/Batch Manufacturing Records/Monitoring Records Quality audits (internal/external) Sanitation checklist List of approved suppliers, certificate of analysis of raw materials and packaging materials Calibration of monitoring/measuring instruments/equipment Pest control program and records (including service reports and chemicals used) Personnel training program and records (in-house/third party) Health certificates of personnel Documents relative to subcontracting of manufacturer Verification of submitted licensing documentary requirements Franchise agreement (if applicable) See Administrative Order 153 as reference for Good Manufacturing Practices (GMP) **REPORT WRITING** **EXIT MEETING**
INSPECTION AGENDA- VACCINE AND/OR BIOLOGICALS

Inspection Activity
Opening Meeting
Introduction from FDA Lead Inspector
Discussion of Scope, Inspection Plan and GMP Standard
Timetable & Attendance Taking
Company Introduction and Overview/Presentation
Design and Lay-out Review prior to Site Inspection
Warehouse
Production Areas
Cleanroom air classification

Personnel Flow
Material Flow
Waste Flow
Utilities P & ID
Quality Control Laboratory

Site Inspection
Warehouse (Starting Materials and Finished Goods)
Receipt (Handling and Storage) and Dispatch
Sampling
Method of sampling and inspection
Sampling tools and kits
Storage Areas (quarantine, approved, reject)
Storage condition (temperature and RH monitoring)
Cells/Seed lots
Finished Product Vaccines/Biologicals (Quarantine and Approved/Released/ Lot Release)
Inventory System

Manufacturing Facility
Gowning and Hand washing Procedure (Primary and final)
Dispensing of starting materials (including control measures)
Cell and Seed Cultivation/ Harvest/Disruption/ Purification/ Semi-Finished Product
Serum, Albumin, Media, Buffers etc.
Ultrafiltration/ Virus Inactivation
Drug Product
Formulation
Vial Filling and Sealing
Freeze-Drying

Leak Testing Visual Inspection and Packaging Operations Final Bulk Storage **Utilities** (Site Inspection and Document Review) Air Handling Units Design and Structure-Supply and Return/Exhaust System Operation, Qualification and Maintenance Monitoring and Testing Water System (Pre-treatment, Purification and WFI) Design and Structure Operation, Qualification and Maintenance Monitoring and Testing Compressed Gas/ Sterile Gases Design and Structure Operation and Maintenance Monitoring and Testing Sterile Gases Monitoring and Testing Maintenance
Quality Control QC Laboratory walk through Personnel Qualification and Training Handling of samples, reference standards, microorganism Test Specifications Test Method and Results Tests on seed lots and reagents Test for Adventitious Agents

Method Validation In-process Testing Virus Titration Finished Product Testing Water Analysis QC Instruments (Computer System Validation) Validation of major QC instruments Preventive Maintenance and Calibration Microbiological Testing Production Media Testing and Qualification Environmental Monitoring (Production and QC Lab) Qualification of Sterility Room Bioburden, Sterility, Bacterial Endotoxins Animal House and Animal Testing Stability Studies (On-Going) Out-of- Specification Retention Samples Other related QC tests and records
Qualification and Validation Validation Master Plan Master and Working Cell Qualification Process Validation Cell Culture/ Expansion Purification Validation Sterile Filtration Validation Viral Inactivation Hold Time Studies Aseptic Process Validation

Critical equipment Qualification (PQ)- e.g. Sterilizers/Dry Heat Cold Chain Management and Transport Validation Computer System Validation Cleaning and Disinfectant Validation Studies
Documentation Pharmaceutical Quality System Product Quality Review CAPA System Change Control Deviation Quality Risk Management Supplier Qualification Batch Release Procedure Personnel Organizational Chart Job Description Training Program and records PPE Requirements and Gowning Qualification Health Examination records Batch Manufacturing Record Control of Source material Traceability of materials Line Clearance Reconciliation Release for supply Approved Marketing Authorization

Other relevant documents Procedure for Cleaning and Disinfection of Clean Areas and Equipment Waste Management System Handling of Product Complaints and Recall Pest Control Outsourced Activities Self-Inspection
Exit Meeting Discussion of audit findings CAPA submission instructions **Report Writing**

INSPECTION AGENDA – STEM CELL

Inspection Activity
Opening Meeting Introduction from FDA Lead Inspector Discussion of Scope, Inspection Plan and GMP Standard Timetable Attendance Sheet Company Introduction and Overview **Design and Lay-out Review prior to Site Inspection** (Storage Area, Production Areas, Utilities, Quality Control Laboratory) **Site Inspection** **Storage Area** Storage of cells *(cryogenic vessels)* Cell bank system *(if applicable)* Cryopreservation Temperature and Nitrogen level monitoring Preventive Maintenance of cryogenic vessels Alarm system of cryogenic vessels Backup system in case of power failure

Contingency plan in case of equipment break down

Processing Area

Gowning and Handwashing Procedures

Receiving of cells

Cell Culture Area

Contamination control measures

In-process checks

Handling of cultured cells

Labeling of finished product

Waste Disposal

Quality Control Laboratory

Donor Testing

Handling of Reagents and Media

Sterility Room Qualification

Quality Control checks *but not limited to:* ***(specifications and records)***

Cell Characterization

Cell Count and Viability

Endotoxin

Sterility Test

Microbial Contamination Testing

Mycoplasma

Out of Specification Procedure

Documentation

Quality System

Quality Risk Management

Release Procedure

Change Control

Deviation

CAPA
Supplier Qualification
Handling of reject cells
Qualification and Validation
Air Handling Unit System
Cleanroom Qualification
Biosafety cabinet
Biosafety level
Quality Control Instruments
Water System *(if applicable)*
Computer System *(if applicable)*
Patient Record
Source of cells (*autologous or allogenic*)
Unique numbering system
Donor Selection
Donor Screening
Patient Monitoring Sheets
Release controls prior to administration of product to patient
Other relevant documents
Collection of cells from donor (*procedure*)
Freezing and thawing of cells *(procedure)*
Handling of Product Complaint, ADR/ADE
Clinical Protocol
Outsourced Activities
Self-Inspection
Report Writing
Discussion of audit findings

INSPECTION AGENDA – TRADITIONAL MEDICINES

Inspection Activity
Opening Meeting Introductions, Attendance record, Inspection standard and scope Major Changes Key personnel Brief description of the company Buildings and facilities overview (for initial; if applicable) Floor plan / Lay-out plan Product and personnel flows **On-site inspection** Plant Tour Warehouse (starting materials, packaging materials and finished goods) Production Cutting and drying* Expression of plants* Distillation* Comminution, processing of exudates, extraction from plants, fractionation, purification, concentration or fermentation of herbal substances* Processing into dosage form Packaging Quality Control Laboratory Utilities Water HVAC

Compressed Air

Document Inspection

Establishment Records:

License to Operate
List of Products Manufactured
Site Master File

Registered Pharmacist's Records:

PRC ID, PTR

Pharmaceutical Quality System:

Quality Manual
Quality Risk Management
Finished Product Release procedure
Product Quality Review
Supplier Qualification including audits
Manufacturing Authorization of the supplier
Validation Master Plan
Process Validation
Cleaning Validation
Computer Validation*
Procedure, Records and logs:
Deviation
Change control
Corrective Action and Preventive Action

Personnel:
Organizational Chart
Duties and Responsibilities / Job Description
Training:
Training program
Training records & traceability of training history
Assessment of effectiveness of training
Medical and Health Examinations including eye check-ups

Premises and Equipment:
Warehouse (Starting Materials, Packaging Materials and Finished Goods)
Receipt, handling & storage
Identification
Storage areas – quarantine, release, reject
Approval for use (materials)
Temperature & humidity monitoring
Dispatch
Inventory control
Storage for rejects, returns and recall
Production areas
Dust extraction
Surfaces and finishes
Lighting and Ventilation
Dedicated premises / areas
Equipment
Storage
Cleaning
Qualification

Repair and Maintenance
Calibration
Compatibility from the extraction solvent*
Engineering and Services:
Pest Control
Housekeeping
Back-up system
Water
Lay-out
Qualification
Monitoring and Testing (method, specifications and results including trending)
Maintenance
HVAC
Lay-out
Qualification
Environmental Monitoring and Testing (method, specifications and results including trending)
Maintenance
Compressed air
Lay-out
Specifications of filters
Monitoring and Testing
Maintenance and Cleaning

Documentation:
Batch Record Review
Document control (history, issuing, superseded, obsolete)
Specifications for starting materials (sample of the dried plant)
Certification from National Museum for the plant with a reference authentic specimen

Documentation for herbal substances / preparations:
Binomial scientific name of plant (genus, species, subspecies / variety and author (e.g. Linnaeus); other relevant information such as the cultivar name and the chemotype
Details of the source of the plant (country or region of origin and where applicable, cultivation, time of harvesting, collection procedures, possible pesticides used, possible radioactive contamination, etc.)
Part(s) of the plant is/are used
Drying system used, when a dried plant is processed
Description of the herbal substance and its macro and microscopic examination
Suitable identification tests including, where appropriate, identification tests for constituents with known therapeutic activity, or *markers*. Specific distinctive tests are required where an herbal substance is liable to be adulterated / substituted. A reference authentic specimen should be available for identification purposes
Water content for herbal substances, determined in accordance with the relevant Pharmacopoeia
Assay of constituents of known therapeutic activity or, where appropriate, of markers; the methods suitable to determine possible pesticide contamination and limits accepted in accordance with relevant Pharmacopoeia methods or, in absence of thereof, with an appropriate validated method, unless otherwise justified
Tests to determine fungal and/or microbial contamination, including aflatoxins, other mycotoxins, pest-infestations and limits accepted, as appropriate
Tests for toxic metals and for likely contaminants and adulterants, as appropriate
Tests for foreign materials, as appropriate
Any other additional test according to the relevant Pharmacopoeia general monograph on herbal substances or to the specific monograph of the herbal substance, as appropriate
SOPs
Delivery documents
Lot Numbering System
Records
Specifications
Distribution records

Production:
Process Flow
Sorting*
Cleaning*
Drying*
Crushing and sifting*
Extraction*
Gowning procedures
Inspection procedures
Sampling
Method of sampling and inspection
Sampling tools and kits
Dispensing / Weighing
Processing
Formulation
Batch processing documentation
In-process and Line clearance checks
Rework/reprocessing
Packaging
Storage of bulk product
Control of labels & pre-printed packaging materials
In-process controls
Line clearance checks
Reconciliation
Batch packaging documentation
Storage of packed product
Control of materials (starting, in-process, finished and returned materials)

Quality Control:
Sample receipt
Method validation
QC Testing Procedure and Results (bulk gas, finished products)
Equipment Calibration and Maintenance
Handling of OOS
Test Methods & References (i.e. official pharmacopeia) and Specifications
Reference Standards and reagents
Markers
Reference standards from the authentic reference sample
Analysts work books/records & test results (if available)
Training & assessment
Particular expertise and experience in herbal substances, herbal preparations and/or herbal medicinal products (especially inspectors and samplers)
Retention samples
Stability program
Identification test procedure and specifications of starting materials
Pesticide residue testing
Heavy metals testing
Microbiology Laboratory testing
Equipment / Laminar Flow hood
Testing procedure, references and results
Media preparation
Growth Promotion Testing
Storage of Reagents
Strains
Receipt
Certificate of Analysis

Identification tests
Passage (procedure and records)
Storage

Outsourced Activities: Contract Manufacturing Agreement, Testing laboratories agreement, others

Complaints and Product Recall (procedure and records)

Self-inspection (procedure and records)

Report Writing
Exit Meeting

INSPECTION AGENDA – DRUG TRADER

Inspection Activity

Opening Meeting
Introductions, Attendance record,
Inspection standard and scope
Confirmation of Confidentiality
Major Changes

On-site and Document Inspection	*Registered Pharmacist's Records:*
Establishment Records:	PRC ID, PTR
License to Operate	Certificate of Attendance to Licensing Seminar
List of Toll Manufacturers and Activities	Number of LTO and products being handled
Franchise agreement (if applicable)	

Pharmaceutical Quality System:
Quality Manual
Quality Risk Management / RMP
Finished Product Release procedure (including Batch Notification control) including filing of Certificates of Analysis and Batch Notification (if available)
Personnel:
Duties and Responsibilities
Training (SOP and Records): GMP and GDP, GSP (if warehouse was handled by the company)
Premises and Equipment (Warehouse; if applicable):
Inventory control including Computer System (if applicable)
Pest Control and Cleaning (Procedure and Records)
Temperature monitoring device calibration and records of monitoring including temperature mapping (if applicable)
Storage for rejects, returns and recall
Storage of retention sample

Documentation:

Contract of Lease or TCT (office and warehouse; if applicable)
LTO and GMP Certificates of toll manufacturer
Certificate of Product Registration and list of products status
Audit to toll manufacturer and Vendor rating of PM and RM Suppliers (procedure and records)
System of Distribution
Dispatch Records (Sales Invoice, etc)
Monitoring of transport conditions
SOPs:
Receipt and Dispatch
Handling of rejects and returns
Destruction
Batch Notification control

Outsourced Activities: Contract Manufacturing Agreement LTO and contract if distributors were available Agreement with Pest Control Provider (if applicable) *Complaints and Product Recall* (procedure and records) *Pharmacovigillance system and records of PV activities* **Report Writing** **Exit Meeting**

INSPECTION AGENDA – DRUG, MEDICAL DEVICE and COSMETIC REPACKER/ PACKER

Inspection Activity
Opening Meeting
Introduction from FDA Lead Inspector
Discussion of Scope, Inspection Plan and GMP Standard
Timetable
Attendance Sheet
Company Introduction and Overview
Design and Lay-out Review prior to Site Inspection
(Warehouse, Repacking/Packing Area)
Site Inspection
Warehouse (Starting Materials and Finished Goods)
Receipt
Sampling
Storage area (quarantine, approved, reject, cool room)
Storage condition (temperature, humidity)
Approval for use / release prior to repacking or packing
Dispatch

Premises and Equipment
Plan or description of manufacturing areas with scale
Nature of construction and finishes
Special areas for the handling of highly toxic, hazardous and sensitizing materials
Production
Brief description of production operations using flowsheets and charts, if possible, specifying important parameters
Arrangements for the handling of starting materials, packaging materials, bulk and finished products, including sampling, quarantine, release and storage
Arrangements for reprocessing or rework
Arrangements for the handling of rejected materials and products
Brief description of general policy for process validation Repacking / Packing Facility
Building Maintenance and Structure
Gowning Areas / Changing Rooms
Repacking/Packing Area
Storage condition (temperature, humidity)
Line Clearance
In-process controls
Cross contamination prevention measures
Equipment (status: cleaning, maintenance, calibration)
Control of labels and pre-printed packaging materials
Coding
Storage of finished goods
Retention Sample

Utilities and Engineering Services (if applicable)
Air Handling Units
Design and Structure
Operation and Maintenance

Monitoring

Pest Control and Waste Disposal

Documentation
Pharmaceutical Quality System / Quality Management System
Quality Risk Management
Change Control
Deviation
CAPA
Supplier Qualification
Batch Release Procedure
Personnel
Organizational Chart
Job Description
Training and Assessment
Personnel Hygiene
Health Examination
Arrangements for the preparation and revision and distribution of documentation
Description of the documentation system
Responsible for the preparation, revision and distribution of documents
Storage of the master documents
Procedures on the preparation of the documents
Control of the documentation
Related to Product Quality
Equipment specification
Training procedures
Documentation control of process deviations

Calibration and test documents
Validation documents
Reconciliation of batches of raw materials, major packing components
Personnel Hygiene
Health Examination
Batch Packaging Records Review
Packaging Specifications

Other Relevant Documents
Standard Operating Procedures
Receiving and Dispatch
Cleaning and Sanitization of Premise and Equipment
Storage conditions to each category of materials
Quality Control check
Reprocessing / Reworking
Handling of excess packaging materials
Out-of-Specifications Product Complaint and Recall Outsourced Activities Self-Inspection
Franchise agreement (if applicable)
Report Writing
Discussion of audit findings

INSPECTION AGENDA –HOUSEHOLD REMEDY/EXTERNAL OTC

Inspection Activity

Opening Meeting
Introduction from FDA Lead Inspector
Discussion of Scope, Inspection Agenda and GMP Standard

Timetable of activities
Attendance Sheet
Company Introduction and Overview

Design and Lay-out Review prior to Site Inspection
(Warehouse, Production Areas, Utilities, Quality Control Laboratory)

Site Inspection
Warehouse (Starting Materials and Finished Goods)
Receipt
Sampling
Storage area (quarantine, approved, reject, cold room)
Storage condition (temperature, humidity)
Approval for use / release to production
Dispatch
Production Facilities
Building Maintenance and Structure
Dispensing
Gowning Areas / Changing Rooms
Bulk Manufacture (including in-process controls)
Cross contamination prevention measures
Equipment (status: cleaning, maintenance, calibration)
Packaging Operations
Control of labels and pre-printed packaging materials/ prevention of mix-up
Line Clearance
Coding
Reconciliation
Storage of finished goods

Utilities and Engineering Services
Air Handling Units (where applicable)
Design and Structure
Operation and Maintenance
Monitoring and testing
Water System (where applicable)
Design and Structure
Operation and Maintenance
Monitoring and Testing
Pest Control and Waste Disposal

Quality Control Laboratory
Laboratory Design
Laboratory Staff Training and Assessment
Handling of QC Samples
Specifications and Testing Procedures including results
Raw material, packaging materials and finished product
Instrumentation Room (status: calibration, maintenance, logbooks)
Stability Program
Handling of Out-of-Specifications
Retention Samples
Micro laboratory (where applicable)
Media Preparation and controls
Reference Cultures
Testing (Products, Environmental Monitoring, Water)
LAF or BSC (calibration and maintenance)

Documentation
Pharmaceutical Quality System
Quality Risk Management
Product Quality Review
Change Control
Deviation
CAPA
Supplier Qualification
Product Dossier
Batch Release Procedure
Personnel
Organizational Chart
Job Description
Training and Assessment
Personnel Hygiene
Health Examination
Qualification and Validation
Validation Master Plan
Utilities Qualification (HVAC, Water, Gases)
Equipment Qualification
Process verification
Computer System Validation
Cleaning Validation
Batch Manufacturing Records
BMR Review
Product Dossier
Release for supply

Other Relevant Documents
Product Complaint and Recall
Outsourced Activities
Self-Inspection
Report Writing
Discussion of audit findings
INSPECTION AGENDA – MEDICINAL GAS

Inspection Activity
Opening Meeting
Introductions, Attendance record, Inspection standard and scope
Major Changes
Key personnel
Buildings and facilities overview (for initial; if applicable)
Floor plan / Lay-out plan
Product and personnel flows
On-site inspection
Plant Tour
Warehouse
Production
Quality Control Laboratory
Document Inspection
Establishment Records:
License to Operate
List of Products Manufactured
Site Master File
Registered Pharmacist's Records:

PRC ID, PTR
Pharmaceutical Quality System:
Quality Manual
Quality Risk Management
Finished Product Release procedure
Procedure, Records and logs:
Deviation
Change control
CAPA
Personnel:
Organizational Chart
Duties and Responsibilities / Job Description
Training:
Training program
Training records & traceability of training history
Assessment of effectiveness of training
Medical and Health Examinations
Premises and Equipment:
Warehouse (Packaging Materials / Cylinders and Finished Goods)
Housekeeping & Pest control
Receipt, handling & storage
Identification and avoidance of mix-ups
Sampling
Storage areas – quarantine, release, reject
Approval for use
Temperature & humidity monitoring
Dispatch
Inventory control

Storage for rejects, returns and recall
Equipment
Storage of starting material (cryogenic tank) specification (dedicated)
Cleaning and Purging
Qualification of pipelines and manifolds (for shared equipment of different gases)
Repair and Maintenance
Delivery tankers (incl. Maintenance and Qualification records)
Storage of pipelines, manifolds, tester, valves and other equipment
Calibration
Air separation unit*
Air inlet
Position
Sequence
Repair and Maintenance including Cleaning
Filters & /Molecular Sieves
Type / Specifications
Regeneration and Maintenance
Installation
Integrity test
Air compressors
Maintenance frequency (incl. oil used, checking of bearings, etc.)
Change and consumption of oil
Water quality
Pressure
Separation Columns
Proper design (valves, sensors)
Maintenance
Usage and Specifications (Liquid levels, pressure)

Calibration of in-line processing monitors
Engineering and Services:
Pest Control
Housekeeping
Quality of water used for testing (e.g. hydrostatic testing)
Back-up system
Documentation:
Batch Record/Production Record Review
Document control (history, issuing, superseded, obsolete)
SOPs
Delivery documents
Records
Specifications
Distribution records
Production:
Process Validation (shared manifold for medicinal and industrial gases)
Process Flow
Air separation/ LOX vaporization
Unloading of bulk gas
Filling of gas
Inspection of cylinders
Control of materials (starting, in-process, finished and returned materials)
Line Clearance Procedures
Traceability of valves and cylinders
Quality Control:
Sampling and receipt of samples
QC or line Testing Procedure and Results (bulk gas, finished products)
Equipment Calibration and Maintenance

Handling of OOS
Test Methods & References (i.e. official pharmacopeia) and Specifications
Analysts work books/records & test results (if available)
Training & assessment
Outsourced Activities: Contract Manufacturing Agreement, Testing laboratories agreement, others
Complaints and Product Recall (procedure and records)
Self-inspection (procedure and records)
Report Writing
Exit Meeting

INSPECTION AGENDA – STERILE DRUG AND MEDICAL DEVICE MANUFACTURERS

Inspection Activity

Opening Meeting
Introduction from FDA Lead Inspector
Discussion of Scope, Inspection Plan and GMP Standard
Timetable of Activities
Attendance Sheet
Company Introduction and Overview

Design and Lay-out Review prior to Site Inspection
(Warehouse, Production Areas, Utilities, Quality Control Laboratory including cleanroom air classification, material and process flow)

Site Inspection
Warehouse (Starting & packaging materials, Bulk &Finished Goods)
Receipt (Handling and Storage)
Storage Areas (quarantine, approved, reject)
Storage condition (temperature and RH monitoring)
Approval for use
Dispatch
Label reconciliation

Production Facilities
Building maintenance and structure
Gowning and hand washing
Dispensing of starting materials (including control measures)
Bulk Manufacture (formulation and/or filtration) and Staging
Cross contamination and Contamination prevention measures/ control strategies
Preparation of packaging materials (e.g. washing of containers, sterilization of packaging materials, garments, equipment parts)
Filling operations (aseptic process implementation)
In process checks

Monitoring (air cleanliness and environment)
Cleaning of premises and equipment
Packaging operations
Control of labels and pre-printed packaging materials
In-process checks
Coding
Line Clearance
Reconciliation
Sterilization (*terminal*)

Utilities
Air Handling Units
Design and Structure
Operation and Maintenance
Monitoring and testing
Water System
Design and Structure
Operation and Maintenance
Monitoring and testing
Compressed Gas and other gas
Design and Structure
Operation and Maintenance
Monitoring and testing

Quality Control Laboratory
Laboratory Staff training and assessment
Sampling

Handling of samples, reference standards, microorganism
Test Specifications
Method Validation
In-process Testing
Finished Product Testing
Instrumentation Room (status: CSV, calibration, maintenance, logbooks)
Validation of major QC instruments
Qualification of Sterility Room
Water Analysis
Microbiological
Environmental Monitoring (Production and QC Lab)
Stability Studies (Accelerated and Real Time)
Out-of- Specification
Retention Samples
Other related QC tests and records

Documentation
Pharmaceutical Quality System
Quality Risk Management
Product Quality Review
Change Control
Deviation
CAPA
Supplier Qualification
Batch Release Procedure
Personnel
Organizational Chart
Job Description

Training Program and records
Gowning qualification
Personnel hygiene
Health examination records

Qualification and Validation
Validation Master Plan
Process Validation
Cleaning Validation
Validation of aseptic process
Washers
Sterilizers (autoclave; dry heat)
Filters (integrity and microbial)
Container Closure integrity
Utilities Qualification (HVAC, Water, Gases)
Computer System
Batch Manufacturing and Packaging Record Review
Traceability of materials
Line Clearance
Reconciliation
Release for supply
Approved Marketing Authorization
Product Dossier

Engineering Services (procedure and records)
Preventive Maintenance
Calibration
Pest Control

Waste Disposal Key Control Other relevant documents Process Simulation / Media Fill Document control *(history, issuing, superseded, obsolete)* Handling of Product Complaints and Recall Outsourced Activities (qualification of suppliers) Self-Inspection **Report Writing** **Discussion of audit findings**
INSPECTION AGENDA – NON-STERILE DRUG AND MEDICAL DEVICE MANUFACTURERS

Inspection Activity
OPENING MEETING Introductions, Attendance record, Inspection standard and scope Brief description of the company (identify key personnel) Buildings and facilities overview (for initial; if applicable) Floor plan / Lay-out plan Product and personnel flows Major changes from the last inspection (if applicable) **ON-SITE INSPECTION** Warehouse (starting materials, packaging materials and finished goods) Receipt (Handling and Storage) Storage Areas (quarantine, approved, reject) Storage condition (temperature and RH monitoring)

Approval for use
Dispatch
Label reconciliation
Production
Dust extraction
Surfaces and finishes
Lighting and Ventilation
Dedicated premises / areas
Sampling
Dispensing
Processing
Packaging
Quality Control Laboratory
Utilities
Water
HVAC
Compressed Air

DOCUMENT REVIEW
Establishment Records
License to Operate
List of Products Manufactured (CPR)
Site Master File

Registered Pharmacist's Records:
PRC ID, PTR

Pharmaceutical Quality System:

Quality Manual
Quality Risk Management
Hormone / Steroid facilities shared with general production
Risk assessment
Cleaning validation
Finished Product Release procedure
Product Quality Review
Supplier Qualification including audits
Validation Master Plan
Process Validation
Cleaning Validation
Computer Validation (if applicable)
Procedure, Records and logs:
Deviation
Change control
Corrective Action and Preventive Action (CAPA)

Personnel:
Organizational Chart
Consultants' credential (if applicable)
Duties and Responsibilities/Job Description
Training
Training program
Training records & traceability of training history
Assessment of effectiveness of training
Medical and Health Examinations

Premises and Equipment:

Warehouse (Starting Materials, Packaging Materials and Finished Goods)
Receipt, handling & storage
Quarantine, approval/release, reject
Including hazardous materials (if applicable)
Temperature & humidity monitoring records
Dispatch
Inventory control
Equipment
Storage
Cleaning
Qualification
Repair and Maintenance
Calibration
Engineering and Services
Pest Control
Housekeeping
Key control
Back-up system
Water
Lay-out
Qualification
Monitoring and Testing (method, specifications and results, including trending)
Maintenance
HVAC
Lay-out
Qualification
Environmental Monitoring and Testing (method, specifications and results, including trending)
Maintenance

Compressed air
Lay-out
Specifications of filters
Monitoring and Testing
Maintenance and Cleaning

Documentation
Batch Record Review
Document control (history, issuing, superseded, obsolete)
Specifications for:
starting materials
packaging materials
bulk product
finished product
SOPs
Delivery documents
Lot/Batch Numbering System
Distribution records
Qualification of suppliers

Production (Process Flow)
Gowning procedures
Sampling
Method of sampling and inspection
Sampling tools and kits
Dispensing / Weighing
Laundry
Processing

Formulation
In-process and Line clearance checks
Rework/reprocessing
Packaging
Storage of bulk product
Control of labels & pre-printed packaging materials
In-process controls
Storage of packed products (quarantine/awaiting approval)

Quality Control
Sample receipt
Method validation
Testing Procedure and Results (starting materials, bulk, finished products)
Identification test procedure
Equipment Calibration and Maintenance
Handling of OOS
Test Methods & References (i.e. official pharmacopeia) and Specifications
Reference Standards and reagents
Special storage and directions
Traceability of primary and secondary standards
Analysts work books/records & test results (if available)
Training & assessment
Retention samples
Stability program
Microbiology Laboratory testing
Equipment / Laminar Flow hood/ BSC
Testing procedure, references and results
Media preparation

Growth Promotion Testing
Storage of Reagents
Strains
Receipt
Certificate of Analysis
Identification tests
Passage (procedure and records)
Storage

Outsourced Activities (Contract Manufacturing Agreement, Testing laboratories agreement, others)

Complaints and Product Recall (procedure and records)
Mock recall

Self-inspection (procedure and records)

REPORT WRITING

EXIT MEETING

INSPECTION AGENDA – RADIOPHARMACEUTICALS

Inspection Activity
Opening Meeting Introductions, Attendance record, Inspection standard and scope Major Changes Key personnel

Brief description of the company
Buildings and facilities overview (for initial; if applicable)
Floor plan / Lay-out plan
Product and personnel flows

On-site inspection
Plant Tour
Warehouse (starting materials, packaging materials and finished goods)
Production
Reactor/Cyclotron Production** - Non-GMP
Chemical synthesis
Purification
Processing, formulation and dispensing
Aseptic or final sterilization
Packaging
Quality Control Laboratory
Utilities
Water
HVAC

Document Inspection
Establishment Records:
License to Operate
List of Products Manufactured
Site Master File
Necessary licenses from PNRI
License to Construct

License to Operate for commissioning
Radioactive material license
LTO for controlled facility

Registered Pharmacist's Records:
PRC ID, PTR

Pharmaceutical Quality System:
Quality Manual
Quality Risk Management
Determine the extent of qualification/validation, focusing on a combination of Good Manufacturing Practice and Radiation Protection
Usage of closed or open equipment
Pressure differences, air flow direction and air quality
Finished Product Release procedure
Assessment by a designated person of batch processing records
Assessment of the final analytical data
Radionuclides with long half-lives
Product Quality Review
Supplier Qualification including audits
Validation Master Plan including protocols and reports
Prospective Process Validation
Cleaning Validation
Computer Validation
Procedure, Records and logs:
Deviation
Change control
Corrective Action and Preventive Action (CAPA)

Personnel:
Organizational Chart
Duties and Responsibilities / Job Description
Training:
Training program
Training records & traceability of training history
Assessment of effectiveness of training
Training on radiation safety and cleaning and maintenance of radiopharmaceuticals
QA / Plant manager / Key personnel
Training on Radiation protection
Training on radiopharmaceutical specific aspects of the quality management system
Medical and Health Examinations including eye check-ups
Personnel monitoring
Radiation activity
Equipment used
Disinfection / Decontamination of personnel

Premises and Equipment:
General
Controlled (environmental and radioactive) areas
Self-contained facilities for radiopharmaceuticals
Thickness of wall and non-straight line building walls for facilities with reactor / cyclotron production
Detection of radioactivity contamination
Prevention of cross-contamination from personnel, materials, radionuclides
Closed or contained equipment
Open equipment
Gowning area
Procedure

Appropriate gown / suits
Personnel protective equipment such as ring badge, pendosimeter
Warehouse (Starting Materials (excipients), Packaging Materials)
Receipt, handling & storage
Storage areas – quarantine, release, reject
Approval for use (materials)
Temperature & humidity monitoring
Dispatch
Inventory control
Production areas
Surfaces and finishes
Lighting and Ventilation
Dedicated premises / areas
Air locks
Environmental monitoring
Radioactivity
Particle
Microbiological quality
Equipment
Storage
Cleaning
Qualification
Hot cells – filtered feed air
Isolator / Laminar
Repair and Maintenance
Calibration and reading of radiation monitor devices
Engineering and Services:
Pest Control

Housekeeping
Back-up system
Radioactive waste disposal
Drainage system
Water
Lay-out
Qualification
Monitoring and Testing (method, specifications and results including trending)
Maintenance
HVAC
Lay-out
One-pass air
Exhaust filter (Carbon filters)
Alarm system
Qualification – Classification should be the same with sterile production
Environmental Monitoring and Testing (method, specifications and results including trending)
Maintenance

Documentation:
Batch Record Review
Document control (history, issuing, superseded, obsolete)
Specifications for starting materials
Specifications of packaging materials
Specifications of bulk product
SOPs
Delivery documents
Lot Numbering System
Records of equipment

Usage
Cleaning
Sanitization / Sterilization
Specifications
Starting materials
Packaging materials
Critical items (such as process aids, gaskets, sterile filtering kits)
Distribution records
Acceptance criteria
Criteria for release
Shelf-life (chemical identity of the isotope, radioactive concentration, purity, and specific activity)

Production:
Process Flow
Gowning procedures
Preparation
Processing
Assembly of sterilized equipment under aseptic conditions
Formulation
Filter sterilization (aseptic)
Integrity testing with radiation protection and maintenance of filter sterility
Process simulation (Media fill)
Batch processing documentation
Sterilization processes
Labelling
In-process and Line clearance checks
Packaging
Control of labels & pre-printed packaging materials

In-process controls
Line clearance checks
Reconciliation
Batch packaging documentation
Storage of packed product
Control of materials (starting, in-process, finished and returned materials)

Quality Control:
Sample receipt
Method Validation
QC Testing Procedure and Results (bulk gas, finished products)
Equipment Calibration and Maintenance
Handling of OOS
Test Methods & References (i.e. official pharmacopeia) and Specifications
Radioactivity decay
Identification of radionuclide
Identification of radiopharmaceutical
Reference Standards and reagents
Special storage and directions
Traceability of primary and secondary standards
Analysts work books/records & test results (if available)
Training & assessment
Period of validity (finished product)
Reference and Retention Samples
Stability program
Identification test procedure and specifications of starting materials
Microbiology Laboratory testing
Sterility tests

Bacterial Endotoxin test
Equipment / Laminar Flow hood
Testing procedure, references and results
Media preparation
Growth Promotion Testing
Storage of Reagents
Strains
Receipt
Certificate of Analysis
Identification tests
Passage (procedure and records)
Storage

Outsourced Activities: Contract Manufacturing Agreement, Testing laboratories agreement, others

Complaints and Product Recall (procedure and records)

Self-inspection (procedure and records)

Report Writing
Exit Meeting

INSPECTION AGENDA – TOYS AND CHILDCARE ARTICLES MANUFACTURER

Inspection Activity
OPENING MEETING
Presentation of Inspection / Audit Plan
Presentation of Floor Plan and Plant Lay-Out

Scope of Inspection

PLANT INSPECTION
Premises & Equipment
Production areas
Sampling Area
Packaging
Maintenance of facilities
Cleaning of equipment
Maintenance/Calibration of Equipment
Pest Control
Waste Disposal

Warehouse
Raw Materials
Packaging Materials
Finished Goods

DOCUMENTATION REVIEW
Duly Accomplished Integrated Application Form
DTI / SEC Registration
Business Permit / Ma
yor's Permit
Contract of Lease of Office or Proof of Ownership (TCT) or Certificate of Occupancy
Contract of Lease of Warehouse or Proof of Ownership (TCT) or Certificate of Occupancy
Training Certificates
Internal Audit
201 File of Technical Person / Authorized Person

Standard Operating Procedures (if applicable)
Certificate of Analysis of Finished Goods (Third Party)
Disposal Plan
Recall Plan
Incoming Delivery Receipts and Distribution Records
Franchise agreement (if applicable)

REPORT WRITING
EXIT MEETING

INSPECTION AGENDA – COSMETICS & HOUSEHOLD URBAN PESTICIDES DISTRIBUTOR

Inspection Activity
<u>Opening Meeting</u> Introductions Inspection scope Attendance record **<u>Document Review</u>** **Organization, Management & Personnel** Organizational Chart Job Description / Duties and responsibilities of personnel involved in supply chain Training Plan Training Records and/or Competency evaluation of personnel **QMS & Documentation** License to Operate Proof of Business Registration (DTI / SEC and Business / Mayor's Permit) Standard Operating Procedures

Franchise agreement (if applicable)
Records
Distribution Records
Importation documents
Receipts from suppliers
Receipts issued to customers
Product complaints
Product recall

Summary list with status of notification
Recorded temperature and relative humidity (RH) monitoring data (where applicable)
Calibration records of temperature/RH monitors (where applicable)
Stock Reconciliation/ Inventory

Contract activities

Distribution agreements with suppliers (quality agreements)
FDA Licenses (for local suppliers) / GMP Certificates or other equivalent document (for foreign suppliers)
Agreement with third party (TP) logistics or carrier (when applicable)

III. <u>Walk-through Inspection</u>

Warehouse facilities

Adequate/ sufficient and labeled or identified areas for products:
Commercial stocks/Rejects /Returns/Recalled
Facilities & equipment (PPEs for HUPs)
Storage conditions (must be in compliance with the recommendations of manufacturer or instructions on the label)
Temperature monitors
Sanitation /Pest Control Records
Stock Rotation ((first expiry/first out (FEFO) system must be observed)

Products

Labeling compliance Status of Notification/ Product registration Sample collection (as necessary) **Other Requirements** **Product Information File for Cosmetic Products** Part I Administrative Documents & product Summary Part II Quality Data of Raw Materials Part III Quality Data of Finished Product Part IV Safety & Efficacy Data **Report Writing** Consolidation and discussion of findings **Exit Meeting** Attendance record Presentation/ discussion of findings Signing of Inspection Report

INSPECTION OF MANUFACTURER/REPACKER – COSMETICS/HOUSEHOLD URBAN PESTICIDES /TOYS AND CHILD CARE ARTICLES (TCCAs)

INSPECTION AGENDA		
Presence of all Key Personnel	**Opening Meeting** Introduction from FDA Lead Inspector Discussion of Scope, Inspection Plan Attendance Sheet Company Introduction and Overview Design and Lay-out Review prior to Site Inspection	GMP Cosmetics Team
Company Key Person Assigned	**Site Inspection**	

	QUALITY MANAGEMENT SYSTEM Quality Manual Suppliers of materials/ accreditation Site Master File **PERSONNEL** Organizational Chart/ number of personnel Qualification Responsibilities Training/records **PREMISES** Location Plant Construction & Design Changing rooms and facilities Toilets Defined areas Materials receiving. Material Sampling Incoming goods and quarantine. Starting materials storage. Weighing and dispensing. Processing. Storage of bulk products. Packaging. Quarantine storage before final release of products. Storage of finished products. Loading and unloading.	

	Laboratories. Equipment washing. Wall, Ceiling & Floor Drains Air Intakes and Exhausts Lighting & Ventilation Laboratories Storage Areas Cleaning and Maintenance of facilities Water System (Lay-out, Monitoring / records) **EQUIPMENT** Design and Construction Installation and Location Maintenance Calibration Cleaning Records **SANITATION & HYGIENE** **Personnel** Medical Examination Records Hygienic Practices Gowning & de-gowning procedures **Premises** Employee's hand washing facilities	

	Locker facilities Cleaning and Maintenance Waste Material Pest Control **Equipment and Apparatus** Cleaning Procedure and records **PRODUCTION** Control of Starting Materials Water Verification of Materials Rejected materials Batch Numbering System Weighing and Measurement Procedures and Processing Dry products Wet products Labeling and Packaging Finished Product: Quarantine and Delivery to Finished Stock **QUALITY CONTROL** Quality Control System Reprocessing (Procedure and records) Returned Products (Procedure and records) **DOCUMENTATION** Documentation Control System	

	Specifications Raw and packaging materials Bulk and finished products Documents for Production Master Formula BMR Records of Quality Control Standard Operating Procedures Distribution Records **INTERNAL AUDIT** Inspection Program and Procedure Records **STORAGE** Stock Handling and Control (Inventory system) Receiving Control Reject/return materials Segregated storage area for flammable and toxic substances (if applicable) **CONTRACT MANUFACTURING AND ANALYSIS** Written Contract between the principal and the contract manufacturer Duties and responsibilities Quality of product **PRODUCT COMPLAINTS** Procedure Responsible Person Handling Complaints	

	Records **PRODUCT RECALL** Procedure Responsible Person in Execution and coordination of Recalls Records	

OFFICE OF THE DIRECTOR GENERAL
EXTERNAL SERVICE

1.RECEIVING OF LETTERS AND OTHER EXTERNAL COMMUNICATIONS

Letters, Invitation and Inquiry

Center/Office/Division	**:**	Office of the Director General (ODG)
Classification	**:**	Simple
Type of Transaction	**:**	External
Who May Avail	**:**	FDA Centers, Personnels and Clients

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Letter/ Request with attached references or invitations	Client, FDA Info (FDAC)

EXTERNAL CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Forward document/ email to ODG	Receive Document/ email, encode to ODG Database and DockTrack System (FIS) Reply to Client (Acknowledgement of receipt)	None	1 working day upon receipt	ODG Receiving Staff
	Review of Documents	None	1 – 3 working days depending on the nature of request or letter received	ODG Technical Personnel
	Referral to Concerned Office/Center	None	1 working day	ODG Releasing Staff
	Releasing of Documents	None		
	TOTAL:	**None**	**3 to 5 Working days**	

POLICY AND PLANNING SERVICE
EXTERNAL SERVICE

1.REGISTRATION PROCEDURE FOR FDA ACADEMY TRAININGS/SEMINARS OFFERED FOR FREE

Provision of trainings/seminars to external stakeholders to disseminate policies, procedures and guidelines implemented by the FDA in the exercise of its regulatory powers.

Center/Office/Division	**:**	Policy and Planning Service – FDA Academy
Classification	**:**	Simple
Type of Transaction	**:**	Government to Business - G2B
Who May Avail	**:**	External Stakeholders
Fees to be Paid	**:**	Not Applicable

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Online Registration Form	Thru the registration link or QR code provided on the FDA Website or FDA Official Facebook Page
Valid email address	Applicant

INTERNAL CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Registers through the link or QR Code provided on the FDA Website and FDA Official Facebook Page	1. Checks the accomplished registration form and send confirmation of registration together with the webinar link including the webinar rules thru the registered email of the applicant	None	Within three (3) working days after the desired number of participants is reached	Administrative Assistant II Administrative Assistant I
	TOTAL:	**None**	**Within three (3) working days**	

2.REGISTRATION PROCEDURE FOR FDA ACADEMY TRAININGS/SEMINARS OFFERED WITH REGISTRATION FEE

Provision of trainings/seminars to external stakeholders to disseminate policies, procedures and guidelines implemented by the FDA in the exercise of its regulatory powers.

Center/Office/Division	**:**	Policy and Planning Service – FDA Academy
Classification	**:**	Complex
Type of Transaction	**:**	Government to Business - G2B
Who May Avail	**:**	External Stakeholders
Fees to be Paid	**:**	Registration Fee for a particular training is stated in the Announcement and/or Poster posted on the FDA website and official Facebook Page PRC Resolution No. 1520 s. 2022 “Supplemental Guidelines on the Determination of CPD Providers Seminar/Registration Fees” Approved MDG

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Online Registration Form	Thru the registration link or QR code provided on the FDA Website or FDA Official Facebook Page
Valid email address	Applicant
Course Assessment Slip (CAS)	PPS-PDTD-FDA Academy
Proof of payment	Applicant

INTERNAL CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Registers through the link or QR Code provided on the FDA Website and FDA Official Facebook Page	1. Checks the accomplished registration form and send Course Assessment Slip (CAS) CAS contains the following: Reference Number Applicant's Information Training Details Payment Details Terms and Conditions CAS has five (5) working day validity once sent Failure to pay within the validity perio shall mean automatic cancellation of the application	None	Within three (3) working days once desired number of participants is reached	Administrative Assistant II Administrative Assistant I FDA Academy
Pays the corresponding training/seminar fee at any branch of the Development Bank of the Philippines (DBP) thru Account Name: FDA Academy Trust Fund under Account Number: 00-0-00291-430-9 and sends a clear scanned copy of the proof of payment and CAS with signature and bank's validation within five (5) working day validity period to the FDA Academy	2. Checks proof of payment and signed CAS and sends corresponding training confirmation slip/confirmation email bearing the training details thru the registered email address of the applicant	Registration Fee for a particular training is stated in the Announcement and/or Poster posted on the FDA website and official Facebook Page	Within three (3) working days	Administrative Assistant II Administrative Assistant I FDA Academy

via e-nroll@fda.gov.ph, copy furnished the FDA Cashier at fdaacademycollections@fda.gov.ph and Accounting Division at accountingdivision@fda.gov.ph				
	TOTAL:	**None**	**Within 6 working days**	

FEEDBACK AND COMPLAINTS MECHANISM

FEEDBACK AND COMPLAINT MECHANISM	
How to send feedback	Accomplish the Client Satisfaction Measurement Form  a. Included in the email responses provided by FDA personnel b. Provided by Records-Releasing personnel at the Records-Releasing Section Clients may call the Food and Drug Action Center (FDAC) at telephone numbers : (02) 8857-1900 local 1000, (02) 8842-5635 Clients may also send messages/comments via the FDA's official social media accounts : Facebook : https://www.facebook.com/fdagovph Instagram : https://www.instagram.com/fdagovph YouTube : www.youtube.com/@fdagovph Tik Tok: https://www.tiktok.com/@fdagovph?lang=en

How feedbacks are processed	The Customer Satisfaction Team gathers all feedbacks sent using the Client Satisfaction Measurement Form on a weekly basis. The same will be referred to the Center/Office concerned for information and appropriate action. Responses are communicated to the clients via email. For comments sent via the FDA's official social media accounts, the Social Media Team of the FDA monitors daily these accounts and provides appropriate response to clients.
How to file a complaint	Thru eReport@fda.gov.ph : Client sends complaint with detailed information supported by pictures and documents. eReport Team acknowledges receipt of the complaint and issues 14-digit Document Tracking Number. Sends the client's email to the concerned Center/Office for appropriate action. Clients can also send hardcopy of their complaint addressed to the FDA Director General via PhilPost and courier services. The Food and Drug Action Center (FDAC) accommodates walk-in complainants.
How complaints are processed	All complaints received via eReport@fda.gov.ph are acknowledged and given 14-digit Document Tracking Number (DTN) for traceability. The FDAC shall coordinate with the concerned Center or Office for the appropriate action to be taken. The eReport Team or concerned Center/Office shall give feedback to the client or complainant via email or letter.

LIST OF OFFICES

OFFICE	ADDRESS	CONTACT INFORMATION
Corporate Headquarters	Civic Drive, Filinvest City, Alabang, Muntinlupa City	Telephone No. : +632 8 857-1900 Email Address : info@fda.gov.ph
Food and Drug Action Center (FDAC) Satellite Office	Government Center Ali Mall Cubao, Quezon City	
Field Regulatory Operations Office (FROO) – South Luzon Cluster		
National Capital Region	7/F Kingston Excell Building, Civic Drive, Filinvest City, Alabang, Muntinlupa City	Email Address : rfoncr@fda.gov.ph
Region IV-A	D&A Building Ilang-Ilang Corner Cadena De Amor Streets, Dolor Subdv. Brgy. Uno, Calamba Laguna	Email Address : rfo4a@fda.gov.ph
Region IV-B	2F, Rodie Commercial Space, Roxas Drive, Brgy. Lumangbayan, Calapan City, Oriental Mindoro, Philippines, 5200	Email Address : rfo4b@fda.gov.ph
Region V	DOH Regional Office V, Legazpi City, Albay	Telephone No. : (052) 204-0040 local 119 Email Address : rfov@fda.gov.ph
Field Regulatory Operations Office (FROO) – North Luzon Cluster		
Region I	2nd Floor Gnet Bldg. Quezon Ave., Brgy. III, San Fernando City, La Union	Email Address : rfo1@fda.gov.ph
Region II	G/F Edward C. De Yro Commercial Building, Mabini St. Tuguegarao City, Cagayan	Email Address : rfo2@fda.gov.ph
Region III	3rd Floor, Greene Manor Hotel, Lazatin Blvd., City of San Fernando, Pampanga.	Email Address : rfoiii@fda.gov.ph
Cordillera Autonomous Region (CAR)	49 SAJJ Building, Rimando Road, Aurora Hill Proper, Baguio City	Email Address : rfocar@fda.gov.ph
Field Regulatory Operations Office (FROO) – Visayas Cluster		
Region VI	3F Gaisano City Capital, Luna St., Lapaz, Iloilo City	Telephone No. : 0330 500-5609 / Email Address : rfo6@fda.gov.ph

Region VII	One Central Hotel & Suites Corp., Leon Kilat St., cor. Sanciangko St., Pahina Central, Cebu City	Email Address : rfo7@fda.gov.ph
Region VIII	Perpetual Help Credit Cooperative Bldg., Calanipawan Road, Barangay 62-A, Tacloban City	Telephone No. : (053) 888-1806 Email Address : rfoviii@fda.gov.ph
Field Regulatory Operations Office (FROO) – Mindanao West Cluster		
Region IX	3/F Prime Arcade Bldg., National Highway, Tiguma, Pagadian City	Email Address : rfo9@fda.gov.ph
Region XII	FDA Bldg., Prime Regional Government Center, Brgy.Carpenter Hill, Koronadal City	Email Address : rfo12@fda.gov.ph
Field Regulatory Operations Office (FROO) – Mindanao East Cluster		
Region X	2/F Almie Rose Chan Yu Bldg., St. John Caltex, Zone 7, Bulua, Cagayan De Oro City, Misamis Oriental	Telephone No.: (088) 882-2842 Email Address : rfo10@fda.gov.ph
Region XI	2nd Floor Tavera Business Center, Pardo de Tavera cor. Araullo Street, Barangay 9-A Poblacion District, Davao City	Email Address : rfo11@fda.gov.ph
Region XIII (CARAGA)	Nimfa Tiu Bldg., Acosta Subdivision, Libertad, Butuan City	Telephone No. : (085) 815-8001 Email Address : rfo13@fda.gov.ph