DEPARTMENT OF HEALTH

FOOD AND DRUG ADMINISTRATION
CITIZEN'S CHARTER

2021 (1st Edition)

Effectivity: 04 February 2021

Profile

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

EXTERNAL SERVICES:

LICENSE TO OPERATE

A. SIMPLE

B. COMPLEX

C. HIGHLY TECHNICAL

Food and Drug Action Center (FDAC)

Issuance of Electronic Portal (E-Portal) User Account

Center/Office/Division	:	FDAC Account Section
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	Manufacturers traders, distributors, importers, exporters, wholesalers, and other establishment and facilities of health products, as determined by Food and Drug Administration
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1.Signed and notarized Authorization Letter (Annex B – FDA Circular No. 2016-004) (pdf format)	**Food and Drug Administration Philippines Website** **FDA Circular No. 2016-004** "Procedure on the Use of the New Application Form for License to Operate (LTO) thru the Food and Drug Administration (FDA) Electronic Portal"

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Send an email request to fdac@fda.gov.ph	1. Check the received email as to completeness and appropriateness of the request	None	15 Minutes	FDAC Staff Information Officer II
2. Receive username and password	2. Issue user account (username and password) to the client	None	Next Working Day	FDAC Staff Information Officer II

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

Issuance of Appointment Schedule and Document Tracking Number

Center/Office/Division	:	FDAC Account Section
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	Manufacturer, Traders, Distributors, Importers, Exporters, Wholesalers, Drug Outlets, and other Establishment and Facilities of health products, as determined by the Food and Drug Administration
Fees to be paid	:	No required payment

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Accomplished Integrated Application Form (IAF) (pdf format) 2. Signed and Notarized Petition (pdf format)	**Food and Drug Administration Philippines Website** **FDA Circular No. 2014-003** **"**Filling and Receiving of Registration, Licensing and Other Application using the Integrated Application Form**"**

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Send application through e-mail to fdac@fda.gov.ph	1.Check the received e-mail as to completeness and appropriateness of the request	None	15 Minutes	FDAC Staff Information Officer II
2. Receive Document Tracking Log and Appointment Schedule	2.Issue appointment schedule and Document Tracking Log (DTL) to the client's e-mail	None	Next Working Day	FDAC Staff Information Officer II
	TOTAL:	**None**	**1 Working Day and 15 minutes**	

Receiving of Application(s) and Other Documents of FDAC - Public Assistance and Complaint Desk (PACD) and Letter Section

Center/Office/Division	:	FDAC PACD and Letter Section
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	Manufacturer, Traders, Distributors, Importers, Exporters, Wholesalers, Drug Outlets, and other Establishment and Facilities of health products, as determined by Food and Drug Administration
Fees to be paid	:	Administrative Order 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
1. Issued Document Tracking Log (Scheduled Client) 2. Soft copies (PDF File format) of the documents based on the application requirements	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submit application and other documents to PACD or Letter Section	1. Check the application and other documents if the payment has been made	AO No. 50 s. 2001	5 Minutes	FDAC Information Officer II
2. Receive acknowledgement receipt	2. Check the received application/s and other documents. 3. Stamp the client's Document Tracking Log as an acknowledgement receipt of the document/s	None	3 minutes	FDAC Information Officer II

	4. Route the received application and/or other document to the concerned center/office	None	Next Working Day (Before 12nn)	FDAC Courier Information Officer II
	TOTAL:		**1 Working Day, 8 minutes**	

ISSUANCE OF OFFICIAL RECEIPT

Center/Office	**:**	Administrative and Finance Service (AFS) – Cashier
Classification	**:**	Simple
Type of Transaction	**:**	**G2B – Government to Businesses, G2G – Government to Government**
Who May Avail	**:**	All Manufacturers, Traders, Distributors (Importers, Wholesalers, Exporters) of Cosmetics, Toys and Child Care Notification, Household Urban Pesticides (HUSP),
Fees to be Paid	**:**	**AO 50 s. 2001**

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Order of Payment Form	Eportal
2. Integrated Application Form/Document Tracking No.	FDAC Center/Regional Offices
3. Manual Assessment Form	FDAC Center/Regional Offices
4. Corresponding cash/check for payment	Applicant/ Qualified Person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Collection of Payment			
1. Applicants with Order of Payment, Assessment form and DTN scheduled for the day will be accommodated by the FDA Cashier		None	0	Qualified Person

2. Get a number from the Guard on Duty on a first come first served basis.	1. Priority number will be given to Senior Citizens, Persons with Disability and Pregnant Women.	None	0	Qualified Person
3. Wait for your number to be called. Otherwise the next client will be served. Clients who have waived their turn must secure another number and wait for their turn.	2. Maximum of five (5) applications per transaction per client. In excess of 5 applications, clients must secure for another number to be called before he/she can pay the remaining applications.	None	0	Qualified Person
4. Client submit/present the Order of payment/DTN to FDAC Cashier (2 copies)	3. Receives and verifies the copy of the DTN/IAOPF downloaded by the client or as filled up by the client/s as reference for acceptance of payment	None	1 minute	FDAC SCO
	4. Encodes the details of payment and Prints the pre-numbered or and affix signature above the name of the SCO and CO (Name is currently pre-encoded in the OR)	None	5 minutes	FDAC SCO
5. Payment in Cash/ Check/Combination of Cash and Check	5. Release the original Official Receipt and the DTN/ IAOPF with stamped "PAID" in the Client's copy.	Refer to AO 50 s. 2001	1 minute	FDAC SCO
	6. Attached copy of the DTN/IAOPF and file the duplicate and triplicate copy of Official Receipt	None	1 minute	FDAC SCO
	TOTAL:		**8 minutes**	

POSTING OF PAYMENT

Verified payment through Over-the-counter report of collection and for Online Bancnet and LBP OnColl payment through Bank reports	1 minute per application
Log in to FDA Information System for DTN Posting or in FDA E Portal System for EPS Posting	2 minutes per application

Note:	
Over-the-Counter payment	Within 2 working days
Online Bancnet Payments	Within 3 working days
LBP OnColl Payments	Within 5 working days

FEEDBACK AND COMPLAINT MECHANISM	
How to send feedback	Answer the Customer Satisfaction Survey form in the receiving area and drop it in the suggestion box Food and Drug Action Center (FDAC) Contact info: (8)821-1177, (8)8211176, (8)8211159, (8)8211220, (8)8211162
How feedback are processed	The admin verifies the nature of feedback after a month. The same will be referred to the office concerned. Upon receiving the response of the concerned center/office, the client will be informed via e-mail. For follow-up, the contact information are as follows: 8)821-1177, (8)8211176, (8)8211159, (8)8211220, (8)8211162 For queries, the contact information are as follows: 8)821-1177, (8)8211176, (8)8211159, (8)8211220, (8)8211162 info@fda.gov.ph
How to file a complaint	To file a complaint against the Food and Drug Administration (FDA) or product under jurisdiction of FDA, provide the following details via e-mail or walk-in ▪ Full name and contact information of the complainant ▪ Narrative of the complaint ▪ Evidence, if applicable ▪ Name of the person being complained, if applicable Send all complaints against the FDA or product to e-report@fda.gov.ph or through walk-in at Food and Drug Action Center (FDAC)
How complaints are processed	All complaints received will be monitored by the E-Report Section at the Food and Drug Action Center (FDAC) The FDAC shall coordinate with the concerned Center or Office to answer the complaint and shall investigate, if necessary. The E-Report Section or concerned Center or Office shall give the feedback to the client/complainant via e-mail or letter.

LICENSE TO OPERATE OF ESTABLISHMENT

I. LICENSE TO OPERATE – INITIAL APPLICATION FOR MANUFACTURERS OF DRUGS, PROCESSED FOOD, MEDICAL DEVICE, COSMETICS, TOYS AND CHILD CARE ARTICLES (TCCAS) AND HOUSEHOLD URBAN PESTICIDES (HUPS)

Center/Office/Division	:	Center for Drug Regulation and Research (CDRR), Center for Food Regulation and Research (CFRR), Center for Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR) and Center for Device Regulation, Radiation Health and Research (CDRRHR)
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Manufacturers of Health Products except Household/Urban Hazardous Substances (HUHS)
Fees to be Paid	:	**Drug Manufacturer:** 20 Million and below Php 10,000 +1 % LRF over 20 Million but below 50 Million Php 15,000 +1 % LRF 50 Million and above Php 20,000 +1 % LRF **Food 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 **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 **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 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 (www.fda.gov.ph) 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) ● 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).	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) Site Master File (shall be presented to the FDA inspectors during inspection)	Applicant/Qualified person
6) Risk Management Plan (shall be presented to the FDA inspectors during inspection)	Applicant/Qualified person
7) 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. Log in to the e-portal (http://eportal.fda.gov.ph) using the issued username and password, and		None	0	Qualified Person

upload the required documentary requirements (in PDF format) for e-LTO application				
2. Download and print the generated Order of Payment through the ePortal and Email notification.		None	0	Qualified Person
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). Timeline of posting for each mode of payment: 1.Over the counter (FDA Cashier) – the payment will be posted after 2 days 2. Bank payment □ Landbank OnColl Payment – the payment will be posted after 5 days □ Bancnet – the payment will be posted after 2 days	1. FDA Cashier receives the payment for FDAC Cashier payments/ receives notification of payment for bank payments;	See above table	0	Qualified Person and FDA Cashier Administrative and Finance Service
	2. Post payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center.	None	0	FDA Cashier Administrative and Finance Service (AFS)

	3. 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
	4. Evaluation on the completeness and veracity of the documents submitted.	None	13 working days	FDA Evaluator (Center/Licensing and Registration)
	5. Checking of the evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of specific Center of jurisdiction
	6. Quality assurance of the evaluation.	None	1 working day	Technical Officer of specific Center of jurisdiction
	7. 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
4. Receive notification and link of LTO for printing				Qualified Person
TOTAL:			**20 working days**	

II. LICENSE TO OPERATE – INITIAL APPLICATION FOR MANUFACTURERS OF HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) based on FDA Circular 2020-025

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
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:	

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-Portalv2 (www.fda.gov.ph) Qualified Person 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) ● 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).	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) Site Master File (shall be presented to the FDA inspectors during inspection)	Applicant/Qualified person
6) Risk Management Plan (shall be presented to the FDA inspectors during inspection)	Applicant/Qualified person
7) 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 (http://eportal2.fda.gov.ph) log in by entering the issued username and password		None	0	Qualified person
2. 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.		None	0	Qualified person
3. 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.		None	0	Qualified person
4. 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.		None	0	Qualified person
5. Pay the assessed fee as per the system generated Order of Payment Form through FDAC Cashier or any other means prescribed by FDA.	1. FDA Cashier receives the payment for FDAC Cashier payments. / receives notification of payment for bank payments;	See above table	0	Qualified Person and FDA Cashier

(e.g. BANCNET, LANDBANK ONCOLL). Timeline of posting for each mode of payment: 1.Over the counter (FDA Cashier) – the payment will be posted after 2 days 2. Bank payment □ Landbank OnColl Payment – the payment will be posted after 5 days □ Bancnet – the payment will be posted after 2 days				Administrative and Finance Service
	2. Post payment in ePortalv2 for confirmed payments. This will prompt automatic decking of application to respective Center.	None	0	FDA Cashier Administrative and Finance Service (AFS)
	3. 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
	4. Evaluation on the completeness and veracity of the documents submitted.	None	13 working days	FDA Evaluator (Center/Licensing and Registration)
	5. Checking of the evaluation and veracity of documents submitted.	None	3 working day	Technical Officer of specific Center of jurisdiction

	6. Quality assurance of the evaluation.	None	1 working days	Technical Officer of specific Center of jurisdiction
	7. 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 day	Center Director of jurisdiction
6. Receive notification and link of LTO for printing				Qualified person
TOTAL:			**20 working days**	

III. LICENSE TO OPERATE – INITIAL APPLICATION FOR TRADERS, DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER) OF DRUGS, DRUGSTORES/RETAILOUTLETS FOR NON-PRESCRIPTION DRUGS, SPONSORS AND CLINICAL RESEARCH ORGANIZATION

Center/Office/Division	**:**	Center for Drug Regulation and Research (CDRR)
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B – Government to Business
Who May Avail	**:**	All Traders, Distributors (Importer, Exporter, Wholesaler) of Drugs, Drugstores/Retail Outlets for Non-Prescription Drugs, Sponsors and Clinical Research Organization
Fees to be Paid	**:**	**Drug Trader:** 20 Million and below – Php 3,000 over 20 Million but below 50 Million – Php 5,000

		50 Million and above – Php 7,000 **Drug Distributors:** Importer, Exporter, Wholesaler- Php 5,000 **Drug Outlets:** Drugstore (including Institutional Pharmacy, Chinese Drugstore) **Retail outlet for non-prescription drugs** only- Php 1,000 **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) 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) ● 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)	Applicant/Qualified person

• 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.	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 online application portal through (http://eservices.fda.gov.ph) "Applications"		None	0	Qualified person
2. Select the product category (Drug) and the type of business (Drug Distributor, Drug Trader, Drugstores and RONPD) establishment before proceeding to Initial Application		None	0	Qualified Person
3. Click "I agree to the Declaration and Undertaking". Declining the declaration shall mean forfeiture of the opportunity to proceed with the application		None	0	Qualified Person
4. Upload the required documents as indicated on the Checklist of Requirements (ex. Proof of Business Name Registration with DTI/SEC) in		None	0	Qualified Person

pdf format. File size should not be more than 5MB (per document requirement)				
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. Assess the completeness of the application. 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	0	Qualified Person and FDA Evaluator (Center/Licensing and Registration)
6. Print the Order of Payment form with Reference Number sent through the declared e-mail address		None	0	Qualified Person

7. 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). Timeline of posting for each mode of payment: 1. Over the counter (FDA Cashier) – the payment will be posted after 2 working days 2. Bank payment □ Landbank OnColl Payment – the payment will be posted after 5 working days □ Bancnet – the payment will be posted after 2 working days	2. FDA Cashier receives the payment for FDAC Cashier payments/ receives notification of payment for bank payments;	See above table	0	Qualified Person and FDA Cashier Administrative and Finance Service (AFS)
	3. 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	0	FDA Cashier Administrative and Finance Service (AFS)
8. Receives acknowledgement receipt through email	4. Checking and quality assurance of the documents provided and compliance	None	4 working days	Technical Officer of specific Center of jurisdiction

	5. 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
9. Receive notification and link of LTO for printing				Qualified Person
TOTAL:			**7 working days**	

IV. LICENSE TO OPERATE – INITIAL APPLICATION FOR TRADERS, DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER) OF PROCESSED FOOD, MEDICAL DEVICE, 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), Center for Food Regulation and Research (CFRR) and Center for Device Regulation Radiation Health, and Research (CDRRHR)
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B – Government to Business
Who May Avail	**:**	All Traders, Distributors (Importer, Exporter, Wholesaler) Food, Medical Device, Cosmetics, Toys and Child Care Articles (TCCAs) and Household Urban Pesticides (HUPs)
Fees to be Paid	**:**	**Cosmetics Distributors:** Importer, Exporter, Wholesaler- Php 3,000+ 1 % LRF **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 **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

		Food Traders: 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 **Food Distributors:** Importer, Exporter, Wholesaler – Php 4,000 + 1% LRF Iodized Salt Importer – Php 1,000 + 1% LRF **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* **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. ● 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) 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: ● 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. Log in to the e-portal (http://eportal.fda.gov.ph) using the		None	0	Qualified Person

issued username and password, and upload the required documentary requirements for e-LTO application				
2. Download and print the generated Orde of Payment through the ePortal and Email notification.		None	0	Qualified Person
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). Timeline of posting for each mode of payment: 1. Over the counter (FDA Cashier) – the payment will be posted after 2 days 2. Bank payment □ Landbank OnColl Payment the payment will be posted after 5 days □ Bancnet – the payment will be posted after 2 days	1. FDA Cashier receives the payment for FDAC Cashier payments/ receives notification of payment for bank payments;	See above table	0	Qualified Person and FDA Cashier Administrative and Finance Service (AFS)
	2. Post payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center	None	0	FDA Cashier Administrative and Finance Service (AFS)
	3. Evaluation of correctness of the submitted documentary requirements.	None	8 working days	FDA Evaluator (Center/Licensing and Registration Division)

	4. Checking and quality assurance of the documents provided and compliance	None	3 working days	Technical Officer of specific Center of jurisdiction
	5. Approval of LTO If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working day	Center Director of jurisdiction
4. Receive notification and link of LTO for printing		None		Qualified person
TOTAL:			**14 working days**	

V. LICENSE TO OPERATE – INITIAL APPLICATION FOR TRADERS, DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER) HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) based on FDA Circular 2020-025

Center/Division	:	Center for Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Highly Technical
Type of Transactio	:	G2B – Government to Business
Who May Avail	:	All Traders, Distributors (Importer, Exporter, Wholesaler) Household Urban Hazardous Substances
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: ● 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-Portalv2 (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: ● 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 v.2 (http://eportal2.fda.gov.ph) Log-in by entering the issued username and password		None	0	Qualified person
2 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.		None	0	Qualified person
3. 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.		None	0	Qualified person
4. 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.		None	0	Qualified person
5. 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		None	0	Qualified person

6. 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). Timeline of posting for each mode of payment: 1. Over the counter (FDA Cashier) – the payment will be posted after 2 days 2. Bank payment □ Landbank OnColl Payment the payment will be posted after 5 days □ Bancnet – the payment will be posted after 2 days	1. FDA Cashier receives the payment for FDAC Cashier payments/receives notification of payment for bank payments;	See above table	0	Qualified Person and FDA Cashier Administrative and Finance Service (AFS)
	2. Post payment in ePortal V.2 for confirmed payments. This will prompt automatic decking of application to respective Center	None	0	FDA Cashier Administrative and Finance Service (AFS)
	3. Evaluation of correctness of submitted documentary requirements.	None	8 working days	FDA Evaluator (Center/Licensing and Registration Division)
	4. Checking and quality assurance of the documents provided and compliance	None	3 working days	Technical Officer of specific Center of jurisdiction

	5. Approval of LTO If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	3 working day	Center Director of jurisdiction
7. Receive notification and link of LTO for printing		None		Qualified Person
TOTAL:			**14 working days**	

VI. LICENSE TO OPERATE – RENEWAL APPLICATION FOR MANUFACTURERS OF DRUGS, PROCESSED FOOD, MEDICAL DEVICE, COSMETICS, TOYS AND CHILD CARE ARTICLES (TCCAS) AND HOUSEHOLD URBAN PESTICIDES (HUPS)

Center/Office/Division	**:**	Center for Drug Regulation and Research (CDRR), Center for Food Regulation and Research (CFRR), Center for Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR) and Center for Device Regulation, Radiation Health and Research (CDRRHR)
Classification	**:**	Complex
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	All Manufacturers of Health Products except Household/Urban Hazardous Substances (HUHS)
Fees to be Paid	**:**	**Drug Manufacturer:** 20 Million and below Php 20,000 +1 % LRF over 20 Million but below 50 Million Php 30,000 +1 % LRF 50 Million and above Php 40,000 +1 % LRF **Food Manufacturer:** 1 Million and below – 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

		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 **Medical Device Manufacturer:** 20 Million and below – Php 10,000 +1% LRF over 20 Million but below 50 Million – Php 14,000 +1% LRF 50 Million and above – Php 20,000 +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) 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. Log in to the e-portal (http://eportal.fda.gov.ph) using the issued username and password, and upload the required documentary requirements (in PDF) for e-LTO application		None	0	Qualified person
2. Download and print the generated Order of Payment through the ePortal and Email notification		None	0	Qualified person
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). Timeline of posting for each mode of payment: 1.Over the counter (FDA Cashier) – the payment will be posted after 2 days 2. Bank payment □ Landbank OnColl Payment – the payment will be posted after 5 days □ Bancnet – the payment will be posted after 2 days	1. FDA Cashier receives the payment for FDAC Cashier payments/ receives notification of payment for bank payments;	See above table	0	Qualified person and FDA Cashier Administrative and Finance Service

	2. Post payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center.	None	0	FDA Cashier Administrative and Finance Service (AFS)
	3. Pre-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
	4. Evaluation of Center on the completeness and veracity of the documents submitted	None	3 working days	FDA Evaluator (Center/Licensing and Registration
	5. Checking of the evaluation and veracity of documents submitted.	None	1 working day	Technical Officer of specific Center of jurisdiction
	6. Quality assurance of the evaluation.	None	1 working day	Technical Officer of specific Center of jurisdiction
	7. 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
4. Receive notification and link of LTO for printing		None		Qualified person

TOTAL:			**7 working days**	

VII. LICENSE TO OPERATE – RENEWAL APPLICATION FOR MANUFACTURERS OF HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) based on FDA Circular 2020-025

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 Household Urban Hazardous Substances
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:	
● 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 V.2 at (http://eportal2.fda.gov.ph) log in by entering the issued username and password		None	0	Qualified person
2. In the Home tab, select New Application in the navigation pane and click e-License to Operate (Renewal Application) to proceed to the LTO application form.		None	0	Qualified person
3. 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.		None	0	Qualified person

4. 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.		None	0	Qualified person
5. 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). Timeline of posting for each mode of payment: 1.Over the counter (FDA Cashier) – the payment will be posted after 2 days 2. Bank payment □ Landbank OnColl Payment – the payment will be posted after 5 days □ Bancnet – the payment will be posted after 2 days	1. FDA Cashier receives the payment for FDAC Cashier payments/ Receives notification of payment for bank payments;	See above table	0	Qualified Person and FDA Cashier Administrative and Finance Service
	2. Post payment in ePortalv2 for confirmed payments. This will prompt automatic decking of application to respective Center.	None	0	FDA Cashier Administrative and Finance Service (AFS)
	3. Pre-Inspection by the Regional Field Office (RFO)	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			
	5. Evaluation on the completeness and veracity of the documents submitted.	None	3 working days	FDA Evaluator (Center/Licensing and Registration
	6. Checking of the evaluation and veracity of documents submitted.	None	1 working day	Technical Officer of specific Center of jurisdiction
	7. Quality assurance of the evaluation.	None	1 working day	Technical Officer of specific Center of jurisdiction
	8. 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
6.Receive notification and link of LTO for printing		None		Qualified person
TOTAL:			**7 working days**	

VIII. LICENSE TO OPERATE – RENEWAL APPLICATION FOR TRADERS, DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER) OF DRUGS, DRUGSTORES/RETAILOUTLETS FOR NON-PRESCRIPTION DRUGS, SPONSORS AND CLINICAL RESEARCH ORGANIZATION

Center/Office/Division	**:**	Center for Drug Regulation and Research (CDRR)

Classification	**:**	Simple
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	All Manufacturers, Traders, Distributors (Importer, Exporter, Wholesaler) of Drugs, Drugstores/Retail Outlets for Non-Prescription Drugs, Sponsors and Clinical Research Organization
Fees to be Paid	**:**	**Drug Distributors:** Importer, Exporter, Wholesaler- Php 10,000 +1 % LRF **Drug Outlets:** Drugstore (including, Institutional Pharmacy, Chinese Drugstore) Retail outlet for non-prescription drugs only- Php 2,000 +1 % LRF **Drug 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 – Php 14,000 +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-Services (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 online application portal through (http://eservices.fda.gov.ph) "Applications".		None	0	Qualified Person
2. Select the product category and the type of business establishment before proceeding to Renewal Application		None	0	Qualified Person
3. Click "I agree to the Declaration and Undertaking". Declining the declaration shall mean forfeiture of the opportunity to proceed with the application.		None	0	Qualified Person
4. Provide the required information completely and accurately detailing the License to Operate Number, its validity and security code		None	0	Qualified Person
5. Update the contact information if needed		None	0	Qualified Person
6. 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.		None	0	Qualified Person
7. Print the Order of Payment form with Reference Number sent through the declared e-mail address		None	0	Qualified Person

8. 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). Timeline of posting for each mode of payment: 1. Over the counter (FDA Cashier) – the payment will be posted after 2 days 2. Bank payment □ Landbank OnColl Payment – the payment will be posted after 5 days □ Bancnet – the payment will be posted after 2 days	1. FDA Cashier receives the payment for FDAC Cashier payments / receive notification of payment for bank payments.	See above table	0	Qualified Person and FDA Cashier Administrative and Finance Service (AFS)
	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	0	FDA Cashier Administrative and Finance Service (AFS)

9. Receives acknowledgement receipt through email	3. 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
10. Receive notification and link of LTO for printing				Qualified person
TOTAL:			**3 working days**	

IX. LICENSE TO OPERATE – RENEWAL APPLICATION LICENSE TO OPERATE FOR TRADERS, DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER) OF PROCESSED FOOD AND MEDICAL DEVICE 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), Center for Food Regulation and Research (CFRR) and Center for Device Regulation Radiation Health, and Research (CDRRHR)
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government to Business
Who May Avail	:	All Traders, Distributors (Importer, Exporter, Wholesaler) Food, Medical Device, Cosmetics, Toys and Child Care Articles (TCCAs) and Household Urban Pesticides (HUPs)
Fees to be Paid	:	**Food Distributors:** Importer, Exporter, Wholesaler – Php 8,000 + 1% LRF Iodized Salt Importer – Php 2,000 + 1% LRF **Cosmetics Distributors:** Importer, Exporter, Wholesaler Php 6,000 + 1 % LRF

		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 **Household Hazardous Substances:** Importer, Exporter, Wholesaler - Php 6,000 + 1 % LRF **Medical Device Trader:** 20 Million and below – Php 6,000 +1% LRF over 20 Million but below 50 Million – Php 10,000 50 Million and above – Php 14,000 **Medical Device Distributors:** Importer, Exporter, Wholesaler – Php 8,000 +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) 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. Log in to the e-portal (http://eportal.fda.gov.ph) using the issued username and password, and upload the required documentary requirements for e-LTO application		None	0	Qualified person
2. Download and print the generated Order of Payment through the ePortal and Email notification		None	0	Qualified person
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). Timeline of posting for each mode of payment: 1. Over the counter (FDA Cashier) – the payment will be posted after 2 days 2. Bank payment □ Landbank OnColl Payment the payment will be posted after 5 days □ Bancnet – the payment will be posted after 2 days	1. FDA Cashier receives the payment for FDAC Cashier payment / receives notification of payment for bank payments;	See above table	0	Qualified Person and FDA Cashier Administrative and Finance Service (AFS)
	2. Post payment in ePortal for confirmed payments. This will	None	0	FDA Cashier

	prompt automatic decking of application to respective Center			Administrative and Finance Service (AFS)
	3. Evaluation of correctness of submitted documentary requirements.	None	3 working days	FDA Evaluator (Center/Licensing and Registration Division)
	4. Checking and quality assurance of the documents provided and compliance	None	8 working days	Technical Officer of specific Center of jurisdiction
	5. 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
4. Receive notification and link of LTO for printing				Qualified person
TOTAL:			**14 working days**	

X. LICENSE TO OPERATE- RENEWAL APPLICATION FOR MANUFACTURERS OF HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) based on FDA Circular 2020-025

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
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: ● Accomplished e-Application Form as prescribed by FDA regulations. ● Declaration and Undertaking	FDA ePortalV.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 (http://eportal2.fda.gov.ph) Log-in by entering the issued username and password		None	0	Qualified Person
2 In the Home tab, select New Application in the navigation pane and click e-License to		None	0	Qualified Person

Operate (Renewal Application) to proceed to the LTO application form.				
5. 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 t be filled-in. Mark required fields with N/A, if not applicable.		None	0	Qualified Person
6. 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.		None	0	Qualified Person
5. 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		None	0	Qualified Person
6. 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). Timeline of posting for each mode of payment: 1. Over the counter (FDA Cashier) – the payment will be posted after 2 days 2. Bank payment	1. FDA Cashier receives the payment for FDAC Cashier payments/ receive notification of payment for bank payments;	See above table	0	Qualified Person and FDA Cashier Administrative and Finance Service (AFS)

□ Landbank OnColl Payment the payment will be posted after 5 days □ Bancnet – the payment will be posted after 2 days				
	2. Post payment in ePortal V.2 for confirmed payments. This will prompt automatic decking of application to respective Center	None	0	FDA Cashier Administrative and Finance Service (AFS)
	3. Evaluation of correctness of submitted documentary requirements.	None	8 working days	FDA Evaluator (Center/Licensing and Registration Division)
	4. Checking and quality assurance of the documents provided and compliance	None	3 working days	Technical Officer of specific Center of jurisdiction
	5. 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
7.Receive notification and link of LTO for printing		None		Qualified Person
TOTAL:			**14 working days**	

XI. LICENSE TO OPERATE – MAJOR VARIATION APPLICATION

Center/Office/Division	**:**	Center for Drug Regulation and Research (CDRR), Center for Food Regulation and Research (CFRR), Center for Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR) and Center for Device Regulation, Radiation Health and Research (CDRRHR)
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	All Manufacturers of Health Products except 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. Log in to the e-portal (http://eportal.fda.gov.ph) using the issued username and password, and upload the required documentary requirements for e-LTO application		None	0	Qualified Person
2. Download and print the generated Order of Payment through the ePortal and Email notification		None	0	Qualified Person
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). Timeline of posting for each mode of payment: 1.Over the counter (FDA Cashier) – the payment will be posted after 2 days 2. Bank payment □ Landbank OnColl Payment – the payment will be posted after 5 days	1. FDA Cashier receives the payment for FDAC Cashier payments/ receives notification of payment for bank payments;	See above table	0	Qualified Person/ FDA Cashier Administrative and Finance Service

□ Bancnet – the payment will be posted after 2 days				
	2. Post payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center.	None	0	FDA Cashier Administrative and Finance Service (AFS)
	3. 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
	4. Evaluation on the completeness and veracity of the documents submitted.	None	13 working days	FDA Evaluator (Center/Licensing and Registration
	5. Checking of the evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of specific Center of jurisdiction
	6. Quality assurance of the evaluation.	None	1 working day	Technical Officer of specific Center of jurisdiction
	7. 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
8. Receive notification and link of LTO for printing				Qualified Person

TOTAL:			**20 working days**	

XII. LICENSE TO OPERATE – MAJOR VARIATION FOR MANUFACTURERS OF HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) based on FDA Circular 2020-025

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	Qualified Person

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	
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 (http://eportal2.fda.gov.ph) Log-in by entering the issued username and password		None	0	Qualified Person
2. 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.		None	0	Qualified Person
3. 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.		None	0	Qualified Person
4. 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.		None	0	Qualified Person
5. Order of payment- A computer generated document will appear reflecting the appropriate		None	0	Qualified Person

fees and charges. Applicant should save and print a copy of document as reference for payment				
6. 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). Timeline of posting for each mode of payment: 1. Over the counter (FDA Cashier) – the payment will be posted after 2 days 2. Bank payment □ Landbank OnColl Payment the payment will be posted after 5 days □ Bancnet – the payment will be posted after 2 days	1. FDA Cashier receives the payment for FDAC Cashier payments / receives notification of payment for bank payments;	See above table	0	Qualified Person/ FDA Cashier Administrative and Finance Service (AFS)
	2. Post payment in ePortal V.2 for confirmed payments. This will prompt automatic decking of application to respective Center	None	0	FDA Cashier Administrative and Finance Service (AFS)
	3. 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

	4. Evaluation of correctness of submitted documentary requirements.	None	13 working days	FDA Evaluator (Center/Licensing and Registration Division)
	5. Checking and quality assurance of the documents provided and compliance	None	3 working days	Technical Officer of specific Center of jurisdiction
	6. Quality assurance of the evaluation.	None	1 working day	Technical Officer of specific Center of jurisdiction
	7. 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
7. Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			**20 working days**	

XIII. LICENSE TO OPERATE – MINOR VARIATION APPLICATION FOR DRUG DISTRIBUTOR/TRADERS/ DRUGSTORES / RONPDS / SPONSORS AND CLINICAL RESEARCH ORGANIZATION

Center/Office/Division	**:**	Center for Drug Regulation and Research (CDRR)
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	All Traders, Distributors (Importer, Exporter, Wholesaler) of Drugs, Drugstores, RONPDS, Sponsors and Clinical Research Organization

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 and FDA Circular 2020-030: 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 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. Transfer of Location of Drug Retailers - Physical transfer of the drug retailer	Applicant/Qualified Person

Documentary Requirement: 1. Business permit reflecting new address - Physical transfer of the drug retailer ● For Single Proprietorship: Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new location of drug retailer; ● For SEC-registered establishments: a) Amended Articles of Incorporation (if transferred from one city/ municipality/province); or b) Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality/province) ● Mayor's Permit or Barangay Business Permit/Clearance reflecting new location of drug retailer C. 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 D. Transfer or Addition of Warehouse -Physical transfer and addition of warehouse of the establishment Documentary Requirement: 1. Mayor's Permit of Barangay Business Permit/Clearance reflecting new warehouse location C. Additional Drugstore Activities Documentary Requirement: 1. Additional Credentials of Pharmacist, as applicable 2. Other documents related or specific to the additional activity (see Annex C of AO 2020-0017)	

F. 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 G. 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 H. Change of Business Name -Change only in the business name of the establishment Documentary Requirement: 1. Business name registration reflecting new business name. I. 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 J. 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: Certificate of Attendance to seminars, training, learning and development activities on drug safety, quality, and efficacy and other applicable trainings (e.g. Training for Pharmacy Assistant, Basic and Advance Course on Good Clinical Practice for CROs/ sponsors) - Annex B of AO 2020-0017 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 K. 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 3. Updated contact details	
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 online application portal through (http://eservices.fda.gov.ph) “Applications”		None	0	Qualified Person
2. Select the product category and the type of business establishment before proceeding to Variation		None	0	Qualified Person
3. Click “I agree to the Declaration and Undertaking”. Declining the declaration shall mean forfeiture of the opportunity to proceed with the application.		None	0	Qualified Person
4. Upload the documentary requirements depending on the variation or circumstances of the establishment as shown in Annex C AO No. 2020-0017		None	0	Qualified Person
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. Assess the completeness of the application. If complete, 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. Notice of deficiency will be given to the client thru eService and Email notification.	None	0	Qualified Person and FDA Evaluator (Center/Licensing and Registration)
6. Print the Order of Payment form with Reference Number sent through the declared e-mail address		None	0	Qualified Person
7. Pay the assessed fee as per the system generated Order of Payment Form through	2. FDA Cashier receives the payment for FDAC Cashier payments /	See above table	0	Qualified Person/ FDA Cashier

FDAC Cashier or any other means prescribed by FDA (e.g. BANCNET, LANDBANK ONCOLL). Timeline of posting for each mode of payment: 1. Over the counter (FDA Cashier) – the payment will be posted after 2 days 2. Bank payment □ Landbank OnColl Payment – the payment will be posted after 5 days □ Bancnet – the payment will be posted after 2 days	receives notification of payment for bank payments.			Administrative and Finance Service (AFS)
	3. 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	0	FDA Cashier Administrative and Finance Service (AFS)
8. Receive acknowledgement receipt through email	4. Checking and quality assurance of the documents provided and compliance.	None	4 working days	Technical Officer of specific Center of jurisdiction

	5. Approval of Variation 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
9. Receive notification and link of LTO with appropriate amendment for printing		None		Qualified Person
TOTAL:			**7 working days**	

XIV. LICENSE TO OPERATE – MINOR VARIATION APPLICATION FOR TRADERS, DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER) OF PROCESSED FOOD, MEDICAL DEVICE, COSMETICS, TOYS AND CHILD CARE ARTICLES (TCCAS) AND HOUSEHOLD URBAN PESTICIDES (HUPS)

Center/Office/Division	**:**	Center for Food Regulation and Research (CFRR), Center for Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR) and Center for Device Regulation, Radiation Health and Research (CDRRHR)
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	All Traders, Distributors (Importer, Exporter, Wholesaler) Food, Medical Device, Cosmetics, Toys and Child Care Articles (TCCAs) and Household Urban Pesticides (HUPs)
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: c) Amended Articles of Incorporation (if transferred from one city/ municipality/province); or d) 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:	Qualified Person

1. Mayor's Permit of 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: c) Current floor plan d) 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 3. Updated contact details	
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. Log in to the e-portal (http://eportal.fda.gov.ph) using the issued username and password, and upload the		None	0	Qualified Person

required documentary requirements for e-LTO application				
2. Download and print the generated Order of Payment through the ePortal and Email notification.		None	0	Qualified Person
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). Timeline of posting for each mode of payment: 1. Over the counter (FDA Cashier) – the payment will be posted after 2 days 2. Bank payment □ Landbank OnColl Payment the payment will be posted after 5 days □ Bancnet – the payment will be posted after 2 days	1. FDA Cashier receives the payment for FDAC Cashier payments/ receive notification of payment for bank payments;	See above table	0	Qualified Person and FDA Cashier Administrative and Finance Service (AFS)
	2. Post payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center	None	0	FDA Cashier Administrative and Finance Service (AFS)
	3. Evaluation of correctness of submitted documentary requirements.	None	2 working days	FDA Evaluator (Center/Licensing and Registration Division)
	4. Checking and quality assurance of the documents provided and compliance	None	2 working days	Technical Officer of specific Center of jurisdiction

	5. 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
4. Receive notification and link of LTO for printing		None		Qualified Person
TOTAL:			**7 working days**	

XV. LICENSE TO OPERATE – MINOR VARIATION APPLICATION FOR DISTRIBUTORS/ TRADERS OF HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) based on FDA Circular 2020-025

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 Traders, Distributors (Importer, Exporter, Wholesaler) of Household Urban Hazardous Substances
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	Qualified Person

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: e) Amended Articles of Incorporation (if transferred from one city/ municipality/province); or f) 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: 2. 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 of 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: e) Current floor plan f) 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 (http://eportal2.fda.gov.ph) Log-in by entering the issued username and password		None	0	Qualified Person
2. In the Home tab, select New Application in the navigation pane and click e-License to Operate		None	0	Qualified Person

(Initial Application) to proceed to the LTO application form.				
3. 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.		None	0	Qualified Person
4. 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.		None	0	Qualified Person
5. 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		None	0	Qualified Person
6. 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). Timeline of posting for each mode of payment: 1. Over the counter (FDA Cashier) – the payment will be posted after 2 days 2. Bank payment □ Landbank OnColl Payment the payment will be posted after 5 days	1. FDA Cashier receives the payment for FDAC Cashier payments / receive notification of payment for bank payments;	See above table	0	Qualified Person and FDA Cashier Administrative and Finance Service (AFS)

□ Bancnet – the payment will be posted after 2 days				
	2. Post payment in ePortal V.2 for confirmed payments. This will prompt automatic decking of application to respective Center	None	0	FDA Cashier Administrative and Finance Service (AFS)
	3. Evaluation of correctness of submitted documentary requirements.	None	2 working days	FDA Evaluator (Center/Licensing and Registration Division)
	4. Checking and quality assurance of the documents provided and compliance	None	2 working days	Technical Officer of specific Center of jurisdiction
	5. 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
7. Receive notification and link of 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 LTO shall be on the anniversary of its issuance and shall be valid for three 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.

Regional Field Office (RFO)

Issuance of Certificate of Compliance (COC), Recommendation for Disapproval (RFD) and Recommendation Letter (RL)

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
1. 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 HUHP and TCCA, medical device and large and medium food manufacturers, among others	Applicant Establishment/ Qualified Person
2. 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

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	1. Receives electronic application via FDA e-Portal System or Manual application trough FDA- Document Tracking System (DTS)	None	1 working day	Data Controller/ Assigned Personnel Regional Field Office
	2. Generates Document Tracking Number (DTN) thru DTS and Encodes in the Internal Database (IDB)	None		Data Controller/ Assigned Personnel Regional Field Office
	3. Decks and forwards application to Licensing Officer/ Designated Officer	None		Licensing Team Leader Regional Field Office
	4. Receives application via FDA e-Portal System or thru DTS	None	2 working days	Licensing Officer/ Assigned Personnel Regional Field Office
	5. Evaluates application: 5.1 If compliant and inspection is not needed, proceed to Step 12 (for RL) 5.2 If with major deficiencies, proceed to Step 12 (for LOD) 5.3 If with minor deficiencies, notify applicant thru e-mail/ declared contact no. to comply within 5 days ***STOP CLOCK*** 5.3.1 Receives and evaluates compliance: (Follow step 5.1, 5.2 or 5. 4)	None		Licensing Officer/ Assigned Personnel Regional Field Office

	Note: Non -compliance within the 5 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			
	6. Receives Electronic and Manual application thru DTS and decks to Inspectors	None	2 working days	Inspection Section Team Leader Regional Field Office
	7. Pre -inspection activities: 7.1 Receives application thru 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
	8. Conducts inspection as per approved itinerary: If non -compliant, the establishment is given maximum of 15 calendar days to comply /submit Corrective Action and Preventive Action (CAPA)*****STOP CLOCK*** until RFO receives the CAPA plan**	None	5 working days	FDA Inspectors Regional Field Office

	9. Post -inspection activities: 9.1 Classifies Deficiencies 9.2 Prepares Risk Assessment 9.3 Submits Inspection Report 9.4 Updates 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
	10. Reviews Inspection Report 10.1 Updates DTS and Inspection Database	None	2 working days	Team Leader Regional Field Office
	11. Forwards Inspection Report to Licensing Section	None		
	12. Prepares Certificate of Compliance (COC) / Letter of Disapproval (LOD) / Recommendation Letter (RL) whichever is applicable 12.1 Updates DTS 12.2 Forwards to Licensing TL/Supervisor	None	2 working days	Licensing Officer/Assigned Personnel Regional Field Office

	13. Checks and affixes initials to COC / LOD / RL	None		Team Leader/ Supervisor Regional Field Office
	14. Approves/signs COC/RL/LOD	None		Director/Supervisor Regional Field Office
	15. Updates Database	None		Data Controller/Assigned Personnel Regional Field Office
	16. Releases COC/LOD/RL 16.1 Updates DTS 16.2 Forwards COC / RL to Centers or LOD to Central Releasing cc: Centers	None	1 working day	Data Controller/ Assigned Personnel 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

A. SIMPLE

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
I. **Inspection** [SITE/LOCATION OF CARGO /SHIPMENT]
II. **Opening Meeting** [BOC Examiner and Consignee/ Consignee's authorized representative]
III. **Actual inspection of the cargo/shipment** 3.1 temperature storage condition 3.2 physical examination of the products [appearance and label]
IV. 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]

V. **Collection of product samples** [as applicable and necessary]
VI. **Report Writing** (Observation and findings/recommendation/directives)
VII. **Exit Meeting** (discussion observation and findings/recommendation/directives)

B. COMPLEX

INSPECTION AGENDA – FOOD DISTRIBUTOR

Inspection Activity
I. Opening Meeting
II. 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 Products (physical examination / Collection of samples)

3.3 Transport & Dispatch of products

- Vehicle Maintenance, Personnel, Compliance to Storage Requirements

IV. Report Writing (Consolidation of findings)

V. 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
    a. Copy of valid LTO of Toll Manufacturer / Repacker
    b. Notarized Toll Packing / Food Manufacturing / Repacking Agreement (including warehousing & logistics services)
  - For Importer of Raw Material for own use:
    a. Foreign Agency Agreement (Distributorship Agreement / Proforma Invoice / Commercial Invoice / Certificate/Letter of Appointment;
    b. 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:
  a. Handling Product Recall, Complaints and Returns
  b. Pest Control including Service Records / Contract
  c. Stock Management Control
  d. Dispatching & Transporting of Products
  e. Cleaning & Sanitation
  f. 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

I. <u>Ocular Inspection</u> [declared office address]

1.1 Premise [accessibility, suitability, display of FDA License To Operate (LTO)]

I.1.1 <u>Opening Meeting</u> [Introduction/ Stating Purpose of Inspection/, Presentation of Inspection Agenda, Accomplishment of Attendance Sheet]

I.1.2 <u>Document Review</u>

<u>Note:</u> presentation/provision of the following documents will depend or based on the findings noted during inspection [as applicable and necessary]

<u>GENERAL DOCUMENTS</u>

- 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 <u>if no warehouse facility is declared</u>
- 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

II. 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

III. **Ocular inspection of Transport Vehicle**
IV. **Report Writing** (Observation and findings/recommendation/directives)
V. **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 ☐ Attendance record **II. 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)
- 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*
  - *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*

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

- 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)
  - Temperature monitors
- Sanitation /Pest Control Records
- Arrangement of stocks (to avoid mix-ups)
- Stock Rotation ((first expiry/first out (FEFO) system must be observed)

3.2 Records

- Recorded temperature and relative humidity (RH) monitoring data
- Calibration records of temperature/RH monitors
- Stock Reconciliation/ Inventory
- Dispatch Records

3.3 Products

- 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/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 time and temperature sensitive pharmaceutical products (TTSPPs)
- ☐ Dispensing apparatus including ice packs for dispensing of TTSPPs
- ☐ Product compliance to registration and labeling requirements – may collect product

B 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 or other relevant trainings
- ☐ 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 */ MDRP (EO 821 & EO 104 / IEC materials) / GMAP / EDPMS*
- Temperature Monitoring records (bioref/ refrigerator if with TTSPPs and room)
- Calibration Certificates of temperature monitoring device/s and/or bioref
- Franchise agreement (if applicable)

IV. Report writing

- Consolidation of findings; when necessary

V. 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/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; when necessary

V. Exit Meeting

- Attendance record /Discussion of findings or deficiencies /violation

INSPECTION AGENDA – COSMETICS & HOUSEHOLD URBAN PESTICIDES DISTRIBUTOR

Inspection Activity
I. Opening Meeting • Introductions • Inspection scope • Attendance record **II. Document Review** ***2.1* 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 ***2.2*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

2.3 **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>

3.1 **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)

3.2 **Products**

- Labeling compliance
- Status of Notification/ Product registration
- Sample collection (as necessary)

3.3 **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

IV. Report Writing

- Consolidation and discussion of findings

V. Exit Meeting

- Attendance record
- Presentation/ discussion of findings
- Signing of Inspection Report

INSPECTION AGENDA – HOSPITAL PHARMACY

Inspection Activity
I. Opening Meeting • Introductions / Inspection scope/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

V. Exit Meeting

- Attendance record /Discussion of findings or deficiencies /violation

C. HIGHLY TECHNICAL

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
- Major Changes

On-site and Document Inspection

- *Establishment Records:*
  - License to Operate
  - List of Toll Manufacturers and Activities
  - 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)
- *Registered Pharmacist's Records:*
  - PRC ID, PTR
  - Certificate of Attendance to Licensing Seminar
  - Number of LTO and products being handled

- *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 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 – EXTERNAL 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
    - CAPA
    - Supplier Qualification
    - Product Dossier
    - Batch Release Procedure
  - Personnel
    - Organizational Chart
    - Job Description
    - Training and Assessment
    - Personnel Hygiene
    - Health Examination
  - Qualification and Validation
    - Process verification
  - Batch Manufacturing Records
    - BMR Review
    - 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 (VIE/mobile tank)
      - Design
      - Maintenance
      - Usage and requirements (e.g. liquid levels, pressure etc)
    - Cleaning and Purging
    - Qualification of pipelines and manifolds (for shared equipment of different gases)
    - Repair and Maintenance
    - Delivery tankers (incl. Maintenance and Qualification records)
    - Condition of pipelines, manifolds, tester, valves and other equipment
    - Calibration of in-line process monitors and other equipment
    - 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)
- 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 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
  - Clean Steam
    - Design and Structure
    - Operation and Maintenance
    - Monitoring and Testing
  - Sterile Gases
    - Generation or Procurement
    - Maintenance
    - 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 Laboratory
    - 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
- Environmental Monitoring (Production and QC Lab)
- Stability Studies (Accelerated and Real Time)
- Out-of- Specification
- Retention Samples
- Other related QC tests and records

- Documentation
    - Document control (*history, issuing, superseded, obsolete)*
    - 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
  - Media Fill
  - Disinfectant 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
- Handling of Product Complaints and Recall
- Outsourced Activities (qualification of suppliers)
- Self-Inspection

Report Writing
Discussion of audit findings

INSPECTION AGENDA – NON-STERILE 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
● Plant Tour around premises
● 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
  - Finished Product Release procedure
  - Product Quality Review

- Supplier Qualification including audits
- Validation Master Plan including protocols and records for:
  - 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
    - Storage for flammable and/or 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

- *Production (Process Flow)*
  - Gowning procedures
    - Laundry
  - Sampling
    - Method of sampling and inspection
    - Sampling tools and kits
  - Dispensing / Weighing
  - Processing
    - Formulation
    - In-process and Line clearance checks
    - Rework/reprocessing
    - Storage of bulk product
    - Contamination and Cross-contamination control strategies
  - Packaging
    - Control of labels & pre-printed packaging materials
    - Coding and coded materials
    - Control of mix-up
  - In-process controls
  - Storage of packed product (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
  ▪ Gases

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
    - Parametric Release
    - 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
    - Disinfectant 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
  - Log of entry and exit
- 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
  - 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)
  - 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** o Production areas o Sampling Area o Packaging o Maintenance of facilities o Cleaning of equipment o Maintenance/Calibration of Equipment o Pest Control o Waste Disposal ☐ **Warehouse**

- Raw Materials
- Packaging Materials
- Finished Goods

DOCUMENTATION REVIEW

- ☐ Duly Accomplished Integrated Application Form
- ☐ DTI / SEC Registration
- ☐ Business Permit / Mayor'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
I. <u>Opening Meeting</u> • Introductions

- Inspection scope
- Attendance record

II. Document Review

2.1 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

2.2 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

2.3 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

***3.1* 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)

***3.2* Products**

- Labeling compliance
- Status of Notification/ Product registration
- Sample collection (as necessary)

***3.3*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

VI. Report Writing

- Consolidation and discussion of findings

VII. 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	