COMMON SERVICES LABORATORY
EXTERNAL

1.ACCREDITATION OF PRIVATE TESTING LABORATORY

The Republic Act No. 9711, otherwise known as the “The Food and Drug Administration Act of 2009,” empowers the FDA to accredit private testing laboratories to increase the testing laboratories that may conduct testing, calibration, assay and examination of samples of health products. This application for laboratory accreditation for private testing laboratories follows the rules and regulations stipulated in the FDA Order No. 2012-001.

Center/Office/Division:	Common Services Laboratory (CSL) – Office of the Director, Receiving and Releasing Unit, Laboratory Accreditation Team FDA Cashier
Classification:	Highly Technical Transaction
Type of Transaction:	G2B - Government to Business
Who May Avail:	Private Testing Laboratory
Fees to be Paid:	1) Audit of Testing Laboratory (per visit) Within Metro Manila - PHP 10,000.00 + transportation cost Outside Metro Manila - PHP 10,000.00 + per diem/per auditor + transportation cost 2) Accreditation of Testing Laboratory Fee (per year) – PHP 20,000.00 3) Legal Research Fee (LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Duly Notarized Accomplished Petition Form (FDA Order No. 2012-001 Annex A)	FDA Website (www.fda.gov.ph)
Copy of valid ISO 17025 Certificate of Accreditation with defined scope of accreditation issued by Philippine Accreditation Bureau (PAB) within the last six months prior to date of application with FDA (1 scanned or photocopy)	Applicant
Copy of Laboratory Quality Manual and List of SOPs (1 scanned or photocopy)	Applicant
List of PAB Approved Signatories for the particular test or types of test covered by the Scope of Accreditation (1 scanned or photocopy)	Applicant
Location Map of the Laboratory (1 scanned or photocopy)	Applicant

Copy of latest PAB assessment findings with corresponding corrective action (1 scanned or photocopy)	Applicant
Floor layout with appropriate scale reflecting laboratory areas (1 scanned or photocopy)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submits scanned copy of requirements to info@fda.gov.ph with the email subject: ***CSL_Accreditation of Testing Laboratory [space] Name of Laboratory*** *Note:* Printed copies of the requirements may be forwarded to FDA Central Office, Alabang, Muntinlupa City, through courier.	Receives and acknowledges receipt of the email inquiry and forwards to the CSL.	None	Refer to FDAC Citizen's Charter	*Information Officer II* FDAC
	Receives application requirements and provides Document Track Number (DTN). Pre-evaluates submitted documents as to completeness: If found non-compliant, application is rejected and Applicant is informed of the noted discrepancies on the submitted documents. If found compliant, a tentative date for audit will be scheduled.	None	–	*Laboratory Accreditation Secretariat* CSL – Laboratory Accreditation Team
	Sends Notice of Audit to the Applicant through email.	None	1 Working Day	
	Reviews submitted document as pre-audit assessment.	None		*Laboratory Accreditation Member*

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
				CSL – Laboratory Accreditation Team
Confirms the proposed date of audit within seven (7) working days after receipt of Notice of Audit. *Note:* Non-receipt of confirmation to the scheduled assessment within the stipulated timeline shall mean forfeiture of application.	Conducts audit (remote or on-site) and provides audit report with findings and recommendations.	None	3 Working Days	*Laboratory Accreditation Member* CSL – Laboratory Accreditation Team
Submits signed first corrective action plan through email or courier.	Receives documents sent through courier and forwards to assigned auditors.	None	6 Working Days	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Evaluates first corrective action plan and sends prepared report to the Applicant.	None		*Laboratory Accreditation Member* CSL – Laboratory Accreditation Team
Submits second and/or third corrective action plan through email or courier.	Receives documents sent through courier and forwards to assigned auditors	None	8 Working Days	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Evaluates second and/or third corrective action plan and sends prepared report to the Applicant.	None		*Laboratory Accreditation Member* CSL – Laboratory Accreditation Team
	Provides Final Evaluation Report and notifies Applicant that accreditation is granted or denied.	None		

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Issues assessment slip to the Applicant.	None		*Laboratory Technician* CSL – Receiving and Releasing Unit
Proceeds to their preferred payment option; submits clear copy of proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to csl@fda.gov.ph.	Posting of payment.	PHP 10,000 (x no. of visit) + PHP 20,000 (x year) + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
	Upon confirmation of payment from FDA Cashier, prepares Certificate of Accreditation and Scope and prints on security paper and plain A4 paper with the official receipt no./reference number.	None	2 Working Days	*Laboratory Accreditation Member* CSL – Laboratory Accreditation Team
	Signs Certificate of Accreditation and Scope.	None		*Director II* CSL
	Releases signed Certificate of Accreditation and Scope to the Applicant.	None		*Laboratory Accreditation Member* CSL – Laboratory Accreditation Team
	TOTAL		**20 Working Days**	

2.ISSUANCE OF LOT RELEASE CERTIFICATION FOR VACCINES AND BIOLOGICAL PRODUCTS

The Certificate of Lot or Batch Release or Lot or Batch Release Certificate is a document for each lot or batch of a vaccine or biologic product issued by the NRA of the exporting country or the country of origin. It is part and parcel of a Summary Lot or Batch Protocol, and is accompanied by the following: a) a label of the final container approved by the NRA of the exporting country or country of origin, and b) an instruction leaflet or product insert for users approved by the NRA of the exporting country or country of origin. Issuance of Lot Release Certificate (LRC) for Vaccine and Biological Products to Marketing Authorization Holder (MAH)

Center/Office/Division:	Common Services Laboratory (CSL) – Office of the Director, Receiving and Releasing Unit, Vaccines and Biologicals Unit FDA Cashier FDA Records
Classification:	Complex Transaction
Type of Transaction:	G2B - Government to Business
Who May Avail:	All FDA-Licensed Vaccines and Biologicals Marketing Authorization Holder (Importers and Distributors)
Fees to be Paid:	PHP 1,000.00 + Legal Research Fee (LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Duly notarized accomplished Lot Release Application Form with declaration and undertaking	FDA website (www.fda.gov.ph)
Self-Assessment Checklist for Lot Release Certification.	FDA website (www.fda.gov.ph)
Certificate of Product Registration (CPR) complete with its annexes (Certificate of Variation, if any) and valid at the time of application (1 original scanned copy)	Applicant
Valid License to Operate (LTO) of the: Manufacturer (if applicable) Distributor Importer	Applicant
Certificate of Analysis (CoA) for the Final/ Finished Product (and for the diluent as necessary)	Applicant

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Three (3) final containers of representative product samples in their final packaging representation in proper storage condition as per approved specification. *(Note: For products with multiple final containers in one (1) box, only three (3) final containers are required but will still be submitted inside the box)*	Applicant
SOP for Sampling Method from the license holder	Applicant
Complete Summary Lot Protocol (SLP)	Applicant
Manufacturing Process Flow Diagram	Applicant
. Batch Numbering System	Applicant
. For imported products, Lot Release Certificate (or equivalent National Regulatory Authority (NRA) certification) from the country of origin of the product	Applicant
. One (1) set of final packaging materials as seen on the actual samples (including primary and secondary packaging/labels that of the diluent, and package insert)	Applicant
. Generic Labelling Exemption (if applicable)	Applicant
. Pro forma invoice, packing list, shipping invoice or any document indicating the lot number and actual number of doses/units delivered/shipped in the Philippines (for imported products)	Applicant
. Temperature monitoring data during shipment (Cold Chain Documents)	Applicant
Additional Requirements	
For government-procured products (Expanded Program on Immunization (EPI's) and non-EPI's): Purchase Order and Notice of Award from the Department of Health	Department of Health
For donated vaccines/ biological products: Identification of Medical Officer who will be responsible for prompt reporting Adverse Drug Reaction (ADR)/ Adverse Event Following Immunization (AEFI), among others to FDA and/or Report/ Recommendation of the Field Regulatory Operations Office (FROO) on the inspection of the actual shipment	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submits application for pre-assessment to cslvbu@fda.gov.ph. All submissions shall contain all the specified documentary requirements for National Lot Release in PDF format. *Note:* If a file to be provided is too large to be an email attachment, link to a cloud storage (e.g., Google Drive, Microsoft OneDrive, etc.) may be allowed, provided that all files have download privileges.	1. Pre-assess the application as to the completeness of requirements. If found to be non-compliant, Applicant will be informed via email indicating the deficiencies and/or discrepancies noted and will be advised to submit necessary documents prior to acceptance. If found to be compliant, Applicant will be informed via email and will be issued with Document Tracking Number (DTN) and an assessment slip.	None	–	*Food-Drug Regulation Officer* CSL – Vaccine and Biological Unit
Proceeds to their preferred payment channel.	Posting of payment.	PHP 1,000/ application + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
Sends documentary requirements via csl@fda.gov.ph with the subject: ***National Lot Release Initial Application_DTN(14-digit number)*** Filled out Excel copy of the application form; Scanned copy of proof of acceptance in PDF format; Accomplished assessment slip; and Official receipt or machine-validated Landbank ONCOLL payment slip.	Reviews and checks submitted documentary requirements, and performs the following steps: Assigns LRV No. Fills out the necessary information in the Excel copy of the application form. Records information to CSL-Receiving and Releasing Unit Database.	None	1 Hour	*Laboratory Technician* CSL – Receiving and Releasing Unit

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Inform CSL-Vaccine and Biological Unit and the Applicant on the receipt of the application. Forwards the documentary requirements via email to cslvbu@fda.gov.ph.			
Submits the representative sample/s and notarized application form at the FDA Central Office, Alabang, Muntinlupa City.	1 Checks the application requirements and representative sample/s.	None	2 Hours	*Food-Drug Regulation Officer* CSL – Vaccine and Biological Unit
	2 Receives and reviews documentary requirements, and decks the application for evaluation.	None	2 Hours	
	Evaluates the application and prepare the corresponding worksheet/s. Performs visual examination of samples, updating Section Database, and wrapping and tagging of samples.	None	5 Working Days	
	Review of Worksheet and Preparation of Lot Release Certificate or Letter of Denial (as applicable, indicating noted findings as to why safety and quality could not be established).	None	4 Hours	*Food-Drug Regulation Officer/Laboratory Technician* CSL – Vaccine and Biological Unit
	Reviews and approves Lot Release Certification or Letter of Denial (as applicable).	None	30 Minutes	*Food-Drug Regulation Officer*

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
				CSL – Vaccine and Biological Unit
	Signs the Lot Release Certificate or Letter of Denial (as applicable).	None	10 Minutes	*Director II* CSL
	Forwards signed Lot Release Certificate or Letter of Denial (as applicable) to FDA Records.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Scans and releases Lot Release Certificate or Letter of Denial (as applicable) to the Applicant.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**7 Working Days**	

3.CONDUCT OF ROUTINE LABORATORY ANALYSIS

Conduct of Routine Laboratory Analysis, including testing through Accredited Third Party Laboratory

Laboratory testing involves the physico-chemical and microbiological analysis of health products to determine compliance with the standards of safety, efficacy, purity and quality. Samples received by the Common Services Laboratory are categorized as:

a. Complaints – These are alleging deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a health product after release from distribution. High-risk complaints shall be processed for seven (7) working days.
b. Government Deliveries – These are health products submitted by government agencies like the Department of Health, Local Government Units and government hospitals. Government deliveries for anti-tuberculosis drugs (DOH-LMD) shall be processed for fifteen (15) working days.
c. Donations – Samples coming from government and private institutions intended for donations.
d. Referrals – These are health products referred by the FDA Centers or Offices (CDRR, CFRR, CCHUHSRR, CDRRHR, Regulatory Enforcement Unit, FDA Satellite laboratories)
e. Post Market Surveillance (PMS) – These are health products sampled/collected by the FDA Inspectorates and Regulatory Enforcement Officers, as part of monitoring the safety, effectiveness, efficiency and performance after it has been released on the market. This includes Annual Post-Marketing Surveillance (APMSP) and *motu propio*, among others. PMS is an important part of FDA's advocacy in health/pharmacovigilance.

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Duly Accomplished Request for Analysis (RFA) Form	FDA website (https://www.fda.gov.ph/downloadables/)
Actual Sample/s Quantity should be in accordance with FDA Circular No. 2014-014 "Minimum Number of Samples Units required for Each Test Analysis"	Applicant/Requesting Party https://www.fda.gov.ph/wp-content/uploads/2021/06/FC2014-014-Minimun-Numbers-of-Samples-Units-Required-for-Each-Test-Analysis.pdf
With expiration date at least three (3) months prior to request for analysis	
Actual sample per request should bear the same batch or lot	
Properly handled	
Additional Requirements	
If purpose of collection is **scheduled/planned PMS** - compliance to the current approved APMSP.	
For Complaint Samples	

- Copy of Medical certificate or any document that will serve as a guide to the laboratory on the analyte that has to be checked - Copy of Report on the interview conducted, if any - Endorsement from the concerned FDA Center, if applicable - For food-borne illness outbreak-related samples, information on the onset of symptoms, time of consumption, and other food consumed must be provided. *e:* Sample that will be submitted to the CSL for analysis should be from the same batch or lot number as the subject product of the complaint.	

Center/Office/Division:	Common Services Laboratory (CSL) – Office of the Director, Receiving and Releasing Unit, Laboratory Sections FDA Cashier FDA Records
Classification:	Highly Technical Transaction
Type of Transaction:	G2G - Government to Government; G2C - Government to Client (G2C)
Who May Avail:	Government Agencies, FDA Centers and Offices
Fees to be Paid:	DOH Administrative Order No. 50 s. 2001 (Refer to Table 11.1) + Legal Research Fee (LRF)

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Sends Request for Analysis (RFA) per request through email: For Alabang Testing and Quality Assurance Laboratory: atqal.rfa@fda.gov.ph For Cebu Testing and Quality Assurance Laboratory: ctqal.rfa@fda.gov.ph For Davao Testing and Quality Assurance Laboratory: dtqal.rfa@fda.gov.ph	Pre-assessment and evaluation of the RFA based on the following requirements: If the above requirements are not met, the Customer shall be informed by email response and/or by telephone communication, indicating that the request is rejected. Consequently, RFA will be	None	–	*Food-Drug Regulation Officer/Health Program Officer/Laboratory Technician* CSL – Receiving and Releasing Unit

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
For Internal Customers (FDA Centers/Offices), email subject shall be: ***Purpose of Collection [space] Center/Region*** For External Customers (other Government Agencies), email subject shall be: ***Name of Agency [space] RFA*** *Note:* For requests for analysis related to food-borne illness outbreak, pre-assessment and evaluation of RFA will be conducted in-person. For requests for analysis from Regulatory Enforcement Unit (REU), pre-assessment and evaluation of RFA will be conducted through videoconferencing.	returned, for appropriate actions. Revised RFA shall be submitted for pre-assessment prior to acceptance. If the above requirements are met, the request is accepted. *Note:* For External Customers, a reference number will be issued during pre-assessment.			
Submits the required number of samples for laboratory analysis, as well as the printed and signed copies of pre-assessed RFA.	Receives and assesses accuracy of information indicated in the RFA vis-a-vis the actual sample. Likewise, checks if compliant with the required handling conditions. If found acceptable, issues Laboratory Number.	None	15 Minutes	*Food-Drug Regulation Officer/Health Program Officer/Laboratory Technician* CSL – Receiving and Releasing Unit

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	If found unacceptable, rejects the RFA and issues Letter for Returned Sample.			
	2 Encodes RFA in CSL database.	None	5 Minutes	*Food-Drug Regulation Officer/Laboratory Technician* CSL – Receiving and Releasing Unit
	3 Forwards the following to the concerned Section: RFA Sample Transmittal Sheet	None	5 Minutes	*Food-Drug Regulation Officer/Laboratory Technician* CSL – Receiving and Releasing Unit
	Receives and updates the FDA Inventory System (FIS), as well as the Database: RFA Sample Transmittal Sheet	None	10 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL– Laboratory Section/s
	Records received samples in respective Section's Database and schedules decking of samples for testing.	None	10 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL– Laboratory Section/s
	Handles and stores samples for testing in designated location.	None	5 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL–

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
				Laboratory Section/s
	Pre-evaluates received samples as per label and/or test required.	None	10 Minutes	*Laboratory Technician/ Administrative Aide* Concerned CSL–Laboratory Section/s
	Conducts laboratory testing with corresponding processing timelines: **A. Complaints** High risk Low-medium risk **B. Government deliveries** Anti-tuberculosis (TB) drugs (DOH-LMD) DOH-LMD, other than TB drugs Other government agencies (LGUs, etc.) **C. Donations** **D. Post-marketing Surveillance** **E. Referrals** **F. Microbiological Tests *(see notes)*** Sterility testing Commercial sterility Evaluation of antimicrobial protection	None	**(A)** 5 Working Days 18 Working Days **(B)** 13 Working Days 18 Working Days 18 Working Days **(C)** 18 Working Days **(D)** 18 Working Days **(E)** 18 Working Days	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
			(F) 18 Working Days 23 Working Days 42 Working Days (note: with pending request to ARTA)	
	Records and compute data gathered from laboratory testing.	None	1 Working Day	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s
	Evaluates data and results from laboratory testing.	None	4 Hours	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s
	Prepares Test Reports	None	1 Hour	*Laboratory Technician/ Administrative Aide* Concerned CSL–Laboratory Section/s
	Signs all test reports	None	10 Minutes	*Food-Drug Regulation Officer* Concerned CSL–Laboratory Section/s
	Signs non-conforming test reports	None	10 Minutes	*Director II* CSL

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Issues assessment slip and/or order of payment for fees for the tests/ parameters conducted.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
Proceeds to their preferred payment channel; submits clear copy of the proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to concerned laboratory email: Alabang (atqal.rfa@fda.gov.ph); Cebu (ctqal.rfa@fda.gov.ph); or Davao (dtqal.rfa@fda.gov.ph).	Posting of payment.	Fee for Test/ Parameters Conducted (refer to Table 11.1) + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
	Upon confirmation of payment, forwards the Test Report with assessment slip and/or order of payment to FDA Records.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Releasing of Test Reports to External Customer.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**20 Working Days except** **(A) High Risk** **7 Working Days** **(B) TB Drugs 15 Working Days**	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
			(F) Antimicrobial Protection **44 Working Days**	

NOTES:

- Samples subject for **Sterility Testing** requires a total number of **twenty-eight (28) calendar days** (equivalent to **twenty (20) working days**), which includes: (1) 1-day media preparation; (2) 2-days preparation of reference culture; (3) 5 days Growth Promotion Test and Method Suitability Test; (4) 14 days Incubation period; (5) 4 days Confirmatory Test and (6) a total of 2 days for receiving, data recording and computation, evaluation, reporting and releasing to RRU. *(Reference: United States Pharmacopeia and the National Formulary USP/NF <71> Sterility Test)*
- Samples subject for **Commercial sterility** of thermally processed foods in hermetically sealed containers requires approximately **thirty-three (33) calendar days** (equivalent to **twenty-three (23) working days**), which includes: (1) 1-day media preparation; (2) 10-days sample pre-incubation; (3) 5-days sample culturing; (4) 15-days (as needed) Sub-culturing, morphological characterization and Confirmatory tests; (5) a total of 2 days for receiving, data recording and computation, evaluation, reporting and releasing to RRU. *(Reference: Bacteriological Analytical Manual (BAM) Chapter 21A: Examination of Canned Foods 8th Edition by AOAC International)*
- Samples subject for **Evaluation of the Antimicrobial Protection** of a Cosmetic Product requires a total number of **sixty (62) calendar days** (equivalent to **forty-four (44) working days**), which includes: (1) 1 day media preparation; (2) 16 days preparation of inoculate; (3) 5 days of demonstration of the neutralizer efficacy, additional 5 days for modification of the neutralizer (if necessary); (4) 33 days of determination of the Preservation Efficacy of the Formulation; and (6) a total of 2 days for receiving, data recording and computation, evaluation, reporting and releasing to RRU. *(Reference: ASEAN Cosmetic Method: Evaluation of the Antimicrobial Protection of a Cosmetic Product ACM No. 008; ISO 11930:2019 – Evaluation of the Antimicrobial Protection of a Cosmetic Product)*

TABLE 11.1. SCHEDULE OF FEES BASED ON DOH ADMINISTRATIVE ORDER NO. 50 s. 2001

CLASSIFICATION	FEES (PHP)
Physico-chemical Analysis	
Drugs and Antibiotics	
Visual Examination	300.00
Assay/Potency (single component)	1,500.00
Assay/Potency (multi-component)	2,000.00
Dissolution Test	2,000.00
Disintegration Test	350.00
Hardness Test	350.00
Identification Test	500.00
Purity Test / Related Substances	500.00
Moisture Content	300.00
Loss on Drying	300.00
pH	300.00
Vitamins	
Vitamin A	1,000.00
Vitamin B1, B2, B6	2,000.00
Vitamin C (Ascorbic Acid)	500.00
Vitamin E	500.00
Other Vitamins	500.00
Minerals	800.00
in vitro Diagnostic Reagents	1,000.00
Medical Devices	1,500.00
Cosmetics	
Assay	1,200.00
Identification Test	500.00
Volatile/Non-volatile Matters	500.00
Food Products	
Moisture	300.00

CLASSIFICATION	FEES (PHP)
Protein	1,000.00
Fat/Oil	500.00
Starch	500.00
Glucose	500.00
Sucrose	500.00
Lactose	500.00
Crude Fibers	500.00
Dietary Fibers	2,000.00
Total Solids	300.00
Soluble Solids	300.00
Water-Insoluble Solids	300.00
Ash	300.00
Acid-insoluble Ash	500.00
Saponification Number	500.00
Viscosity	300.00
Refractive Index	300.00
Peroxide Value	500.00
Free Fatty Acids	500.00
Permanganate Oxidation Number (PON)	500.00
Total Acidity	300.00
Water Activity	500.00
Vacuum	300.00
Minerals	1,000.00
Amino Acids (LC)	2,000.00
Proline	500.00
Additives	
Nitrate	500.00
Nitrite	500.00
Sodium Benzoate	500.00

CLASSIFICATION	FEES (PHP)
Sorbic Acid	500.00
Food Color	300.00 per color
Sodium metabisulfite	500.00
Bromates	500.00
BHT	500.00
BHA	500.00
Aspartame	500.00
Saccharin	500.00
Monosodium Glutamate	500.00
Micronutrients	
Vitamin A	1,000.00
Vitamin E	1,000.00
Beta Carotene	1,000.00
Vitamin C	500.00
Vitamin B1, B6	1,000.00
Vitamin B1, B6, Niacin	1,000.00
Iodine	500.00
Iron	500.00
Contaminants	
Borax	300.00
Aflatoxin	2,000.00
Total heavy metals	500.00
Lead	500.00
Cadmium	300.00
Chromium	300.00
Arsenic	300.00
Mercury	300.00
Tin	300.00
Cyanide	300.00
Histamine	1,500.00

CLASSIFICATION	FEES (PHP)
Filth	500.00
Formalin	500.00
Pesticide residue	2,000.00
Alcohol content	1,000.00
Gas volume	300.00
Total Soluble Solids (Brix)	300.00
pH	300.00
Caffeine	500.00
Food Supplements	4,000.00
Beverages	
Alcohol Content	1,000.00
Gas Volume	300.00
Total Soluble Solids (Brix)	300.00
pH	300.00
Caffeine	500.00
Bottled Water	2,000.00
Food Chemicals/Additives	
Direct	1,000.00
Indirect	500.00
Containers/Wrappers	
Migratable Substances	1,000.00
Plastic Additives	500.00
Cellulosic Materials for Pesticide Residue	1,500.00
Materials Testing	500.00
Microbiological Assay	
Potency of Antibiotics	2,500.00
Sterility Tests	
Injectables, Medical Devices, and Large Volume Parenterals	2,500.00
Microbial Limit Tests	

CLASSIFICATION	FEES (PHP)
Aerobic Plate Count	500.00
Aerobic Halophilic Count	500.00
Aerobic Thermophilic Count	500.00
Coliform Plate Count	500.00
Coliform / *Escherichia coli* (MPN)	500.00
Fecal Streptococci	600.00
Yeast and Mold Count	500.00
Halophilic Yeast Count	500.00
Staphylococcus aureus Count	600.00
Pseudomonas aeruginosa	600.00
Identification of Microorganisms (*Salmonella* sp.)	
Presumptive Test	600.00
Confirmatory Test (complete biochemical reaction)	2,000.00 per organism
Commercial sterility of thermally processed foods in hermetically sealed containers	1,000.00
Bioassay Tests	
Bacterial endotoxin test (LAL)	4,000.00

4.ISSUANCE OF EXPORT CERTIFICATE FOR ACACIA WOODENWARES (VOLUNTARY)

Voluntary application for Issuance of Export Certificate for Acacia Woodenwares.

Center/Office/Division:	Common Services Laboratory (CSL) – Receiving and Releasing Unit, Cosmetic-Toxicology Section Food and Drug Action Center (FDAC) FDA Cashier FDA Records
Classification:	Complex Transaction
Type of Transaction:	G2B - Government to Business
Who May Avail:	Acacia Woodenwares' Exporting Companies
Fees to be Paid:	PHP 500.00 + Legal Research Fee (LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Request Letter stating the intended use of the product (1 signed scan copy)	Applicant
Product Information (1 scanned copy of each, with the product name as the filename) Technical Specification Intended use (State if direct or indirect contact with food) Overview of the production process Packing List including Net and Gross Weight	Applicant
Certificate of Analysis wherein Batch/Lot No. and Production date are indicated (1 original scanned copy, with the product name as the filename)	Applicant
Health and Safety Information / Safety Data Sheet for finished product and raw materials (1 original scanned copy, with the product name as the filename	Applicant

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Formulation/Composition indicating the specific chemical names and corresponding CAS numbers of all raw materials used (including lacquers, colorants and additives, if any (1 original scanned copy, with the product name as the filename)	Applicant
Report of Analysis based on finished article/product being applied for evaluation from an FDA-accredited laboratory. The Batch/Lot No. must be indicated in the Test Report (1 original scanned copy, with product name as the filename)	FDA-accredited Laboratory
Clear photos of the product capturing all parts i.e., inner and outer parts (photos should be in .jpeg, .png, or .pdf file, with product name as the filename)	Applicant
Proof of payment e.g., Official Receipt, LandBank ONCOLL Machine-Validated Payment (1 original scanned copy)	LandBank/Online Banking

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submits the scanned copy of the requirements to info@fda.gov.ph with the email subject: ***CSL_Voluntary Application for Certification of Acacia Wooden Wares***	Receives application and forwards to CSL	None	Refer to FDAC Citizen's Charter	*Information Officer II* FDAC
	Pre-assesses the application as to the completeness of requirements and assigns Document Tracking Number (DTN). If found non-compliant, informs the Applicant via email for	None	–	*Food-Drug Regulation Officer / Health Program Officer / Laboratory Technician* CSL – Receiving and Releasing Unit

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	submission of necessary documents. If found compliant, issues an assessment slip and advise the Applicant to make the necessary payment through acceptable payment channels			
Proceeds to their preferred payment channel; submits a clear copy of the proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to csl@fda.gov.ph.	Verifies, validates, and posting of payment.	PHP 500/ application + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
	Forwards the application to the Cosmetic-Toxicology Section upon receipt of payment confirmation from FDA Cashier.	None	5 Minutes	*Food-Drug Regulation Officer / Health Program Officer / Laboratory Technician* CSL – Receiving and Releasing Unit
	Receives and prints forwarded application/s, records in Section Database, and decks the application for evaluation.	None	30 Minutes	*Food-Drug Regulation Officer / Administrative Assistant* CSL – Cosmetic-Toxicology Section
	Conducts food suitability evaluation.	None	6 Working Days	
	Forwards the result of evaluation and Export Certificate to the CSL-Receiving and Releasing Unit.	None	10 Minutes	*Administrative Assistant* CSL – Cosmetic-Toxicology Section

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Emails the scanned copy of the result of evaluation and Export Certificate to the Applicant.	None	2 Minutes	*Food-Drug Regulation Officer / Health Program Officer / Laboratory Technician* CSL – Receiving and Releasing Unit
	Forwards the result of evaluation and Export Certificate (original printed copy) to the FDA Records Section for release.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Releases the result of evaluation and Export Certificate to Applicant.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**7 Working Days**	

NOTES:

1. Failure to submit the mandatory documentary requirements, and submission of documents that do not substantiate the suitability and safety of the product for its intended use shall be grounds for denial/disapproval of the application. Once denied/disapproved, re-application may opt to be done considering the noted observations on the initial application. Re-application entails payment of the required fee.

5.ISSUANCE OF FOOD EXPORT CERTIFICATE AND FOOD COMMODITY CLEARANCE

Pursuant to Section 3 of Presidential Decree No. 930 otherwise known as Export simplification Decree, the FDA, then BFAD, issued a guidelines through the Administrative Order No. 15-a s. 1981 for the simplified export procedures for the information and guidance of all exporters. The issuance of food export certificate and food commodity clearance applies to all FDA-licensed food establishments.

Center/Office/Division:	Common Services Laboratory (CSL) – Office of the Director, Receiving and Releasing Unit, Food Section FDA Records
Classification:	Simple Transaction
Type of Transaction:	G2B - Government to Business
Who May Avail:	All FDA-Licensed Food Establishments (Manufacturers, Traders, and Exporters)
Fees to be Paid:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Scanned copy of the completely filled-out Application Form in two (2) copies	FDA website (https://www.fda.gov.ph/downloadables/)
Scanned copy of valid License to Operate (as manufacturer/trader/ exporter, whichever is applicable)	Applicant
Scanned copy of a valid Certificate of Product Registration of the product for export	Applicant
Scanned copy of the signed Packing List or Sales Invoice (System generated/electronically signed is also accepted)	Applicant
Excel copy of the filled-out templates of the draft Certificates and database	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Downloads the Application Form, draft template of the Certificate, and database from the FDA website.	Checks email requests lodged at cslexport@fda.gov.ph.	None	30 Minutes	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Applicant to fill-out the required information and submit an email request with attached soft copies of the forms to cslexport@fda.gov.ph.				*Food-Drug Regulation Officer / Laboratory Technician* CSL – Food Section
	Reviews application for completeness of requirements and correctness of Application Form.	None	1 Hour	
	If found non-compliant, the application is returned to the Applicant stating the reason for rejection.	None	30 Minutes	
	If found compliant, a Reference Number is issued for each application received.	None	30 Minute	
	Edits draft Certificate submitted to reflect Reference Number (FE for Food Export and FCO for Food Commodity Clearance).	None	1 Hour	
	Shares the prepared Certificate and/or Clearance at the network with the issued Reference Number as the label.	None	1 Hour	
	Reviews the prepared Certificate and/or Clearance.	None	30 Minutes	
	Prints the final copy of the Certificate and/or Clearance and submits to the CSL Director for signature.	None	30 Minutes	
	Signs the Certificate and/or Clearance.	None	30 Minutes	*Director II* CSL

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Seals the approved and signed Certificates and/or Clearances.	None	30 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Updates the CSL Main Database.	None	30 Minutes	
	Prints the transmittal slip in two (2) copies	None	30 Minutes	
	Forwards Certificates and Clearances and transmittal slip to FDA Records for release.	None	30 Minutes	
	Releases the Certificates and/or Clearances to the Applicant.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**1 Working Day**	

NOTES:

1. Failure to submit the mandatory documentary requirements and submission of incorrect and misleading information shall be grounds for denial of the application. Once denied, another email request together with the required documents should be sent to cslexport@fda.gov.ph.

6.ISSUANCE OF ONLINE BATCH NOTIFICATION FOR ANTIBIOTIC PRODUCTS

Batch Notification refers to the filing by a manufacturer, trader or distributor/importer of a notice to the Department of Health, through the Food and Drug Administration, concerning the manufactured or imported batch or batches of antibiotic drug product/s prior to release for sale, offer for sale, distribution, transfer, donation, or offer as Physician Samples of such particular batch or batches of drug product/s. Issuance of Batch Notification for antibiotic products is done online following the FDA Circular No. 2017-011.

Center/Office/Division:	Common Services Laboratory (CSL) – Antibiotic Section FDA Cashier
Classification:	Simple Transaction
Type of Transaction:	G2B - Government to Business
Who May Avail:	All FDA-Licensed Pharmaceutical Establishment (Manufacturer, Importer, Distributor, and Trader)
Fees to be Paid:	PHP 5,000.00 + Legal Research Fee (LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Pre-Evaluation	
Clear scanned copy of the Online Batch Notification Application Form in A4 size page, completely and correctly filled out and signed by the current company pharmacist	E-mailed by the cslbn@fda.gov.ph
Electronic copy (Excel format) of the Online Batch Notification Application Form	E-mailed by the cslbn@fda.gov.ph
Commitment Letter for submission	Applicant
Clear scanned copy of valid License to Operate (as manufacturer/trader/exporter, whichever is applicable)	Applicant
Clear scanned copy of valid Certificate of Product Registration (CPR) and/or Certificate for Variation (COV) application	Applicant

<table>
<tr><th>CHECKLIST OF REQUIREMENTS</th><th>WHERE TO SECURE</th></tr>
<tr><td>Clear scanned / electronic copy of valid Certificate of Analysis of the finished product reflecting similar batch/lot number with the sample submitted, batch size, theoretical and actual yield</td><td>Applicant</td></tr>
<tr><td>For imported products (1) Clear scanned / electronic copy of commercial invoice and/or packing list reflecting the expiry date and batch/lot number of the product or any document to prove the actual volume of importation; and (2) Transport Documents (Bill of Lading / Airway Bill / Seaway Bill) for the particular shipment. The volume of importation must be the same in the application form</td><td>Applicant</td></tr>
<tr><td>Clear scanned / electronic copy of Notice of Minor Variation/s (if applicable)</td><td>Applicant</td></tr>
<tr><td>Clear scanned / electronic copy of updated Document Tracking Number or status of the request (if applicable)</td><td>Applicant</td></tr>
<tr><td>. Image of the representative sample (as illustrated below) including the product insert and box in commercial presentation bearing the Principal Label, Batch/Lot No., Company Address, Registration No., Manufacturing and Expiration Date.
<table>
<tr><th>SAMPLE TYPE</th><th>QUANTITY REQUIRED</th></tr>
<tr><td>Tablet or capsule</td><td>1 blister pack or foil strip</td></tr>
<tr><td>Oral Suspension</td><td>1 bottle per presentation</td></tr>
<tr><td>Granules or Powder for Suspension</td><td>1 bottle</td></tr>
<tr><td>Cream or Ointment</td><td>1 tube per presentation</td></tr>
<tr><td>Ophthalmic, Otic, Nasal Drops</td><td>1 bottle per presentation</td></tr>
<tr><td>Injectables
Liquid Preparations</td><td>1 ampoule or vial per presentation</td></tr>
<tr><td>Solid Preparations</td><td>1 vial</td></tr>
</table></td><td>Applicant</td></tr>
<tr><td>Post-Evaluation</td><td></td></tr>
</table>

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Clear scanned copy / electronic copy of the Proof of Payment	LandBank / Online Banking
Two (2) sets of NOTARIZED APPROVED BATCH NOTIFICATION APPLICATION ON-LINE FORM with the company pharmacist's original signature on Page 3. 1.1. Applicants that submitted Notarized BN Application Form must submit it, together with the APPROVED BN FORM (with or without the notarial requirements for the latter) with the company pharmacist's original signature on Page 3. 1.2. Post-submission for nonnotarized BN application/s must follow the guidelines of the notarial requirements of the FDA Circular No.2017-011 - Batch Notification under II. SPECIFIC INSTRUCTIONS 2.e.: "...dates should be within the week of actual submission of the BN Form." or within 5 working days from the date of notarization. Submission of antedated application/s will not be accepted.	Applicant
Other required documents	Applicant
Commitment Letter	Applicant
Representative Sample	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Download, accomplish, print, and scan the Online Batch Notification Application Form; take a clear image of the representative sample and its packaging; and submit an email request with the link of the compressed/zipped documents or attached electronic and scanned copies of the requirements to cslbn@fda.gov.ph.	Checks email requests lodged at cslbn@fda.gov.ph.	None	30 Minutes	*Food-Drug Regulation Officer / Laboratory Technician* CSL-Antibiotic Section
	Reviews the application for completeness of requirements and	None	30 Minutes	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	correctness of the Application Form and the actual sample submitted.			
	If found non-compliant, the application is returned, and the Applicant will be informed of the reason/s for rejection. Note: Applicant is advised to re-submit all documents the next working day.	None	30 Minutes	
	If found compliant, the following steps are performed: Assigns BN Number and initials of the evaluator; and Issues payment details for each application received.	None	2 Hours	
. Proceeds to their preferred payment option; submits a clear copy of the proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to cslbn@fda.gov.ph.	Verifies, validates, and posting of payment.	PHP 5,000/ application + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
	Reviews e-mailed proof of payment and completes the portion of Payment Information on the online BN application form.	None	1 Hour	*Food-Drug Regulation Officer / Laboratory Technician* CSL-Antibiotic Section

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Stamps the name and electronic signature of the approving personnel on the online BN application form.	None	1 Hour	
	Sends approved and signed Online BN application form	None	30 Minutes	
. Submits the hard copies of the notarized approved online BN application and representative sample to the FDA Central Office.	Checks for the correctness and completeness of the documents.	None	1 Hour	
	Records the BN Number to the Releasing Logbook and releases the signed BN form to the applicant.	None	1 Hour	
	TOTAL		**1 Working Day**	

NOTES:

1. The approved BN shall be paid within 5 working days, any late payment will invalidate your application. Any payment before the approval of your application shall be voided.
2. Walk-in post-submission of online applications will be accepted every Wednesday from 9:00 AM to 4:00 PM only, except during holidays and suspension of work. All post-submission beyond the set schedule shall not be accommodated. Only those post-submission requirements forwarded via courier, dispatch riders, or other forwarding services with no definite arrival time shall be accepted by the on-duty guard, which shall be subjected to further evaluation and shall not guarantee acceptance by the CSL.
3. Submit only one (1) hard copy of the NOTARIZED APPROVED BATCH NOTIFICATION APPLICATION ONLINE FORM, with the company pharmacist's signature (Page 3 of BN Form) together with the required documents and the representative sample within twenty (20) working days. Failure to submit requirements and samples within the required timeline will be subject to termination of the application and non-refundable payment.

7.ONLINE APPLICATION FOR FOOD SUITABILITY CERTIFICATION OF FOOD CONTACT ARTICLES (VOLUNTARY)

Regulation of Food Contact Articles (FCA) is specified in Republic Act No. 10611, also known as the Food Safety Act of 2013, which states that food is adulterated if it is in a container having in whole or in part any poisonous or deleterious substance. As such, any food packaging material which results or may reasonably be expected to result, or indirectly in it becoming a component or otherwise affecting the characteristics of any food is considered a food additive according to the Bureau Circular No. 2006-016 or the Updated List of Food Additives. This service shall cover both locally manufactured and imported food contact articles, in finished or final form, with or without applied adhesives and/or printing inks limited to direct food contact articles for pre-packaged processed food products and articles with incidental contact to processed food products as indicated in the FDA Circular No. 2022-011 or the Guidelines on the Application and Issuance of Voluntary Certification of Food Contact Articles (FCA) Used for Prepackaged Processed Food Products.

Center/Office/Division:	Common Services Laboratory (CSL) – Receiving and Releasing Unit, Cosmetic-Toxicology Section Food and Drug Action Center (FDAC) FDA Cashier FDA Records
Classification:	Highly Technical Transaction
Type of Transaction:	G2B - Government to Business
Who May Avail:	All Food Contact Articles Manufacturers and Distributors
Fees to be Paid:	PHP 500.00 + Legal Research Fee (LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Request Letter stating the product and its intended use (1 signed scan copy)	Applicant
Product Information (1 scanned copy of each, with the product name as the filename) Technical Specification Intended use (state if to be used as primary or secondary packaging/ if to have direct or indirect contact with food) Overview of the production process	Applicant

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
For products wherein part of its component is recycled material, additional requirements must be submitted as well: Recycling process Source of starting material or major material that will be recycled	
Certificate of Analysis wherein Batch/Lot No. and Production date are indicated (1 original scanned copy, with the product name as the filename)	Applicant
Health and Safety Information / Safety Data Sheet for finished product and raw materials (1 original scanned copy, with the product name as the filename)	Applicant
Formulation/Composition indicating the specific chemical names and corresponding CAS numbers of all raw materials used (including colorants and additives, if any (1 original scanned copy, with the product name as the filename) *Note:* For products made from metals and alloy, the specific alloy should be indicated along with its elemental composition. For products wherein part of its component is recycled materials, all the chemicals used in the recycling process must be reflected.	Applicant
Report of Analysis based on finished article/product being applied for evaluation from an FDA-accredited laboratory. The Batch/Lot No. must be indicated in the Test Report (1 original scanned copy, with product name as the filename)	Applicant
Clear photos of the product capturing all parts i.e., inner and outer parts (photos should be in .jpeg, .png, or .pdf file, with product name as the filename)	Applicant
Proof of payment e.g., Official Receipt, LandBank ONCOLL Machine-Validated Payment (1 original scanned copy)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submits the scanned copy of the requirements to info@fda.gov.ph with the email subject:	Receives and acknowledges receipt of the copy of requirements and forwards to CSL.	None	Refer to FDAC Citizen's Charter	*Information Officer II* FDAC

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
CSL_Voluntary Application for Certification of Food Contact Articles				
	Pre-assesses the submitted requirements as to their completeness and assigns Document Tracking Number (DTN). If found non-compliant, the Client will be informed via email for submission of necessary documents. If found compliant, issues an assessment slip and advise the Client to make the necessary payment through acceptable payment channels.	None	–	*Food-Drug Regulation Officer / Health Program Officer / Laboratory Technician* CSL – Receiving and Releasing Unit
Proceeds to their preferred payment channel; submits a clear copy of the proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to csl@fda.gov.ph.	Verifies, validates, and posting of payment.	PHP 500/ application + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
	Forwards the application to the Cosmetic-Toxicology Section upon receipt of payment confirmation from FDA Cashier.	None	5 Minutes	*Food-Drug Regulation Officer / Health Program Officer / Laboratory Technician*

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
				CSL – Receiving and Releasing Unit
	Receives and prints forwarded application/s, records in Section Database, and decks the application for evaluation.	None	30 Minutes	*Food-Drug Regulation Officer / Administrative Assistant* CSL – Cosmetic-Toxicology Section
	Conducts food suitability evaluation.	None	11 Working Days	
	Forwards the result of evaluation to the CSL-Receiving and Releasing Unit.	None	10 Minutes	*Administrative Assistant* CSL – Cosmetic-Toxicology Section
	Emails the scanned copy of the result of the evaluation to the Client.	None	2 Minutes	*Food-Drug Regulation Officer / Health Program Officer / Laboratory Technician* CSL – Receiving and Releasing Unit
	Forwards the result of the evaluation (original printed copy) to the FDA Records.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Releases the reply letter to the Client.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**12 Working Days**	

NOTES:

1. Failure to submit the mandatory documentary requirements, and submission of documents that do not substantiate the suitability and safety of the product for its intended use shall be grounds for denial/disapproval of the application. Once denied/disapproved, re-application may opt to be done considering the noted observations on the initial application. Re-application entails payment of the required fee.

8.ONLINE PRE-APPLICATION QUERY FOR FOOD SUITABILITY EVALUATION OF FOOD CONTACT ARTICLES (VOLUNTARY)

Regulation of Food Contact Articles (FCA) is specified in Republic Act No. 10611, also known as the Food Safety Act of 2013, which states that food is adulterated if it is in a container having in whole or in part any poisonous or deleterious substance. As such, any food packaging material which results or may reasonably be expected to result, or indirectly in it becoming a component or otherwise affecting the characteristics of any food is considered a food additive according to the Bureau Circular No. 2006-016 or the Updated List of Food Additives. This service shall cover both locally manufactured and imported food contact articles, in finished or final form, with or without applied adhesives and/or printing inks limited to direct food contact articles for pre-packaged processed food products and articles with incidental contact to processed food products as indicated in the FDA Circular No. 2022-011 or the Guidelines on the Application and Issuance of Voluntary Certification of Food Contact Articles (FCA) Used for Prepackaged Processed Food Products.

Center/Office/Division:	Common Services Laboratory (CSL) – Receiving and Releasing Unit, Cosmetic-Toxicology Section Food and Drug Action Center (FDAC) FDA Records
Classification:	Complex Transaction
Type of Transaction:	G2B - Government to Business
Who May Avail:	All Food Contact Articles Manufacturers and Distributors
Fees to be Paid:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Email inquiry to be sent to info@fda.gov.ph containing the following information, at a minimum: Product/Article that will be applied for evaluation Composition/Formulation of the product/article Intended use of the product/article Specific condition of use and the food that it will be in contact with the product/article	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Sends email inquiry to info@fda.gov.ph with the email subject: ***CSL_Pre-application Query for Food Contact Articles***	Receives and acknowledges receipt of the email inquiry and forwards to the CSL.	None	Refer to FDAC Citizen's Charter	*Information Officer II* FDAC
	Receives the email and checks the completeness of necessary information. If found incomplete, responds to the Applicant requesting additional necessary information.	None	5 Minutes	*Food-Drug Regulation Officer / Health Program Officer / Laboratory Technician* CSL – Receiving and Releasing Unit
	Forwards email inquiry to CSL-Cosmetic-Toxicology Section once all necessary information is received from the Applicant.	None	5 Minutes	
	Receives and prints forwarded application/s, records in Section Database, and decks the application for evaluation.	None	30 Minutes	*Food-Drug Regulation Officer / Administrative Assistant* CSL – Cosmetic-Toxicology Section
	Drafts and finalizes reply letter to the query.	None	6 Working Days	
	Forwards the reply letter to the CSL – Receiving and Releasing Unit.	None	10 Minutes	*Administrative Assistant* CSL – Cosmetic-Toxicology Section

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Emails the scanned reply letter to the Applicant.	None	2 Minutes	*Food-Drug Regulation Officer / Health Program Officer / Laboratory Technician* CSL – Receiving and Releasing Unit
	Forwards the reply letter (original printed copy) to the FDA Records.	None	10 Minutes	*Laboratory Technician* CSL – Receiving and Releasing Unit
	Releases the reply letter to the Applicant.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**7 Working Days**	

9.REQUEST FOR CONDUCT OF CALIBRATION OF RADIOTHERAPY DOSIMETER

Conduct of Calibration of Radiotherapy Dosimeter.

Center/Office/Division:	Common Services Laboratory (CSL) - Physics Laboratory Support Division (PLSD), Secondary Standard Dosimetry Laboratory (SSDL) FDA Cashier
Classification:	Highly Technical
Type of Transaction:	G2G – Government to Government, G2B – Government to Business
Who May Avail:	Government (DOH, LGUs) hospitals, private hospitals and clinics
Fees to be Paid:	PHP 1,600.00/equipment assembly* + Legal Research Fee (LRF) **Equipment assembly includes the electrometer with power cable, farmer type ionization chamber, and ionization chamber extension cable only.*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Schedule of calibration of radiotherapy dosimeter (RTDM) *Note:* The PLSD personnel assigned in SSDL informs the Radiation Oncology Medical Physicist (ROMP) thru email regarding the annual calibration schedule of their radiotherapy dosimeters. The schedule is preferably set during dry months. Request forms are collected for scheduling purposes.	PLSD Personnel in SSDL

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submits scheduled equipment for calibration at the SSDL located in DOH Office, Tayuman, Manila City.	1. Pre-assesses the submitted requirements, as well as the	None	–	*Health Physicists* CSL – Physics Laboratory Support

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Note: Applicant's entrance is at the gate of the new Dr. Jose Fabella Memorial Hospital in Tayuman Street, Manila City.	completeness of equipment and accessories submitted. If found non-compliant, the Client will be informed via email for submission of necessary documents. If found compliant, issues Document Tracking Number (DTN) and Order of Payment, and advise the Client to make the necessary payment through acceptable payment channels.			Division, Secondary Standard Dosimetry Laboratory
Proceeds to their preferred payment channel; submits a clear copy of the proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to csl-plsd@fda.gov.ph.	Posting of payment.	PHP 1,600/ equipment assembly + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
	Upon confirmation of payment from FDA Cashier, confirms schedule date for equipment calibration.	None	1 Working Day	*Health Physicists* CSL – Physics Laboratory Support Division, Secondary Standard Dosimetry Laboratory
	Conducts performance test and calibration of radiotherapy dosimeter.	None	5 Working Days	
	Prepares and reviews performance test repot and	None	6 Working Days	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	calibration certificate of radiotherapy dosimeter.			
	Signs performance test report and calibration certificate.	None	3 Working Days	*Laboratory Division Chief* CSL – Physics Laboratory Support Division
	Notifies ROMP on the schedule of releasing of radiotherapy dosimeter.	None	1 Working Day	*Health Physicists* CSL – Physics Laboratory Support Division, Secondary Standard Dosimetry Laboratory
	Releases equipment, performance test report, and calibration certificate, and scans signed receiving copy of released equipment and documents for filing.	None	3 Working Days	
	TOTAL		**20 Working Days**	

10.REQUEST FOR CONDUCT OF QUALITY AUDIT OF MEDICAL LINAC IN RADIOTHERAPY FACILITY

Conduct of Quality Audit of Radiotherapy Facility.

Center/Office/Division:	Common Services Laboratory (CSL) – Office of the Director, Receiving and Releasing Unit, Physics Laboratory Support Division (PLSD) FDA Cashier FDA Records
Classification:	Highly Technical
Type of Transaction:	G2G – Government to Government, G2B – Government to Business
Who May Avail:	Government (DOH, local) hospitals, private hospitals and clinics
Fees to be Paid:	PHP 7,920.00/radiologic equipment + Legal Research Fee (LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Request for Quality Audit of Radiotherapy Facility (Request for Performance Testing RPT Form)	FDA website (www.fda.gov.ph)

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submit accomplished and signed Performance Testing of Radiological Equipment Request form through email at csl-plsd@fda.gov.ph.	1. Receives and evaluates submitted request form. If found non-compliant, request will be rejected. If found compliant, issues Document Track Number (DTN), Order of Payment, and PLSD code.	None	–	*Administrative Aide* CSL – Physics Laboratory Support Division

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Proceeds to their preferred payment channel; submits a clear copy of the proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to csl-plsd@fda.gov.ph.	Posting of payment.	PHP 7,920/ radiologic equipment + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
	Upon confirmation of payment from FDA Cashier, provides a tentative schedule date to the Applicant for the performance testing.	None	1 Working Day	*Administrative Aide* CSL – Physics Laboratory Support Division
	Determines the availability of the Health Physicists/ Radiologic Technologists and endorses the accomplished request form submitted by Applicant.	None	2 Working Days	*Administrative Aide* CSL – Physics Laboratory Support Division
Confirms the readiness of the facility, functionality of the Co-60 and/or LINAC, availability of medical physicist/s in-charge, and travel arrangements for Health Physicist/Radiologic Technologist.	Evaluates documents and information submitted and communicates the proposed date of performance testing.	None	3 Working Days	*Health Physicist/ Radiologic Technologist* CSL – Physics Laboratory Support Division
	Prepares travel documents, gate pass for performance testing equipment, test forms, and test protocols, and recommends approval of travel to the CSL Director.	None	3 Working Days	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Conducts quality audit of facility and functionality of radiologic equipment[1] and prepares initial test report to be received by the representative of the facility.	None	3 Working Days	
	Drafts performance test report and submits final performance test report for review and approval.	None	5 Working Days	
	Reviews and attests performance test report.	None	1 Working Day	*Laboratory Division Chief* CSL – Physics Laboratory Support Division
	Forwards signed performance test reports and endorsement letter for signature.	None		*Administrative Aide* CSL – Physics Laboratory Support Division
	Signs endorsement letter to be attached to the performance test report.	None		*Director II* CSL
	Forwards signed endorsement letter and attached performance test report for releasing.	None		*Laboratory Technician* CSL – Receiving and Releasing Unit
	Releases performance test report: Forwards one (1) copy of the signed performance test report to FDA Records for mailing to the Applicant.	None	1 Working Day	*Administrative Aide* CSL – Physics Laboratory Support Division

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Scans the signed copy of performance test report and sends as an email attachment to the Radiation Regulation Division (RRD) of the Center for Device Regulation, Radiation Health and Research (CDRRHR) and to the Applicant.			
	.Releases the endorsement letter with attached performance test report to the Applicant.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**20 Working Days**	

[1]Conduct of performance testing may be prolonged depending on the type of radiological equipment and the location of the facility.

11.REQUEST FOR PERFORMANCE TESTING OF RADIOLOGIC EQUIPMENT

Request for Performance Testing of Radiological Equipment.

Center/Office/Division:	Common Services Laboratory (CSL) – Office of the Director, Receiving and Releasing Unit, Physics Laboratory Support Division (PLSD) FDA Cashier FDA Records
Classification:	Highly Technical
Type of Transaction:	G2G – Government to Government, G2B – Government to Business
Who May Avail:	Government (DOH, Local) hospitals, private hospitals and clinics
Fees to be Paid:	PHP 7,920.00/radiologic equipment + Legal Research Fund (LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Request for Performance Testing of Radiologic Equipment (Request for Performance Testing RPT Form)	FDA website (www.fda.gov.ph)

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Submit accomplished and signed Performance Testing of Radiological Equipment Request form through email at csl-plsd@fda.gov.ph.	Receives and evaluates submitted request form: If found non-compliant, request will be rejected. If found compliant, issues Document Track Number (DTN), Order of Payment, and PLSD code.	None	–	*Administrative Aide* CSL – Physics Laboratory Support Division

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
Proceeds to their preferred payment channel; submits a clear copy of the proof of payment to cashierposting@fda.gov.ph and copy furnish (cc:) to csl-plsd@fda.gov.ph.	Posting of payment.	PHP 7,920/ radiologic equipment + LRF	Refer to FDA Cashier Citizen's Charter	*Cashier Staff* FDA Cashier
	Upon confirmation of payment from FDA Cashier, provides a tentative schedule date to the Applicant for the performance testing.	None	1 Working Day	*Administrative Aide* CSL – Physics Laboratory Support Division
	Determines the availability of the Health Physicists/ Radiologic Technologists and endorses the accomplished request form submitted by Applicant.	None	2 Working Days	
Confirms the readiness of the facility, functionality of the radiologic equipment to be tested, availability of service engineer, and travel arrangements for Health Physicist/Radiologic Technologist.	Evaluates documents and information submitted and communicates the proposed date of performance testing.	None	3 Working Days	*Health Physicist/ Radiologic Technologist* CSL – Physics Laboratory Support Division
	Prepares travel documents, gate pass for performance testing equipment, test forms, and test protocols, and recommends approval of travel to the CSL Director.	None	3 Working Days	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Conducts on-site performance testing[1] of radiologic equipment and prepares initial test report to be received by the representative of the facility.	None	3 Working Days	
	Drafts performance test report and submits final performance test report for review and approval.	None	5 Working Days	
	Reviews and attests performance test report.	None	1 Working Day	*Laboratory Division Chief* CSL – Physics Laboratory Support Division
	Forwards signed performance test reports and endorsement letter for signature.	None		*Administrative Aide* CSL – Physics Laboratory Support Division
	Signs endorsement letter to be attached to the performance test report.	None		*Director II* CSL
	Forwards signed endorsement letter and attached performance test report for releasing.	None		*Laboratory Technician* CSL – Receiving and Releasing Unit
	Releases performance test report: Forwards one (1) copy of the signed performance test report to FDA Records for mailing to the Applicant.	None	1 Working Day	*Administrative Aide* CSL – Physics Laboratory Support Division

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Scans the signed copy of performance test report and sends as an email attachment to the Radiation Regulation Division (RRD) of the Center for Device Regulation, Radiation Health and Research (CDRRHR) and to the Applicant.			
	Releases the endorsement letter with attached performance test report to the Applicant.	None	Refer to FDA Records Citizen's Charter	*Records Staff* FDA Records
	TOTAL		**20 Working Days**	

[1]Conduct of performance testing may be prolonged depending on the type of radiological equipment and the location of the facility.