DEPARTMENT OF HEALTH
FOOD AND DRUG ADMINISTRATION

CITIZEN'S CHARTER

COMMON SERVICES LABORATORY
2022 (3rd Edition)

Effectivity Date: 31 March 2022

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; developing and maintaining evidence-based standards and policies, in a healthy and safe work environment.

Common Services Laboratory

LIST OF EXTERNAL SERVICES

COMMON SERVICES LABORATORY

1. ONLINE ISSUANCE OF EXPORT CERTIFICATE FOR ACACIA WOODENWARES (VOLUNTARY APPLICATION)

Voluntary application for Issuance of Export Certificate for Acacia Woodenwares

Center/Office/Division	**:**	Common Services Laboratory (CSL)
Classification	**:**	Complex Transaction
Type of Transaction	**:**	Government to Business
Who May Avail	**:**	Acacia Woodenwares' Exporting Companies
Fees to be Paid	**:**	Php 500.00 + LRF = Php 510.00

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
1. Request Letter (Stating the intended use of the product)	Company applicant
2. Product Information - Technical Specification - Intended use (state if direct or indirect contact with food) - Overview of production process - Packing List including Net and Gross Weight	Company applicant
3. Certificate of Analysis (Batch/Lot No. and Production date stated)	Company applicant
4. Health and Safety Information / Safety Data Sheet (Finished product and raw materials)	Company applicant
5. Formulation/Composition - Specific Chemical Names and Corresponding CAS Numbers of all raw materials used (including lacquers, colorants and additives, if any)	Company applicant
6. Report of Analysis (based on finished article/product being applied for evaluation) from FDA-recognized laboratory (Batch/Lot No. must be indicated in the Test Report)	Company applicant
7. Clear Photo of the product (All parts – i.e. inner and outer parts)	Company applicant
8. Proof of payment (e.g. Official Receipt, Landbank Oncoll Machine-Validated Payment, verified and posted payment by the FDA Cashier)	Company applicant

CLIENT STEPS	**AGENCY ACTION**	**PROCESSING TIME**	**PERSON RESPONSIBLE**
Submits the scanned copy of the requirements to csl@fda.gov.ph			Company applicant

	1. Reviews the application for completeness of requirements If incomplete: application is returned stating the reason for rejection. If complete: assigns a Reference Number and forwards the application to the Toxicology Section (Client to pay fees thru Landbank and sends scanned copy of deposit slip to csl@fda.gov.ph) - refer to Note 1	5 Minutes	CSL/Receiving and Releasing Unit (RRU)/ Laboratory Technician I (Lab Tech)
	2. Forwards the application to the Toxicology Section	5 Minutes	CSL/RRU/Lab Tech I
	3. Printing, Recording (Section's Database) and Scheduling (Decking)	30 minutes	CSL/Toxicology Section/Admin Assistant and FDRO III or IV
	4. Food Suitability Evaluation	6 days	CSL/Toxicology Section/Admin Assistant and FDRO III or IV
	5. Forwards the Evaluation Report / Export Certificate to the CSL RRU	10 minutes	CSL/Toxicology Section/Admin Assistant
	6. Forwards the Evaluation Report / Export Certificate to the CSL Director for signature Signs and return the Evaluation Report / Export Certificate to the CSL RRU	10 minutes	CSL/RRU/Lab Tech I CSL Director II
	7. Emails the Scanned Copy of the Evaluation Report / Export Certificate to the client	2 minutes	CSL/RRU/Lab Tech I
	8. Forwards the Evaluation Report / Export Certificate (Original Hard Copy) to the FDA - Records	10 minutes	CSL/RRU/Lab Tech I
	9. Releases Export Certificate (Original Hard Copy) to client	-	FDA Records

TOTAL:	**7 Working Days**	

Note:

1. Commencement of Day 1 processing is applicable only to applications with submitted verified and posted payment by the FDA Cashier.
2. Failure to submit the mandatory documentary requirements, and submission of documents which do not substantiate 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 initial application. Re-application entails payment of the required fee.

2. ON-SITE ISSUANCE OF EXPORT CERTIFICATE FOR ACACIA WOODENWARES (VOLUNTARY APPLICATION)

Voluntary application for Issuance of Export Certificate for Acacia Woodenwares

Center/Office/Division	**:**	Common Services Laboratory (CSL)
Classification	**:**	Complex Transaction
Type of Transaction	**:**	Government to Business
Who May Avail	**:**	Acacia Woodenwares' Exporting Companies
Fees to be Paid	**:**	Php 500.00 + LRF = Php 510.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Request Letter (Stating the intended use of the product)	Company applicant
2. Product Information - Technical Specification - Intended use (state if direct or indirect contact with food) - Overview of production process - Packing List including Net and Gross Weight	Company applicant
3. Certificate of Analysis (Batch/Lot No. and Production date stated)	Company applicant
4. Health and Safety Information / Safety Data Sheet (Finished product and raw materials)	Company applicant
5. Formulation/Composition - Specific Chemical Names and Corresponding CAS Numbers of all raw materials used (including lacquers, colorants and additives, if any)	Company applicant
6. Report of Analysis (based on finished article/product being applied for evaluation) from FDA-recognized laboratory (Batch/Lot No. must be indicated in the Test Report)	Company applicant
7. Representative sample	Company applicant
8. Proof of payment (e.g. Official Receipt, Landbank Oncoll Machine-Validated Payment, verified and posted payment by the FDA Cashier)	Company applicant

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
Submits the requirements to the Food and Drug Action Center (FDAC)			Company applicant
	1. Reviews the application for completeness of requirements If incomplete: application is returned stating the reason for rejection. If complete: assigns Reference Number and forwards application to the Common Services Laboratory Receiving and Releasing Unit (CSL RRU) - refer to Note 1	5 minutes	CSL/Receiving and Releasing Unit (RRU)/ Laboratory Technician I (Lab Tech) at FDAC
	2. Forwards the application to the Toxicology Section	10 minutes	CSL/RRU/Lab Tech I
	3. Receiving, Recording (Section's Database) and Scheduling (Decking)	30 minutes	CSL/Toxicology Section/Admin Assistant and FDRO III or IV
	4. Food Suitability Evaluation	6 days	CSL/Toxicology Section/Admin Assistant and FDRO III or IV
	5. Forwards the Evaluation Report / Export Certificate to the CSL RRU	10 minutes	CSL/Toxicology Section/Admin Assistant
	6. Forwards the Evaluation Report / Export Certificate to the CSL Director for signature Signs and return the Evaluation Report / Export Certificate to the CSL RRU	10 minutes	CSL/RRU/Lab Tech I CSL Director II
	7. Forwards the Evaluation Report / Export Certificate to the FDAC	4 hours	CSL/RRU/Lab Tech I
	8. Releases Evaluation Report / Export Certificate to the client	5 minutes	CSL Frontline Officer at FDAC

TOTAL:	**7 Working Days**	

Note:

1. Commencement of Day 1 processing is applicable only to applications with verified and posted payment by the FDA Cashier.
2. Failure to submit the mandatory documentary requirements, and submission of documents which do not substantiate 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 initial application. Re-application entails payment of the required fee.

3. ISSUANCE OF ONLINE BATCH NOTIFICATION FOR ANTIBIOTIC PRODUCTS

Issuance of Online Batch Notification for Antibiotic Products (Online)

Center/Office/Division	**:**	Common Services Laboratory
Classification	**:**	Simple Transaction
Type of Transaction	**:**	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 fees

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
Pre-Evaluation	
1. Clear scanned copy of the Online Batch Notification Application Form completely and correctly filled out and signed by the current company pharmacist in A4 size page	E-mailed by the cslbn@fda.gov.ph
2. Electronic copy (Excel format) of the Online Batch Notification Application Form	E-mailed by the cslbn@fda.gov.ph
3. Commitment Letter for submission	Company applicant
4. Clear scanned copy of valid License to Operate (as manufacturer/trader/exporter, whichever is applicable)	Company applicant
5. Clear scanned copy of valid Certificate of Product Registration (CPR) and/or Certificate for Variation (COV) application	Company applicant
6. 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	Company applicant
7. 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 actual volume of importation; and (2)	Company applicant

<table>
<tr><td>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></td></tr>
<tr><td>8. Clear scanned / electronic copy of notice of Minor Variation/s (if applicable)</td><td></td></tr>
<tr><td>9. Clear scanned / electronic copy of updated Document Tracking Number or status of the request (if applicable)</td><td></td></tr>
<tr><td>10. Image of the representative sample (as illustrated below) including the product insert and box in commercial presentation bearing the Principle 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

Solid Preparations</td><td>
1 ampoule or vial per presentation

1 vial</td></tr></table></td><td>Company applicant</td></tr>
<tr><td>Post Evaluation</td><td></td></tr>
<tr><td>1. Clear scanned copy / electronic copy of the Proof of Payment</td><td>Landbank / online banking / FDAC Cashier</td></tr>
<tr><td>2. 2 sets of NOTARIZED APPROVED BATCH NOTIFICATION APPLICATION ON-LINE FORM with the company pharmacist’s original signature on Page 3. 1.1. Clients 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 unnotarized 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</td><td></td></tr>
</table>

notarization. Submission of antedated application/s will not be accepted.	
3. Other required documents	
4. Commitment Letter	
5. Representative Sample	

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
Download, accomplish, print, and scan Online Batch Notification Application Form			Company applicant
Take a clear image of the representative sample and its packaging			Company applicant
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			Company applicant
	Checks email requests lodge at cslbn@fda.gov.ph Reviews application for completeness of requirements and correctness of Application Form and the actual sample submitted If found unacceptable, application is returned and inform the client the reason/s for rejection ***Note:*** *If found unacceptable, clients are advised to re-submit all documents the next working day*	1 minute 10 minutes 2 minutes	CSL/ Antibiotic Section /Laboratory Technician II and Food Drug Regulation Officer

	If found satisfactory, the following steps are performed: ● Assigns BN Number and initials of the evaluator; and ● Payment details is issued for each application received	2 minutes 2 minutes	
Applicant proceeds to their preferred payment option			FDA Cashier/ Administrative Staff / Company Applicant
Applicant submits clear copy of the proof of payment to cslbn@fda.gov.ph and carbon copy (Cc:) to cashier@fda.gov.ph			Company Applicant
	Reviews e-mailed proof of payment and completes Payment Information portion of the online BN application form	3 minutes	CSL/ Antibiotic Section /Laboratory Technician II and Food Drug Regulation Officer
	Stamp the name and electronic signature of the approving personnel on the online BN application form	3 minutes	CSL/ Antibiotic Section /Laboratory Technician II and Food Drug Regulation Officer
	Sends approved and signed Online BN application form	2 minutes	CSL/ Antibiotic Section /Laboratory Technician II and Food Drug Regulation Officer
Applicant submits to the FDAC CSL counter the hardcopies of the notarized approved online BN application and sample			Company Applicant

	Checks for the correctness and completeness of the documents	3 minutes	CSL/ Antibiotic Section /Laboratory Technician II and Food Drug Regulation Officer
	Log the BN Number to the Releasing Logbook and release the signed BN form to the applicant	2 minutes	CSL/ Antibiotic Section /Laboratory Technician II and Food Drug Regulation Officer
	TOTAL:	**30 minutes**	

NOTES:

1. Applications are accommodated online through cslbn@fda.gov.ph from 9 a.m. to 2 p.m., Mondays to Fridays except holidays and suspension of work when deemed necessary (e.g. acts of nature). Applications including proof of payments submitted beyond the given schedule will be processed on the next working day.
2. 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.
3. Post-submission of online applications will be accepted at FDAC CSL Counter within office hours, Monday to Friday except holidays.
4. 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 20 working days. Failure to submit requirements and samples within the required timeline will be subjected for termination of the application and non-refundable payment.
5. Commencement of Day 1 processing is applicable only to applications with verified and posted payment by the FDA Cashier.

4. ISSUANCE OF BATCH NOTIFICATION FOR ANTIBIOTIC PRODUCTS

Issuance of Batch Notification for Antibiotic Products (On-site)

Center/Office/Division	**:**	Common Services Laboratory
Classification	**:**	Simple Transaction
Type of Transaction	**:**	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 fees

<table>
<tr><th>CHECKLIST OF REQUIREMENTS</th><th>WHERE TO SECURE</th></tr>
<tr><td>Pre-Evaluation
1. Two (2) original hardcopies and notarized Application Form completely and correctly filled out by the current company pharmacist)</td><td>FDA website (www.fda.gov.ph)</td></tr>
<tr><td>2. Electronic copy (Excel format) of the Batch Notification form</td><td>FDA website (www.fda.gov.ph)</td></tr>
<tr><td>3. Two (2) photocopy of valid License to Operate (as manufacturer/trader/exporter, whichever is applicable)</td><td>Company applicant</td></tr>
<tr><td>4. One (1) clear photocopy of valid Certificate of Product Registration (CPR) and/or Certificate for Variation (COV) application</td><td>Company applicant</td></tr>
<tr><td>5. One (1) clear photocopy 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>Company applicant</td></tr>
<tr><td>6. For imported products (1) clear photocopy of commercial invoice and/or packing list reflecting the expiry date and batch/lot number of the product or any document to prove actual volume of importation; and two (2) airway bill /bill of lading for the particular shipment. The volume of importation must be the same in the application form</td><td>Company applicant</td></tr>
<tr><td>7. Representative sample (as illustrated below) including the product insert and box in commercial presentation

<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
- Solid Preparations</td><td>
1 ampoule or vial per presentation
1 vial</td></tr>
</table>
</td><td>Company applicant</td></tr>
</table>

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
Downloads the Application Form, draft template of the Certificate and database at the FDA website			Company applicant

Submits the requirements at the Food and Drug Action Center (FDAC)			Company applicant
	Reviews application for completeness of requirements and correctness of Application Form and the actual sample submitted If found unacceptable, application is return, and inform the client any deficiency in the requirements. If found satisfactory, the following steps are performed: ● Assign and stamp BN Number; and ● Save electronic copy of the application from the USB flash drive to the computer terminal ● Returns the USB flash drive and receiving copy of the Application Form to the client.	5 minutes 2 minutes 1 minute 1 minute	CSL/ Receiving and Releasing Unit (RRU)/Laboratory Technician II and Food Drug Regulation Officer II & III
	Applicant proceeds to Cashier Section for payment	10 minutes	FDA Cashier/ Administrative Staff
	Applicant submits to the CSL counter the hardcopies of the application and sample	1 minute	Company Applicant
	CSL front liner checks the details on the Payment Information portion and Assessment Form	1 minute	CSL/RRU/Lab Tech II and FDRO II & III
	Stamp the name of the approving personnel on the application form and sign the BN Form	2 minutes	CSL/Antibiotic Section/FDRO III & IV
	Log the BN Number to the Releasing Logbook and release the signed BN form to the applicant	2 minutes	CSL/RRU/Lab Tech II and FDRO II & III
	TOTAL:	**25 minutes**	

NOTE:

6. Applications for Batch Notification will be accepted at FDAC CSL Counter from 9 AM to 2 PM, every Monday to Wednesday except holidays and declared suspension of work, when deemed necessary (e.g. act of nature). Applications including proof of payments submitted beyond the given schedule will be processed on the next working day.
7. 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.
8. Post-submission of online applications will be accepted at FDAC CSL Counter within office hours, Monday to Friday except holidays.
9. 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 20 working days. Failure to submit requirements and samples within the required timeline will be subjected for termination of the application and non-refundable payment.
10. Commencement of Day 1 processing is applicable only to applications with verified and posted payment by the FDA Cashier.

5. ONLINE APPLICATION FOR FOOD SUITABILITY EVALUATION OF FOOD CONTACT ARTICLES (VOLUNTARY)

Voluntary Application for Food Suitability Evaluation of Food Contact Articles

Center/Office/Division	**:**	Common Services Laboratory (CSL)
Classification	**:**	Highly Technical Transaction
Type of Transaction	**:**	Government to Business
Who May Avail	**:**	All Food Contact Articles Manufacturers and Distributors
Fees to be Paid	**:**	Php 500.00 + LRF = Php 510.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Request Letter (Stating the product and its intended use)	Company applicant
2. Product Information - 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 production process Note: For products wherein part of its component is recycled material, the following should be submitted: a. Recycling process b. Source of starting material or major material that will be recycled	Company applicant
3. Certificate of Analysis (Batch/Lot No. and Production date stated)	Company applicant
4. Health and Safety Information / Safety Data Sheet	Company applicant

(Finished product and raw materials)	
5. Formulation/Composition - Specific Chemical Names and Corresponding CAS Numbers of all raw materials used (including colorants and additives, if any) Note: a. For products made from metals and its alloy, the specific alloy should be indicated along with its elemental composition. b. For products wherein part of its component is recycled materials, all the chemicals used in recycling process must be reflected.	Company applicant
6. Report of Analysis (based on finished article/product being applied for evaluation) from FDA-recognized laboratory (Batch/Lot No. must be indicated in the Test Report)	Company applicant
7. Clear Photo of the product (All parts – i.e. inner and outer parts)	Company applicant
8. Proof of payment (e.g. Official Receipt, Landbank Oncoll Machine-Validated Payment, verified and posted payment by the FDA Cashier)	Company applicant

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
Submits the scanned copy of the requirements to csl@fda.gov.ph			Company applicant
	1. Reviews application for completeness of requirements If incomplete: application is rejected stating the reason of rejection. If complete: assigns a Reference Number and forwards the application to the Toxicology Section (Client to pay fees thru Landbank and sends scanned copy of deposit slip to csl@fda.gov.ph) - refer to note 1	5 Minutes	CSL/Receiving and Releasing Unit (RRU)/ Laboratory Technician I (Lab Tech)
	2. Forwards the application to the CSL- Toxicology Section	5 Minutes	CSL/RRU/Lab Tech I
	3. Printing, Recording (Section's Database) and Scheduling (Decking)	30 minutes	CSL/Toxicology Section/Admin Assistant and FDRO III or IV

	4. Food Suitability Evaluation	12 days	CSL/Toxicology Section/Admin Assistant and FDRO III or IV
	5. Forwards the Evaluation Report to the CSL RRU	10 minutes	CSL/Toxicology Section/Admin Assistant
	6. Forwards the Evaluation Report to the CSL Director for signature Signs and return the Evaluation Report to the CSL RRU	10 minutes	CSL/RRU/Lab Tech I CSL Director II
	7. Emails the Scanned Copy of the Evaluation Report Letter to the client	2 Minutes	CSL/RRU/Lab Tech I
	8. Forwards the Evaluation Report Letter (Original Hard Copy) to the FDA - Records	10 minutes	CSL/RRU/Lab Tech I
	9. Releases Evaluation Report (Original Hard Copy) to client	-	FDA Records
	TOTAL:	**12 Working Days**	

Note:

1. Commencement of Day 1 processing is applicable only to applications with verified and posted payment by the FDA Cashier.
2. Failure to submit the mandatory documentary requirements, and submission of documents which do not substantiate 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 initial application. Re-application entails payment of the required fee.

6. ON-SITE APPLICATION FOR FOOD SUITABILITY EVALUATION OF FOOD CONTACT ARTICLES (VOLUNTARY)

Voluntary Application for Food Suitability Evaluation of Food Contact Articles

Center/Office/Division	**:**	Common Services Laboratory (CSL)
Classification	**:**	Highly Technical Transaction
Type of Transaction	**:**	Government to Business
Who May Avail	**:**	All Food Contact Articles Manufacturers and Distributors

Fees to be Paid	**:**	Php 500.00 + LRF = Php 510.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Request Letter (Stating the intended use of the product)	Company applicant
2. Product Information - 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 production process Note: For products wherein part of its component is recycled material, the following should be submitted: a. Recycling process b. Source of starting material or major material that will be recycled	Company applicant
3. Certificate of Analysis (Batch/Lot No. and Production date stated)	Company applicant
4. Health and Safety Information / Safety Data Sheet (Finished product and raw materials)	Company applicant
5. Formulation/Composition - Specific Chemical Names and Corresponding CAS Numbers of all raw materials used (including colorants and additives, if any) Note: a. For products made from metals and its alloy, the specific alloy should be indicated along with its elemental composition. b. For products wherein part of its component is recycled materials, all the chemicals used in the recycling process must be reflected.	Company applicant
6. Report of Analysis (based on finished article/product being applied for evaluation) from FDA-recognized laboratory (Batch/Lot No. must be indicated in the Test Report)	Company applicant
7. Representative sample	Company applicant
8. Proof of payment (e.g. Official Receipt, Landbank Oncoll Machine-Validated Payment, verified and posted payment by the FDA Cashier)	Company applicant

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
Submits the requirements at the Food and Drug Action Center (FDAC)			Company applicant
	1. Reviews application for completeness of requirements	5 Minutes	CSL/Receiving and Releasing Unit (RRU)/ Laboratory Technician I (Lab Tech) at FDAC

	If incomplete: application is returned stating the reason for rejection. If complete: assigns a Reference Number and forwards application to the Common Services Laboratory Receiving and Releasing Unit (CSL RRU) - refer to Note 1		
	2. Forwards the application to the CSL-Toxicology Section	10 minutes	CSL/RRU/Lab Tech I
	3. Receiving, Recording (Section's Database) and Scheduling (Decking)	30 minutes	CSL/Toxicology Section/Admin Assistant and FDRO III or IV
	4. Food Suitability Evaluation	12 days	CSL/Toxicology Section/Admin Assistant and FDRO III or IV
	5. Forwards the Evaluation Report to the CSL RRU	10 minutes	CSL/Toxicology Section/Admin Assistant
	6. Forwards the Evaluation Report to the CSL Director for signature Signs and return the Evaluation Report to the CSL RRU	10 minutes	CSL/RRU/Lab Tech I CSL Director II
	7. Forwards the Evaluation Report to the FDAC	4 hours	CSL/RRU/Lab Tech I
	8. Releases the Evaluation Report to the client	5 minutes	CSL/RRU/Lab Tech I at FDAC FDA Records
	TOTAL:	**12 Working Days**	

Note:

1. Commencement of Day 1 processing is applicable only to applications with verified and posted payment by the FDA Cashier.
2. Failure to submit the mandatory documentary requirements, and submission of documents which do not substantiate 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 initial application. Re-application entails payment of the required fee.

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

Pre-application Query for Food Suitability Evaluation of Food Contact Articles (Voluntary)

Center/Office/Division	**:**	Common Services Laboratory (CSL)
Classification	**:**	Complex Transaction
Type of Transaction	**:**	Government to Business
Who May Avail	**:**	All Food Contact Articles Manufacturers and Distributors
Fees to be Paid	**:**	NONE

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Email Inquiry (Containing at least the following information about the product/article to be applied for evaluation: formulation/composition, intended use and the specific food that will be contained.)	Company applicant

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
Sends email inquiry to csl@fda.gov.ph	1. Receives and acknowledges receipt of the email inquiry.	5 minutes	CSL/Receiving and Releasing Unit (RRU)/ Laboratory Technician I (Lab Tech)
	2. Forwards the email inquiry to the CSL-Toxicology Section	5 Minutes	CSL/RRU/Lab Tech I
	3. Printing, Recording (Section's Database) and Scheduling (Decking)	30 minutes	CSL/Toxicology Section/Admin Assistant and FDRO III or IV
	4. Drafts and Finalizes reply letter to the query	6 days	CSL/Toxicology Section/Admin Assistant and FDRO III or IV
	5. Forwards the reply letter to the CSL RRU	10 minutes	CSL/Toxicology Section/Admin Assistant
	6. Forwards the reply letter to the CSL Director for signature Signs and return the reply letter to the CSL RRU	10 minutes	CSL/RRU/Lab Tech I CSL Director II
	7. Emails the Reply Letter (Scanned Copy) to the client	2 Minutes	CSL/RRU/Lab Tech I

	8. Forwards the Reply Letter (Original Hard Copy) to the FDA - Records	10 minutes	CSL/RRU/Lab Tech I
	9. Releases reply letter (Original Hard Copy) to client	-	FDA Records
	TOTAL:	**7 Working Days**	

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

Pre-application Query for Food Suitability Evaluation of Food Contact Articles (Voluntary)

Center/Office/Division	**:**	Common Services Laboratory (CSL)
Classification	**:**	Complex Transaction
Type of Transaction	**:**	Government to Business
Who May Avail	**:**	All Food Contact Articles Manufacturers and Distributors
Fees to be Paid	**:**	NONE

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of Inquiry (Containing at least the following information about the product/article to be applied for evaluation: formulation/composition, intended use and the specific food that will be contained.)	Company applicant

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
Submits letter of inquiry at the Food and Drug Action Center (FDAC).	1. Receives and forwards the letter of inquiry to the Common Services Laboratory Receiving and Releasing Unit (CSL RRU)	5 minutes	CSL/Receiving and Releasing Unit (RRU)/ Laboratory Technician I (Lab Tech) at FDAC
	2. Forwards the letter of inquiry to the CSL-Toxicology Section	10 minutes	CSL/RRU/Lab Tech I
	3. Receiving, Recording (Section's Database) and Scheduling (Decking)	30 minutes	CSL/Toxicology Section/Admin Assistant and FDRO III or IV
	4. Drafts and Finalizes reply letter to the query	6 days	CSL/Toxicology Section/Admin Assistant and FDRO III or IV
	5. Forwards the reply letter to the CSL RRU	10 minutes	CSL/Toxicology Section/Admin Assistant

	6. Forwards the reply letter to the CSL Director for signature Signs and return the reply letter to the CSL RRU	10 minutes	CSL/RRU/Lab Tech I CSL Director II
	7. Forwards the Reply Letter to the FDAC	4 hours	CSL/RRU/Lab Tech I
	8. Releases the Reply Letter to the client	5 minutes	CSL/RRU/Lab Tech I at FDAC
	TOTAL:	**7 Working Days**	

8. ISSUANCE OF FOOD EXPORT CERTIFICATE AND FOOD COMMODITY CLEARANCE

Issuance of Food Export Certificate and Food Commodity Clearance to All FDA-Licensed Food Establishments

Center/Office/Division	**:**	Common Services Laboratory
Classification	**:**	Simple Transaction
Type of Transaction	**:**	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
2. Scanned copy of the completely filled out Application Form in two (2) copies	FDA website (www.fda.gov.ph)
3. Scanned copy of valid License To Operate (as manufacturer/trader/exporter, whichever is applicable)	Company applicant
4. Scanned copy of valid Certificate of Product Registration of the product for export	Company applicant
5. Scanned copy of the signed Packing List or Sales Invoice (System generated/**electronically signed** is also accepted)	Company applicant
6. Excel copy of the filled templates of the draft Certificates and database	Company applicant

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
Downloads the Application Form, draft template of the Certificate and database at the FDA website			Company applicant
Submits an email request with attached soft copies of the requirements to cslexport@fda.gov.ph			Company applicant

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
	Checks email requests lodge at cslexport@fda.gov.ph Reviews application for completeness of requirements and correctness of Application Form. If found unacceptable, application is returned stating the reason of rejection.	1 minute 5 minutes 2 minutes	CSL/ Food Section / Health Program Officer (HPO) II/ Lab. Tech/-Food-Drug Regulation Officer
	If found satisfactory, a reference number is issued for each applications received	1 minute	CSL/ Food Section / Health Program Officer (HPO) II/ Lab. Tech/-Food-Drug Regulation Officer
	Edits draft Certificate submitted to reflect Reference Number (FE for Food Export and FCO for Food Commodity Clearance)	5 minutes	CSL/ Food Section / Health Program Officer (HPO) II Lab. Tech/-Food-Drug Regulation Officer
	Shares the prepared Certificate and/or Clearance at the network with the issued reference number as the label	1 minute	CSL/ Food Section / Health Program Officer (HPO) II Lab. Tech/-Food-Drug Regulation Officer
	Reviews the prepared Certificate and/or Clearance	3 minutes	CSL /Food Section/ Food-Drug Regulation Officer
	Prints the final copy of the Certificate and/or Clearance for signature of the CSL Director	1 minute	CSL/RRU/ Laboratory Technician I
	Signs the Certificate and/or Clearance	1 minute	CSL Director II
	a. Seals the approved and signed Certificates and/or Clearances b. Updates the CSL Main Database c. Prints transmittal slip in two (2) copies d. Forwards Certificates and transmittal slips to AFS – Records Section for	1 minute 1 minute 1 minute 2 minutes	CSL/RRU/ Laboratory Technician I

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
	endorsement to FDAC Releasing		
	TOTAL:	**25 minutes**	

NOTES :

11. Applications are accommodated online through cslexport@fda.gov.ph from 8 am to 2 pm, Mondays to Fridays except holidays and suspension of work, when deemed necessary (e.g. acts of nature). Applications received after 2 pm shall be treated as submitted on the next working day.
12. 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

9. FOOD AND DRUG ADMINISTRATION'S ACCREDITATION OF PRIVATE TESTING LABORATORY

Application for Laboratory Accreditation for Private Testing Laboratories.

Center/Office/Division	**:**	Common Services Laboratory
Classification	**:**	Highly Technical Transaction
Type of Transaction	**:**	Government to Business (G2B)
Who May Avail	**:**	Private Testing Laboratory
Fees to be Paid	**:**	1) Audit of Testing Laboratory (Per Visit) a) Within Metro Manila - Php 10,000 + transportation cost b) Outside Metro Manila - Php 10,000 + per diem/per inspector + transportation cost 2) Accreditation of Testing Laboratory Fee (Per Year) – Php 20,000 3) Legal Research Fee – 1% of the total amount

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Duly Notarized Accomplished Petition Form (FDA Order No. 2012-001 Annex A)	FDA Website (www.fda.gov.ph)
2.Certified True 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	Private Testing Laboratory - Applicant
3. Copy of Laboratory Quality Manual and List of SOPs	Private Testing Laboratory - Applicant
4. List of PAB Approved Signatories for the particular test or types of test covered by the Scope of Accreditation	Private Testing Laboratory - Applicant
5. Location Map of the Laboratory	Private Testing Laboratory - Applicant
6. Copy of latest PAB assessment findings with corresponding corrective action	Private Testing Laboratory - Applicant
7. Floor layout with appropriate scale reflecting laboratory areas	Private Testing Laboratory - Applicant

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1. Submission completed requirements to FDA	Receiving of Application Applicants will be given a 14-digit Document Tracking Number (DTN). ➢ Pre-Evaluation of submitted documents (as to completeness) – If the requirements are **incomplete**, the application is rejected. Applicant is informed on the result of pre-evaluation indicating the noted discrepancies – If the requirements are **complete**, tentative date of audit is scheduled.	1 working day	Common Services Laboratory – Receiving and Releasing Unit (CSL-RRU) FDA Lab. Accreditation Member
2. Confirmation to the proposed date of audit within seven (7) working days after receipt of the Notice. Otherwise, the schedule of assessment will be cancelled.	- Notice of Audit will be sent to the applicant - Review submitted documents as Pre-audit review	1 working day	FDA Lab. Accreditation Member
3. On-site assessment / Remote Assessment *(if necessary)*	- Audit Proper - Provide the audit report with findings and recommendations	3 working days	FDA Lab. Accreditation Team (Assigned Auditors)
4. Submission of First Corrective Action Plan	Receipt of documents	5 working days	CSL-RRU FDA Lab. Accreditation Team (Assigned Auditors)
	Evaluation of First Corrective Action Plan and send prepared report to the client		FDA Lab. Accreditation Team (Assigned Auditors)
5. Submission of Second and/or Third Corrective Action Plan	- Receipt of documents - Evaluation of Second and/or Third Corrective Action Plan and send prepared report to the client - Provide Final Evaluation Report and notify Client that accreditation is granted or denied	6 working days	CSL-RRU FDA Lab. Accreditation Team (Assigned Auditors)

	- Provide Assessment Slip to client		CSL-RRU
6. Secure payment to all fees (Audit Fee, Accreditation Fee and LRF) and provide copy of Original Receipt (OR) to CSL-RRU	- Acknowledge payment and copy of OR - Preparation of signed Certificate of Accreditation and Scope (Printed on Security paper and plain A4 paper) (OR No. shall be printed on both copies)	4 working days	FDA Lab. Accreditation Team (Assigned Auditors) Director of CSL/ Chairman of FDA Accreditation Team
7. Receipt of Certificate and Scope of Laboratory Accreditation	Release of Certificate and Scope of Laboratory Accreditation. The applicant is notified on the availability of Certificate		FDA Lab. Accreditation Team (Assigned Auditors) CSL-RRU
	TOTAL:	**20 working days**	

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

Issuance of Lot Release Certificate (LRC) for Vaccine and Biological Products to Marketing Authorization Holder (MAH)

Center/Office/Division	**:**	Common Services Laboratory
Classification	**:**	Complex Transaction
Type of Transaction	**:**	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
1. Duly notarized accomplished Lot Release Application Form with declaration and undertaking.	FDA website (www.fda.gov.ph)
2. Self-Assessment Checklist for Lot Release Certification	FDA website (www.fda.gov.ph)
3. Certificate of Product Registration (CPR) complete with its annexes (Certificate of Variation, if any) – valid at the time of application.	Company applicant
4. Valid License to Operate (LTO) of the: a. Manufacturer (if applicable) b. Distributor c. Importer	Company applicant
5. Certificate of Analysis (CoA) for the Final/ Finished Product (and for the diluent as necessary).	Company applicant
6. Three (3) final containers of representative product samples in their final packaging representation in proper storage condition as per approved specification. *(Note:*	Company applicant

For products with multiple final containers in 1 box, only 3 final containers are required but will still be submitted inside said box).	
7. SOP for Sampling Method from license holder	Company applicant
8. Complete Summary Lot Protocol (SLP)	Company applicant
9. Manufacturing Process Flow Diagram	Company applicant
10. Batch Numbering System.	Company applicant
11. Lot Release Certificate (or equivalent National Regulatory Authority [NRA] certification) from the country of origin of the product (for imported products).	Company applicant
12. 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).	Company applicant
13. Generic Labelling Exemption (if applicable).	Company applicant
14. 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).	Company applicant
15. Temperature monitoring data during shipment (Cold Chain Documents)	Company applicant
16. Proof of payment (e.g. Official Receipt, Landbank Oncoll Machine-Validated Payment, verified and posted payment by the FDA Cashier)	Company applicant
Additional Requirements:	
➢ **For government procured products (Expanded Program on Immunization [EPI's] and non-EPI's)**	
1. Purchase Order and Notice of Award from Department of Health.	Department of Health
➢ **For donated vaccines/ biological products**	
1. 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 Field Regulatory Operation Office (FROO) on the inspection on the actual shipment	Company applicant

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
Submit applications for pre-assessment to the CSL – Vaccine and Biological Unit (VBU) through email to cslvbu@fda.gov.ph. All submissions shall contain all the documentary requirements for National Lot Release (specified above) in PDF file format.			Company applicant

Note: If a file to be provided is too large to be an email attachment, a link to a cloud storage (e.g., Google Drive, Microsoft OneDrive, etc.) may be allowed, provided that VBU is given full downloading privileges.			
	Pre-assess application for completion based on the checklist of requirements. If found to be incomplete / unacceptable, the applicant shall be informed by email response, indicating found deficiency/ies or discrepancy/ies. Compliance documents shall be submitted prior to acceptance. If found complete and acceptable, applicant shall be informed by email response, with a 14-digit Document Tracking Number (DTN) provided for payment and tracking purposes	(Day 0) 1 hour	CSL/Vaccine and Biological Unit (VBU)/Food-Drug Regulation Officers II & III (FDROs)
Submit the following requirements: a. The representative samples submitted directly to the FDA Main Office – Experimental Animal House Building. *Note: Email notification must be made prior to sample submission	Receipt and acceptance of Application and samples ● Scheduling of sample submission ● Review and check samples	30 minutes	CSL/VBU/FDRO II & III
b. Documentary requirements emailed to csl@fda.gov.ph with the subject: National Lot Release Initial Application_DTN No.	● Review and Check Documents ● Assign LRV No. ● Fill-out the necessary information in excel copy of the application form. ● Encode to CSL-RRU Database	30 minutes	CSL/Receiving and Releasing Unit (RRU)/ Laboratory Technician I (Lab Tech)

● Filled-out excel copy of the application form; ● Scanned copy (in PDF file) proof of acceptance; ● Accomplished Assessment slip and ● Official Receipt or machine-validated Landbank Oncoll Payment Slip ● Filled-out Sample Acceptance Form	● Inform CSL-VBU and the applicant on the receipt of application.		
	Receipt of Application in the section (VBU) ● Check documents ● Decking	1 hour	CSL/VBU/FDRO II, III & IV
	Evaluates the application/ compliance and preparation of the corresponding worksheet as applicable. ● Visual Examination ● Updating of Database ● Wrapping and Tagging of samples	5 working days	CSL/VBU/FDRO II & III
	Review of Worksheet and Preparation of Lot Release Certificate or Letter of Denial (indicating noted findings as to why safety and quality could not be established; as applicable)	1 hour	CSL/VBU/Lab Tech I & FDRO II & III
	Review and Approval of Lot Release Certification or Letter of Denial (as applicable) ● Finalization and Signature	30 minutes	CSL/VBU/FDRO III & IV
	Signs the Lot Release Certificate or Letter of Denial (as applicable)	10 minutes	CSL Director II
	Forwards Signed Lot Release Certificate or Letter of Denial (as applicable) to AFS-Records Section	10 minutes	CSL/RRU/Lab Tech I
	Releasing of Lot Release Certificate or Letter of Denial (as applicable) ● Scanning	1 working day	AFS – Records Section

	● Forwards LRC or Letter of Denial (as applicable) to Central Releasing		
	TOTAL:	**7 working days**	

NOTE:

- Online Pre-assessment service shall be available from Mondays to Fridays (except holidays), from 8:00 a.m. to 3:00 p.m. Applications submitted beyond 3:00 p.m. shall be pre-assessed the following working day.
- Commencement of Day 1 processing is applicable only to applications with submitted Machine Validated Landbank ONCOLL Payment or applications with verified and posted payment by the FDA Cashier
- Linkbiz payment verification (3-5 days)

11. REQUEST FOR PERFORMANCE TESTING OF RADIOLOGIC EQUIPMENT

Center/Office/Division	**:**	Common Services Laboratory/Physics Laboratory Support Division
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2G, G2B
Who May Avail	**:**	Government (DOH, Local) hospitals, Private hospitals and clinics
Fees to be Paid	**:**	P7,920.00/radiologic equipment (plus 1% LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Request for Performance Testing (RPT)	FDAC/FDA website
2. Order of payment	FDAC/FDA website
3. Prerequisite for Performance Testing	FDAC/FDA website

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE

1. Submit duly accomplished Request for Performance Testing (RPT) .	1. The Administrative Staff will evaluate the RPT as to completeness. Incomplete application will be rejected. 2. For complete application the administrative staff will issue a fourteen (14)-digit Document Tracking Number (DTN), order of payment and PLSD code. The administrative staff will affix an initial signature and date.	One (1) working day	PLSD Administrative Staff
2. Pay the performance testing fee and send a proof of payment to the PLSD official email (csl-plsd@fda.gov.ph)	1. The administrative staff will give a tentative schedule date to the client with the "Prerequisite for Performance Testing Form"	One (1) working day	PLSD Administrative Staff
	2. The administrative staff will determine the availability of the Health Physics Team (HPT) and endorse the accomplished RPT submitted by the client.	Two (2) working day	PLSD Administrative Staff
1. The client will submit the Prerequisite for Performance Testing to the assigned HPT.	1. The HP team assigned on the facility will evaluate the documents submitted and coordinate/communicate with the requesting agency on the proposed date of performance testing	Three (3) working days	Health Physics Team (HPT)
Confirm the readiness of the facility, functionality of the radiologic equipment, availability of the service engineer, logistics	1. Prepare travel authority, other administrative requirements, appropriate test protocol, form and test tools.	Three (3) working days	HPT
	1. Recommend approval of travel to the CSL Director		Division Chief
	2. Conduct of performance testing 3.1 HP Team travel to the specified facility	Three (3) working days*	HPT

	3.2 Conduct of performance testing 3.3 Prepare initial test report to be received by the representative of the facility		
	3. Upon return of HP Team from fieldwork 4.1 Prepare the final performance test report and sign the report 4.2 Submit the test report to the Division Chief	Five (5) working days	HPT
	4. Review and attest the test report	One (1) working day	Division Chief
	5. Endorse test report to CSL Director		PLSD Administrative Staff
	6. Sign the endorsement letter addressed to the facility owner		CSL Director
	7. Return the sign documents to PLSD		Laboratory Technician
	8. Release of Test Report 9.1 Endorse one (1) copy of the signed test report to the PLSD Administrative Staff 9.2 Endorse another copy of the signed test report to Information and Communication Technology Division (ICTMD) for mailing to the client 9.3 The PLSD Administrative Staff will scan the signed copy of test report and email to Radiation Regulation Division (RRD)-Center for Device Regulation, Radiation Health and Research (CDRRHR) and to the client	One (1) working day	PLSD Administrative Staff PLSD Administrative Staff
	TOTAL:	**20 working days**	

** **Conduct of performance testing depends on the type of radiological equipment and the location of the facility.***

Note: Commencement of Day 1 processing is applicable only to applications with submitted proof of payment

12. REQUEST FOR CONDUCT OF QUALITY AUDIT OF RADIOTHERAPY FACILITY TRANSACTION

Center/Office/Division	**:**	Common Services Laboratory/Physics Laboratory Support Division
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2G, G2B
Who May Avail	**:**	Government and Private Health Facilities
Fees to be Paid	**:**	Php7,999.20 (inclusion of 1% LRF) /radiologic equipment *(for initial application only)*

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Request letter for Quality Audit	From the requesting health facility
2. Technical Specification of Radiotherapy equipment	From the requesting health facility
3. Initial Quality Audit Form	FDA-CSL-PLSD
4. Order of payment *(for initial application only)*	FDA-CSL-PLSD

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1. Submit request for Quality Audit	1.1. Receive request and assign a DTN and or acknowledge the DTN from FDAC 1.2. Endorse request to PLSD Health Physics Team 1.3. Issues Order of Payment *(for initial application only)*	One (1) working day	Administrative Aide
2. Evaluation of submitted request	2.1. Evaluate the submitted documents correctness and completeness 2.2. Confirm the readiness of the health facility's therapeutic machine (LINAC and or Co-60) 2.3. Coordinate/communicate with the requesting health facility on the proposed date of Quality Audit	One (1) working day	Health Physics Team
3. Preparation of administrative and technical travel requirements	3.1. Prepare travel authority and other administrative requirements 3.2. Prepare appropriate quality audit protocol and form 3.3. Prepare appropriate quality audit tools and instrument	One (1) working day	Health Physics Team

	3.4. Recommend approval of travel to the CSL Director		Division Chief
4. Conduct of Quality Audit	4.1. Technical Team travel to the specified health facility 4.2. Conduct of Quality Audit 4.3. Prepare initial Quality Audit report to be received by the representative of the facility	Four (4) working days	Health Physics Team
5. Preparation of official Quality Audit report	5.1. Prepare the official Quality Audit report 5.2. Sign the Quality Audit report and submit to the Division Chief	Ten (10) working days	Health Physics Team
	5.3. Review and attest the Quality Audit report	Two (2) working day	Division Chief
	5.4. Endorse Quality Audit report to CSL Director		Administrative Aide
	5.5. Sign the endorsement letter addressed to the health facility owner		CSL Director
	5.6. Return the sign documents to PLSD for releasing to health facility (customer)		Laboratory Technician
6. Releasing of Quality Audit report to health facility.	6.1. Endorse the officially signed Quality Audit report to Information and Communication Technology Division (ICTMD) for mailing 6.2. Endorse the duplicate copy of the officially signed Quality Audit report to SDO for scanning and filing	One (1) working day	Administrative Aide
	TOTAL:	**20* working days**	

Legend :
* 20 working-day added onto the declared number of days may be imposed by the PLSD based on the pre-determined technology enhanced radiotherapy equipment which requires further evaluation as may be considered as highly technical in nature *(R.A. No. 11032 – Ease of Doing Business)*
▯ Inclusion of STOP-CLOCK awaiting confirmatory response from customer

13. CONDUCT OF ROUTINE LABORATORY ANALYSIS

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

[1] *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.*
b. *Government Deliveries – These are health products submitted by government agencies like the Department of Health, Local Government Units and government hospitals*
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.*

Center/Office/Division	**:**	Common Services Laboratory
Classification	**:**	Highly Technical Transaction
Type of Transaction	**:**	Government to Government (G2G); Government to Client (G2C)
Who May Avail	**:**	Government Agencies, FDA Centers & Offices, and Other Stakeholders
Fees to be Paid	**:**	AO No. 50 s. 2001 + Legal Research Fee (LRF)

CLASSIFICATION	**FEES (Php)**
1. Physico-chemical Analysis	
Drugs and Antibiotics	
o Visual Examination	300.00
o Assay/Potency (single component)	1,500.00
o Assay/Potency (multi-component)	2,000.00
o Dissolution Test	2,000.00
o Disintegration Test	350.00

CLASSIFICATION	**FEES (Php)**
o Hardness Test	350.00
o Identification Test	500.00
o Purity test / Related Substances	500.00
o Moisture content	300.00
o Loss on Drying	300.00
o pH	300.00
o 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
o Minerals	800.00
In Vitro Diagnostic Reagents	1,000.00
Medical Devices	1,500.00
Cosmetics	
o Assay	1,200.00
o Identification test	500.00
o Volatile / Non-volatile matters	500.00
Food Products	
o Moisture	300.00
o Protein	1,000.00
o Fat/Oil	500.00
o Starch	500.00
o Glucose	500.00
o Sucrose	500.00

CLASSIFICATION	**FEES (Php)**
o Lactose	500.00
o Crude fiber	500.00
o Dietary fibers	2,000.00
o Total Solids	300.00
o Soluble Solids	300.00
o Water-Insoluble Solids	300.00
o Ash	300.00
o Acid-insoluble ash	500.00
o Saponification number	500.00
o Viscosity	300.00
o Refractive Index	300.00
o Peroxide Value	500.00
o Free fatty acids	500.00
o Permanganate Oxidation Number (PON)	500.00
o Total Acidity	300.00
o Water activity	500.00
o Vacuum	300.00
o Minerals	1,000.00
o Amino Acids (LC)	2,000.00
o Proline	500.00
o Additives	

Nitrate	500.00
Nitrite	500.00
Sodium Benzoate	500.00
Sorbic acid	500.00

CLASSIFICATION	FEES (Php)
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
o 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
o 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

CLASSIFICATION	FEES (Php)
Mercury	300.00
Tin	300.00
Cyanide	300.00
Histamine	1,500.00

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	
o Alcohol content	1,000.00
o Gas volume	300.00
o Total Soluble Solids (Brix)	300.00
o pH	300.00
o Caffeine	500.00
Bottled water	2,000.00
Food Chemicals / Additives	
o Direct	1,000.00
o Indirect	500.00
Containers / wrappers	
o Migratable Substances	1,000.00

CLASSIFICATION	**FEES (Php)**
o Plastic additives	500.00
o Cellulosic Materials for Pesticide Residue	1,500.00
o Materials Testing	500.00
Microbiological Assay (Potency of Antibiotics)	2,500.00
Sterility Test (Injectables, Medical Devices and Large Volume Parenterals)	2,500.00
Microbial Limit	
o Aerobic Plate Count	500.00
o Aerobic Halophilic Count	500.00
o Aerobic Thermophilic Count	500.00
o Coliform Plate Count	500.00
o Coliform / E. coli (MPN)	500.00
o Fecal Streptococci	600.00
o Yeast and Mold Count	500.00
o Halophilic Yeast Count	500.00
o *Staphylococcus aureus* count	600.00

o *Pseudomonas aeruginosa*	600.00
o 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	
o Bacterial endotoxin Test (LAL)	4,000.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
7. Duly Accomplished Request for Analysis (RFA) Form	FDA website (https://ww2.fda.gov.ph/industry-corner/downloadables)
8. Actual Sample/s a. Quantity should be in accordance with FDA Circular No. 2014-014 "Minimum Number of Samples Units required for Each Test Analysis" b. With expiration date at least three (3) months prior to request for analysis c. Actual sample per request should bear the same batch or lot d. Properly handled	Client/Requesting Party https://ww2.fda.gov.ph/attachments/article/161088/FC2014-014%20-%20Minimun%20Numbers%20of%20Samples%20Units%20Required%20for%20Each%20Test%20Analysis.pdf
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 **Note:** 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.	Company applicant
9. For external clients only: Proof of payment (e.g. Official Receipt, Landbank ONCOLL Machine-Validated Payment, verified and posted payment by the FDA Cashier)	Company applicant

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	FEES	PERSON RESPONSIBLE
Submits Request for Analysis (per request) together with other requirements for pre-assessment			None	
	Pre-assessment and evaluation of the RFA **If the above requirements are not met**, the client shall be informed by email response and/or by telephone communication, indicating that the request is rejected. Consequently, RFA will be returned, for appropriate actions. Revised RFA shall be submitted prior to acceptance. **If the above requirements are met**, the request is accepted and a laboratory number will be issued.	10 minutes		CSL/Receiving and Releasing Unit (RRU)/Laboratory Technician I
	Receives and encodes the RFA in CSL Database	10 minutes		CSL/RRU/Lab Tech I
	Forwards to concerned Section the following: ● RFA ● Sample ● Transmittal Sheet	5 minutes		CSL/RRU/Lab Tech I
	Receiving and updating in the FDA Inventory System (FIS), Database ● RFA ● Sample ● Transmittal Sheet	10 minutes		CSL/Sections (Antibiotics, Drugs, Microbiology, Cosmetics, Foods, Toxicology, EAH)/Lab Tech, Admin Assistant
	Recording (Section's Database) and	10 minutes		CSL/Section Concern/Lab

	scheduling (decking of sample)			Tech, Admin Assistant
	Sample handling and storage	5 minutes		CSL/Section Concern/Lab Tech, Admin Assistant
	Pre-evaluation (per label/test required)	10 minutes		CSL/Section Concern/Lab Tech, Admin Assistant
	TESTING [1]			
	A. Complaints ● High-risk ● Low to Medium-risk	5 working days 18 working days		CSL/Section Concern/Food-Drug Regulation Officers I, II & III (FDROs)
	B. Government Deliveries ● Anti-Tuberculosis Drugs (DOH-LMD) ● DOH-LMD, other than TB Drugs ● Other government agencies (LGUs, etc.)	13 working days 18 working days 18 working days		CSL/Section Concern/Food-Drug Regulation Officers I, II & III (FDROs)
	C. Donations	18 working days		CSL/Section Concern/Food-Drug Regulation Officers I, II & III (FDROs)
	D. Post-Marketing Surveillance	18 working days		CSL/Section Concern/Food-Drug Regulation Officers I, II & III (FDROs)
	E. Referrals	18 working days		CSL/Section Concern/Food-Drug Regulation Officers I, II & III (FDROs)
	If Samples will be referred to Third Party Laboratory for Testing: Procurement Process of Third-Party Laboratory Testing Service Fee			BAC†
	Data Recording and Computation	1 working day		CSL/Section Concern/Food-

	Note: this step is excluded if request is conducted by Third Party Laboratory			Drug Regulation Officers I, II & III (FDROs)
	Data/Results Evaluation	4 hours		CSL/Section Concern/FDRO III or IV
	Preparation of Test Reports	1 hour		CSL/Section Concern/Lab Tech, Admin Assistant
	Signing of Test Reports			
	1. Conformance	10 minutes		CSL/Section Concern/FDRO III or IV
	2. Non-Conformance	10 minutes		CSL/Section Concern/FDRO III or IV and CSL Director
	Assessment of fees for the tests/parameters conducted (Test Report)	10 minutes		CSL/RRU/Lab Tech I
	Forwards the Test Report with the Assessment Slip	10 minutes		CSL/RRU/Lab Tech I
Proceeds to Cashier Section for Payment of Fees	Receives payment and issues Official Receipt (OR)	10 minutes		FDA Cashier Staff
	Releasing of Test Reports			
	1. Internal Client	10 minutes		CSL/RRU/Lab Tech I
	2. External Client (Central Releasing - FDAC Starmall)	1 hour		FDAC Staff
TOTAL:		**20 Working days***		

**except for the following:*
- High Risk Complaints: 7 working days
- Government deliveries: Anti-Tuberculosis Drugs (DOH-LMD): 15 working days

†*Procurement process for Third-Party Laboratory Testing will have a separate timeline following the procedures stipulated in the Implementing Rules and Regulations of RA 9184: The Government Procurement Reform Act*

Additional Notes:

- *Samples subject for **Sterility Testing** requires a total number of **thirty-three (33) calendar days** (equivalent to **twenty-five (25) working days**), which includes: (1) 1-day media preparation; (2) 7-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.

- *Samples subject for **Evaluation of the Antimicrobial Protection** of a Cosmetic Product requires a total number of **sixty (62) calendar days** (equivalent to **forty-six (46) 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.*
- *Samples subject for **Commercial sterility** of thermally processed foods in hermetically sealed containers requires approximately **thirty (32) calendar days** (equivalent to **twenty-four (24) working days**), which includes: (1) 1-day media preparation; (2) 10-days sample pre-incubation; (3) 5-days sample culturing; (4) 14-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.*
- *Releasing of Test Reports for those requiring payment will commence once proof of payment is received by the Common Services Laboratory.*

1. 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	:	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	:	No required payment

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. Sends an email request to fdac@fda.gov.ph	1.Checks the received e-mail as to completeness and appropriateness of the request	None	15 Minutes	FDAC Staff Information Officer II
2. Receives username and password	2. Issues user account (username and password) to client	None	Next Working Day	FDAC Staff Information Officer II
	TOTAL:	**None**	**1 Working Day, 15 Minutes**	

2. 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 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 e-mail to fdac@fda.gov.ph	1.Checks the received e-mail as to completeness and appropriateness of the request	None	15 Minutes	FDAC Staff Information Officer II
2. Receives Document Tracking Log and Appointment Schedule	2.Issues 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, 15 Minutes**	

3. Filling of Complaint (Walk-in)

Filing of complaint through personal appearance at the Food and Drug Action Center (FDAC)

Center/Office/Division	:	FDAC CSAT/E-Report Section
Classification	:	Simple
Type of Transaction	:	G2G - Government to Business, G2C - Citizen, or G2G – Government
Who may Avail	:	All
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
Written letter addressed to Director General of Food and Drug Administration (FDA) ▪ Full name ▪ Address ▪ Contact details ▪ Details of the acts complained of ▪ Name of center/office of person(s) charged, if applicable ▪ Evidence of such violation, if applicable	Food and Drug Action Center

CLIENT STEPS	**AGENCY ACTION**	**Fees to be paid**	**PROCESSING TIME**	**PERSON RESPONSIBLE**
1. Submits a written letter addressed to the Director General of the Food and Drug Administration (FDA) to E-Report Section of the Food and Drug Action Center (FDAC) Address: 3rd Flr. Starmall Alabang, Muntinlupa	1. Receives the written letter and encodes the details in the FDA Inventory System and generates Document Tracking Number (DTN)	None	5 Minutes	FDAC E-Report Staff (Administrative Assistant III)

2. Receives an acknowledgement receipt.	2. Encodes the DTN and details of the E-Report Database for tracking and monitoring. 3. Prints the acknowledgement receipt	None	5 Minutes	
	4. Endorses the received document/s to the concerned center/office	None	Day 1	
	TOTAL:	**None**	**1 Working Day, 10 Minutes**	

4. Filling of Complaint (Online)

Filling of complaint through e-mail, **e-report@fda.gov.ph**

Center/Office/Division	:	FDAC CSAT/E-Report Section
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business, G2C - Citizen, or G2G – Government
Who may Avail	:	All
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
For complaint or feedback via e-mail, kindly include the following information if applicable: ▪ Full name: ▪ Address: ▪ Contact details: ▪ Details of the complaint/feedback ▪ Person(s) in-charged ▪ Evidence of such violation	Food and Drug Action Center

CLIENT STEPS	AGENCY ACTION	Fees to be paid	PROCESSING TIME	PERSON RESPONSIBLE
1. Send complaint via e-mail with the detailed information to the Food and Drug Action Center (FDAC) E-mail: e-report@fda.gov.ph customersatisfactionteam@fda.gov.ph	1. Checks the received document along with other attached documents if available.	None	5 Minutes	FDAC E-Report Staff (Administrative Assistant III)
	2. Encodes the complaint details and generates Document Tracking Number (DTN) in the FDA Inventory System	None		
	3. Encodes the DTN and compliant details in the E-Report Database	None		

	for tracking and monitoring.			
2. Receives acknowledgement receipt and DTN	4. Send an acknowledgement receipt including DTN	None	5 Minutes	
	5. Endorse the received document/s to the concerned center/office through e-mail	None	Day 1	
TOTAL:		**None**	**1 Working Day, 10 Minutes**	

5. 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. Submits application and other documents to PACD or Letter Section	1. Checks the application and other documents if the payment has been made	AO No. 50 s. 2001	5 Minutes	FDAC Information Officer II
2. Receives acknowledgement receipt	2. Checks the received application/s and other documents. 3. Stamp the client's Document Tracking Log as an acknowledgement	None	3 minutes	FDAC Information Officer II

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

6. Assistance to Phone Callers

Center/Office/Division	:	FDAC Phone Operator Section
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business, G2C - Citizen, or G2G – Government
Who may Avail	:	All
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
None	None

CLIENT STEPS	**AGENCY ACTION**	**Fees to be paid**	**PROCESSING TIME**	**PERSON RESPONSIBLE**
Calls the FDAC designated landline numbers 8-8211177 8-8211176 8-8211159 8-8211220 8-8211162	1. Answer phone calls and identify the client's concern 2. Acts on client's concern 3. Highly technical concerns are advise to send an e-mail to the designated center/office e-mail address	None	10 Minutes Depending on the complexity of the issue	FDAC Phone Operators Information Officer II
TOTAL:		**None**	**10 Minutes**	

7. Customer Satisfaction Survey (CSS) Form

Center/Office/Division	:	FDAC CSAT/E-Report Section
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business, G2C - Citizen, or G2G – Government
Who may Avail	:	All
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
CSS Form	Food and Drug Action Center (FDAC)

CLIENT STEPS	**AGENCY ACTION**	**Fees to be paid**	**PROCESSING TIME**	**PERSON RESPONSIBLE**

1. Fill-out the CSS form and drops it at the designated suggestion box	1. Consolidates all filled-out CSS forms at the end of the month	None	3 Minutes	FDAC E-Report Staff (Administrative Assistant III)
	2. Routes the consolidated forms to the concerned center/office	None	Day 1	
	TOTAL:	**None**	**1 Working day, 3 Minutes**	

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.