DEPARTMENT OF HEALTH

FOOD AND DRUG ADMINISTRATION

CITIZEN'S CHARTER

2022 (4th Edition)

Effectivity Date: 4 May 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-based standards and policies, in a healthy and safe work environment.

CENTER FOR COSMETICS (AND HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES) REGULATION AND RESEARCH (CCHUHSRR)

List of Health Products Covered

A. Cosmetics
B. Household/Urban Hazardous Substances
C. Household/Urban Pesticides
D. Toys and Childcare Articles
E. Novel Household/Urban Hazardous Substances (Vapor Products)

LIST OF EXTERNAL SERVICES

CERTIFICATE OF PRODUCT REGISTRATION

FIELD REGULATORY OPERATIONS OFFICER INSPECTION AGENDA

Certificate of Product Registration/Notification

1. Cosmetic and Toys and Childcare Articles (TCCA) Notification User Account and Password

Issued to licensed establishments that will apply for product notification.

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

A. INITIAL APPLICATION

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

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

	2. Data Controller creates username and password	None	30 Minutes	CCHUHSRR
	3. Data Controller sends the username and password to applicant	None	30 Minutes	
TOTAL:			**1 working day, 1 Hour**	

B. RENEWAL APPLICATION

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

CLIENT STEPS	**AGENCY ACTION**	**FEED TO BE PAID**	**PROCESSING TIME**	**PERSON RESPONSIBLE**
1. Applicant emails the request following the format stated in FMC 2015-010 to cchuhsrraseannotification2@fda.gov.ph		None		Applicant
	1. Data Controller verifies the information if correct and complete	None	1 Day	Information Technology Officer CCHUHSRR
	2. Data Controller reactivates the username and password and send it to applicant	None	30 Minutes	

TOTAL:		**1 Day, 30 Minutes**

C. CHANGE IN CREDENTIALS APPLICATION

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

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

2. Cosmetic Product Notification

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

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

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

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant request for e-portal username and password		None		Applicant
2. Applicant accomplish the application form and declaration in the e-portal		None		Applicant

3. Applicant generates order of payment and pays the fee through a Landbank Branch or FDA Cashier		Php 510.00 Additional Php 100.00 per variant	30 Minutes	FDA Cashier personnel or Landbank Personnel
	1. Posting of payment. Payment will be posted after bank clearing	None	5 working days	FDA Cashier Personnel
	2. Evaluator checks the correctness of the application *Substantiation may be asked if there will be further clarifications	None	12 working days	Food Drug Regulation Officer CCHUHSRR
	3. CCHUHSRR Director will give the final decision on the application	None	30 Minutes	Director IV CCHUHSRR
	4. Acknowledgement or disapproval will be forwarded to applicants e-portal account	None		Applicant
TOTAL:		Php 510.00 Additional Php 100.00 per variant	**17 working days, 1 Hour**	

3. Toys and Childcare Articles Product Notification

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

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

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

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant request for e-portal username and password		None		Applicant
2. Applicant accomplish the application form and declaration in the e-portal		None		Applicant
3. Applicant generates order of payment and pays the fee through a Landbank Branch or FDA Cashier		Php 110.00	30 Minute	FDA Cashier personnel or Landbank Personnel
	1. Posting of payment. Payment will be posted after bank clearing	None	5 working days	FDA Cashier Personnel
	2. Evaluator checks the correctness of the application	None	12 working days	Food Drug Regulation Officer CCHUHSRR
	3. CCHUHSRR Director will give the final decision on the application	None	30 Minutes	Director IV CCHUHSRR
	4. Acknowledgement or disapproval will be forwarded to applicants e-portal account	None		Applicant
TOTAL:		Php 110.00	**17 working days, 1 Hour**	

4. Certificate of Product Registration (CPR) for Household Urban Pesticides (HUP)

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

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

A. INITIAL REGISTRATION OF ACTIVE INGREDIENT

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Integrated Application Form with Declaration	FDA website (https://www.fda.gov.ph/downloadables/)
2. Valid LTO	FDA-CCHUHSRR
3. Copy of Official Receipt	FDA Cashier
Refer to AO 2019-0008 Annex A for the specific data on the following requirements:	

4. Chemical Identity	Manufacturer or any 3rd Party Laboratory
5. Physical Properties of the Active Ingredient	
6. Product Specifications	
7. Certificate of Analysis	
8. Safety Data Sheet	
9. Any of the following proof of manufacturer's compliance to Good Manufacturing Practices (GMP) 9.1. Certificate of Free Sale (CFS) issued by the National Regulatory Authority of country of origin 9.2. Certificate of Good Manufacturing Practice (GMP) based on international manufacturing standards 9.3. Manufacturing License 9.4. ISO Certificate related to manufacturing *Note: Must be duly authenticated and notarized by the Philippine Embassy*	Manufacturer
10. Submission of Actual Sample and Reference Standard	Applicant or Supplier/Manufacturer
11. Toxicity Data 11.1. Acute Toxicity 11.2. Corrosion / Irritation 11.3. Allergy / Sensitization 11.4. Sub-chronic Toxicity 11.5. Reproduction Effects 11.6. Teratogenicity 11.7. Neurotoxicity 11.8. Mutagenicity 11.9. Carcinogenicity and Chronic (Long Term) Toxicity Studies in Rats	Toxicity Testing Laboratory
12. Human Exposure and Safety 12.1. Medical Data / Poisoning Symptoms / Antidote 12.2. Personal Protective Equipment 12.3. Other precautions	Manufacturer or Supplier

13. Environmental Data	
14. Labeling / Packaging	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant sends a request for schedule of submission of application requirements to FDAC (fdac.pacd@fda.gov.ph). Requests for schedule may be submitted from **Monday to Friday.**	1. Schedules the submission of application requirements for pre-assessment on **Thursdays**, except for Holidays, from **8AM to 12NN.**	None		FDAC Personnel
2. Applicant submits the application requirements for pre-assessment to FDAC (fdac.pacd@fda.gov.ph) on the day of the schedule, from **8AM to 12NN**.	2. Forwards the received application requirements for pre-assessment to CCHUHSRR from **1PM to 2PM.**	None		FDAC Personnel
	3. Pre-assesses the submitted application for completeness of requirements. Only applications with complete requirements shall proceed to payment.			Food-Drug Regulation Officer CCHUHSRR
3. Applicant pays the fee.		2 year validity – Php 1,000 3 year validity – Php 1,500 4 year validity – Php 2,000 5 year validity – Php 2,500 + 1% LRF		FDA Cashier Personnel
4. Applicant submits the paid application (electronic copies	4. Receives the lodged application.	None		FDAC Personnel

of the complete requirements) to FDAC (fdac.pacd@fda.gov.ph).				
	5. Forwards the application to CCHUHSRR.	None		FDAC Personnel
	6. Receives the application and updates the database.	None	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
	7. Evaluates the correctness of documents.	None	10 Working Days	Food-Drug Regulation Officer / Consultant CCHUHSRR
	8. Reviews the bio- efficacy study and/or toxicity study.	None	8 Working Days	
	9. Reviews the recommendation of the consultant and prepares the overall recommendation.	None	2 Working Days	
	10. Checks if the recommendation is appropriate	None	30 Minutes	Food-Drug Regulation Officer CCHUHSRR
	11. Renders the final decision on the recommendation.	None	30 Minutes	Director IV CCHUHSRR
	12. Updates the database and forwards the final issued document/s to records section.	None	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR

5. Applicant receives the final issued document.	13. Releasing			AFS-Releasing Personnel
TOTAL:			**20 Working Days, 2 Hours[1]**	

B. INITIAL REGISTRATION OF FORMULATED PRODUCT

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
1. Integrated Application Form with Declaration	FDA website (https://www.fda.gov.ph/downloadables/)
2. Valid LTO	FDA- CCHUHSRR
3. Copy of Official Receipt	FDA Cashier
Refer to AO 2019-0008 Annex B for the specific data on the following requirements:	
4. Product Identity	Manufacturer
5. Quantitative and Qualitative Composition of Product	
6. Technical Specifications of the Formulated Product	
7. Product Specifications – Tolerance for the Active Ingredient/s	
8. Certificate of Analysis	Manufacturer or any 3rd Party Laboratory
9. Test Procedures/Methods Conducted on the Formulated Product	
10. Safety Data Sheet of the Formulated Product	Manufacturer
11. Any of the following proof of manufacturer's compliance to Good Manufacturing Practices (GMP) 11.1. Certificate of Free Sale (CFS) issued by the National Regulatory Authority of country of origin	

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

11.2. Certificate of Good Manufacturing Practice (GMP) based on international manufacturing standards 11.3. Manufacturing License 11.4. ISO Certificate related to manufacturing *Note: Must be duly authenticated and notarized by the Philippine Embassy*	
12. Substantiation to Support Special Product Claims	Applicant or Manufacturer
13. Product Stewardship Program	Applicant
14. Submission of Actual Sample and Reference Standard	Applicant or Supplier/Manufacturer
15. Toxicity Data 15.1. Acute Toxicity 15.2. Corrosion / Irritation 15.3. Allergy / Sensitization 15.4. Sub-chronic Toxicity 15.5. Reproduction Effects 15.6. Teratogenicity 15.7. Neurotoxicity 15.8. Mutagenicity 15.9. Carcinogenicity and Chronic (Long Term) Toxicity Studies in Rats	Toxicity Testing Laboratory
16. Bio-efficacy Data	3rd Party Testing Laboratory
17. Human Exposure and Safety 17.1. Operators Exposure Data 17.2. Bystanders Exposure Data 17.3. Medical Data / Poisoning Symptoms / Antidote 17.4. Permissible Exposure Level 17.5. Personal Protective Equipment 17.6. Other Precautions	Manufacturer or Supplier
18. Environmental Data	
19. Labeling / Packaging	

CLIENT STEPS	AGENCY ACTION	FESS TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant sends a request for schedule of submission of application requirements to FDAC (fdac.pacd@fda.gov.ph). Requests for schedule may be submitted from **Monday to Friday**.	1. Schedules the submission of application requirements for pre-assessment on **Thursdays**, except for Holidays, from **8AM to 12NN.**	None		FDAC Personnel
2. Applicant submits the application requirements for pre-assessment to FDAC (fdac.pacd@fda.gov.ph) on the day of the schedule, from **8AM to 12NN**.	2. Forwards the received application requirements for pre-assessment to CCHUHSRR from **1PM to 2PM.**	None		FDAC Personnel
	3. Pre-assesses the submitted application for completeness of requirements. Only applications with complete requirements shall proceed to payment.			Food-Drug Regulation Officer CCHUHSRR
3. Applicant pays the fee.		2 year validity – Php 1,000 3 year validity – Php 1,500 4 year validity – Php 2,000 5 year validity – Php 2,500 + 1% LRF		FDA Cashier Personnel
4. Applicant submits the paid application (electronic copies of the complete requirements)	4. Receives the lodged application.	None		FDAC Personnel

to FDAC (fdac.pacd@fda.gov.ph).				
	5. Forwards the application to CCHUHSRR.	None		FDAC Personnel
	6. Receives the application and updates the database.	None	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
	7. Evaluates the correctness of documents.	None	10 Working Days	Food-Drug Regulation Officer / Consultant CCHUHSRR
	8. Reviews the bio-efficacy study and/or toxicity study.	None	8 Working Days	
	9. Reviews the recommendation of the consultant and prepares the overall recommendation.	None	2 Working Days	
	10. Checks if the recommendation is appropriate.	None	30 Minutes	Food-Drug Regulation Officer CCHUHSRR
	9. Renders the final decision on the recommendation.	None	30 Minutes	Director IV CCHUHSRR
	10. Updates the database and forwards the final issued document/s to records section.	None	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
5. Applicant receives the final issued document.	11. Releasing			AFS-Releasing Personnel

TOTAL:		**20 Working Days, 2 Hours[2]**

C. RENEWAL OF PRODUCT REGISTRATION

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

CLIENT STEPS	**AGENCY ACTION**	**FEES TO BE PAID**	**PROCESSING TIME**	**PERSON RESPONSIBLE**
1. Applicant sends a request for schedule of submission of application requirements to FDAC (fdac.pacd@fda.gov.ph). Requests for schedule	1. Schedules the submission of application requirements for pre-assessment on **Thursdays**, except for Holidays, from **8AM to 12NN.**	None		FDAC Personnel

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

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

may be submitted from **Monday to Friday**.				
2. Applicant submits the application requirements for pre-assessment to FDAC (fdac.pacd@fda.gov.ph) on the day of the schedule, from **8AM to 12NN**.	2. Forwards the received application requirements for pre-assessment to CCHUHSRR from **1PM to 2PM.**	None		FDAC Personnel
	3. Pre-assesses the submitted application for completeness of requirements. Only applications with complete requirements shall proceed to payment.			Food-Drug Regulation Officer CCHUHSRR
3. Applicant pays the fee.		2 year validity – Php 1,000 3 year validity – Php 1,500 4 year validity – Php 2,000 5 year validity – Php 2,500 + 1% LRF		FDA Cashier Personnel
4. Applicant submits the paid application (electronic copies of the complete requirements) to FDAC (fdac.pacd@fda.gov.ph).	4. Receives the lodged application.	None		FDAC Personnel
	5. Forwards the application to CCHUHSRR.	None		FDAC Personnel

	6. Receives the application and updates the database.	None	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
	7. Evaluates the correctness of documents and prepares the recommendation.	None	20 Working Days	Food-Drug Regulation Officer CCHUHSRR
	8. Checks if the recommendation is appropriate.	None	30 Minutes	Food-Drug Regulation Officer CCHUHSRR
	9. Renders the final decision on the recommendation.	None	30 Minutes	Director IV CCHUHSRR
	10. Updates the database and forwards the final issued document/s to records section.	None	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
5. Applicant receives the final issued document	11. Releasing			AFS-Releasing personnel
TOTAL:			**20 Working Days, 2 Hours[4]**	

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

D. VARIATION OF PRODUCT REGISTRATION

CHECKLIST OF REQUIREMENTS (*Refer to AO 2019-0008 Annexes A and B for the specific data on the following requirements to amend the product registration of an active ingredient and formulated product, respectively)*	**WHERE TO SECURE**
1. Integrated Application Form	FDA website (https://www.fda.gov.ph/downloadables/)
2. Letter of Request	Applicant
3. Valid LTO	FDA-CCHUHSRR
4. Valid Original CPR	
5. Copy of Official Receipt	FDA cashier
Specific Requirements: Major Variation	
1. Change in Product Name (Brand Name/Variant Name) a. Notarized Affidavit/Declaration of No Change in the Formulation b. Extension of Use or Claim and New Bio-efficacy Study, If There Is Request To Include Additional Target Pests c. Complete Labeling Requirements Reflecting the Change (Primary, Secondary and Inserts, If Any) in English and/or Filipino Language With Local Dialects, As Applicable	 Applicant 3rd Party Testing Laboratory Applicant
2. Change in Rate, Timing or Frequency of Application or Method of Application a. Extension of Use or Claim and New Bio-efficacy Study, If There Is Request To Include Additional Target Pests b. Study or Studies That Shall Justify Request for Change in Rate, Timing or Frequency of Application or Method of Application c. Complete Labeling Requirements Reflecting the Change (Primary, Secondary and Inserts, If Any) in English and/or Filipino Language With Local Dialects, As Applicable	 3rd party testing laboratory 3rd party testing laboratory Applicant

3. Change in Label Claim / Request for Additional Target Pests a. Extension of Use or Claim and New Bio-efficacy Study, If There Is Request To Include Additional Target Pests b. Complete Labeling Requirements Reflecting the Change (Primary, Secondary and Inserts, If Any) in English and/or Filipino Language With Local Dialects, As Applicable	 3rd party testing laboratory Applicant
4. Change in GHS Category / Hazard Class a. Copy of Safety Data Sheet b. Copy of Complete Toxicity Studies, If Request is For Change in Hazard Class c. Complete Labeling Requirements Reflecting the Change (Primary, Secondary and Inserts, If Any) in English and/or Filipino Language With Local Dialects, As Applicable	 Manufacturer Toxicity Testing Laboratory Applicant
Specific Requirements: Minor Variation	
1. Change in Business Name of the Manufacturer or Distributor a. Complete Labeling Requirements Reflecting the Change (Primary, Secondary and Inserts, If Any) in English and/or Filipino Language With Local Dialects, As Applicable	 Applicant
2. Change in Product Ownership a. Copy of Termination Contract / Deed of Assignment b. Copy of the Agreement of the New Market Authorization Holder and Manufacturer c. Complete Labeling Requirements Reflecting the Change (Primary, Secondary and Inserts, If Any) in English and/or Filipino Language With Local Dialects, As Applicable	 Applicant Applicant Applicant
3. Change of Address of the Distributor of the Product a. Any Valid Document/s Showing Proof of Transfer b. Complete Labeling Requirements Reflecting the Change (Primary, Secondary and Inserts, If Any) in English and/or Filipino Language With Local Dialects, As Applicable	 Applicant Applicant

4. Addition or Deletion of Packaging of the Product a. Notarized Affidavit/Declaration of No Change in the Formulation b. Complete Labeling Requirements Reflecting the Change (Primary, Secondary and Inserts, If Any) in English and/or Filipino Language With Local Dialects, As Applicable	 Applicant Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant sends a request for schedule of submission of application requirements to FDAC (fdac.pacd@fda.gov.ph). Requests for schedule may be submitted from **Monday to Friday**.	1. Schedules the submission of application requirements for pre-assessment on **Thursdays**, except for Holidays, from **8AM to 12NN.**	None		FDAC Personnel
2. Applicant submits the application requirements for pre-assessment to FDAC (fdac.pacd@fda.gov.ph) on the day of the schedule, from **8AM to 12NN**.	2. Forwards the received application requirements for pre-assessment to CCHUHSRR from **1PM to 2PM.**	None		FDAC Personnel
	3. Pre-assesses the submitted application for completeness of requirements. Only applications with complete requirements shall proceed to payment.			Food-Drug Regulation Officer CCHUHSRR

3. Applicant pays the fee.		Per variation: Php 500.00 + 1% LRF not less than Php 10.00		FDA Cashier Personnel
4. Applicant submits the paid application (electronic copies of the complete requirements) to FDAC (fdac.pacd@fda.gov.ph).	4. Receives the lodged application.	None		FDAC Personnel
	5. Forwards the application to CCHUHSRR.	None		FDAC Personnel
	6. Receives the application and updates the database.	None	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
	7. Evaluates the correctness of documents and prepares the recommendation.	None	20 Working Days	Food-Drug Regulation Officer CCHUHSRR
	8. Checks if the recommendation is appropriate.	None	30 Minutes	Food-Drug Regulation Officer CCHUHSRR
	9. Renders the final decision on the recommendation.	None	30 Minutes	Director IV CCHUHSRR
	10. Updates the database and forwards the final issued document/s to records section.	None	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
5. Applicant receives the final issued document.	11. Releasing			AFS-Releasing Personnel

TOTAL:		**20 Working Days, 2 Hours[5]**

5. Off-Label Use / Public Health Emergency Exemption Permit for a Household Urban Pesticides (HUP)

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

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

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

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

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant sends a request for schedule of submission of application requirements to FDAC (fdac.pacd@fda.gov.ph). Requests for schedule may be submitted from **Monday to Friday**.	1. Schedules the submission of application requirements for pre-assessment on **Thursdays**, except for Holidays, from **8AM to 12NN.**	None		FDAC Personnel
2. Applicant submits the application requirements for pre-assessment to FDAC (fdac.pacd@fda.gov.ph) on the day of the schedule, from **8AM to 12NN**.	2. Forwards the received application requirements for pre-assessment to CCHUHSRR from **1PM to 2PM.**	None		FDAC Personnel
	3. Pre-assesses the submitted application for completeness of requirements. Only applications with complete requirements shall proceed to payment.			Food-Drug Regulation Officer CCHUHSRR
3. Applicant pays the fee.		Php 500.00 + 1% LRF not less than Php 10.00		FDA Cashier Personnel
4. Applicant submits the paid application (electronic copies of the complete	4. Receives the lodged application.	None		FDAC Personnel

requirements) to FDAC (fdac.pacd@fda.gov.ph).				
	5. Forwards the application to CCHUHSRR.	None		FDAC Personnel
	6. Receives the application and updates the database.	None	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
	7. Evaluates the correctness of documents.	None	10 Working Days	Food-Drug Regulation Officer / Consultant CCHUHSRR
	8. Reviews the bio- efficacy study and/or toxicity study.	None	8 Working Days	
	9. Reviews the recommendation of the consultant and prepares the overall recommendation.	None	2 Working Days	
	10. Checks if the recommendation is appropriate.	None	30 Minutes	Food-Drug Regulation Officer CCHUHSRR
	11. Renders the final decision on the recommendation.	None	30 Minutes	Director IV CCHUHSRR
	12. Updates the database and forwards the final issued document/s to records section.	None	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
5. Applicant receives the final issued document.	13. Releasing			AFS-Releasing personnel

TOTAL:		**20 Working Days, 2 Hours[6]**

6. Bureau of Custom (BOC) Clearance

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

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

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of intent stating the purpose of importation	Applicant
2. Airway Bill or Bill of Lading	Designated courier
3. Packing List	Applicant
4. Proforma Invoice	Applicant
5. For Exhibition 5.1. Notarized affidavit of undertaking 5.2. Product Information (brochure, leaflet, label)	Applicant
6. For clinical trial/research 6.1. Copy of protocol	Applicant

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

7. For Donation 7.1. Letter of endorsement from DOH-BIHC 7.2. Deed of donation	 DOH-BIHC Applicant
8. Copy of valid LTO	FDA- CCHUHSRR
9. Copy of official receipt	FDA cashier

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant submits the requirements to Letters Section in FDAC		None		Applicant
2. Pre assessment of documents	1. Checking of completeness of documents	None	30 Minutes	FDAC officer of the day
3. Applicant pays the fee		Php 510.00	30 Minutes	FDA Cashier personnel
4. Applicant submits requirements (hard copy)	2. Receives complete requirements	None		FDAC officer of the day
	3. Application is forwarded to CCHUHSRR	None		FDAC personnel
	4. Data Controller receives the application and update the database	None	30 Minutes	Administrative Assistant VI CCHUHSRR
	5. Evaluator checks the correctness of documents	None	7 working days	Food Drug Regulation Officer CCHUHSRR
	6. Checks if the recommendation is appropriate	None	30 Minutes	
	7. CCHUHSRR Director signs the final authorization	None	30 Minutes	Director IV CCHUHSRR

	8. Data controller updates the database and forwards the authorization to records section	None	30 Minutes	Administrative Assistant VI CCHUHSRR
	9. Releasing			AFS-Releasing personnel
TOTAL:		**Php 510.00**	**7 working days, 3 Hours**	

7. Certificate of Free Sale CFS (CFS)

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

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

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
1. Integrated application form	FDA website (https://ww2.fda.gov.ph/industry-corner/downloadables)
2. Letter of intent stating the country where the product will be exported	Applicant
3. Valid LTO with activity as exporter	FDA- CCHUHSRR
4. Copy of valid product registration/notification	FDA- CCHUHSRR
5. Copy of official receipt	FDA cashier

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant requests for a schedule of submission of requirements		None		FDAC personnel
2. Pre assessment of documents	1. Checking of completeness of documents	None	30 Minutes	FDAC officer of the day
3. Applicant pays the fee		Php 510.00 per product per country (except for U.S.A. or U.A.E. which is computed per state or emirate)	30 Minutes	FDA Cashier personnel
4. Applicant submits requirements (electronic copy)	2. Receives complete requirements	None		FDAC officer of the day
	3. Application is forwarded to CCHUHSRR	None		FDAC personnel
	4. Data Controller receives the application and update the database	None	30 Minutes	Administrative Assistant VI, CCHUHSRR
	5. Evaluator checks the correctness of documents	None	7 working days	Food Drug Regulation Officer CCHUHSRR
	6. Checks if the recommendation is appropriate	None	30 Minutes	Food Drug Regulation Officer CCHUHSRR
	7. CCHUHSRR Director signs the final authorization	None	30 Minutes	Director IV CCHUHSRR
	8. Data Controller updates the database and forwards the	None	30 Minutes	Administrative Assistant VI

	final authorization to records section			CCHUHSRR
	9.Releasing			AFS-Releasing personnel
TOTAL:			**7 working days, 3 Hours**	

8. Good Manufacturing Practice (GMP) Certificate

Issued to licensed cosmetic manufacturer that are at least one year operational.

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

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

CLIENT STEPS	**AGENCY ACTION**	**FEES TO BE PAID**	**PROCESSING TIME**	**PERSON RESPONSIBLE**
1. Applicant submits the requirements to Letters Section in FDAC		None		Applicant
2. Pre assessment of documents	1. Checking of completeness of documents	None	30 Minutes	FDAC officer of the day

3. Applicant pays the fee through a Landbank Branch or FDA Cashier		Php 1,010.00	30 Minutes	FDA Cashier personnel or Landbank Personnel
4. Applicant submits requirements (hard copy)	2. Receives complete requirements	None		FDAC officer of the day
	3. Application is forwarded to CCHUHSRR	None		FDAC personnel
	4.Data Controller receives the application and update the database	None	30 Minutes	Administrative Assistant VI CCHUHSRR
	5. Evaluator checks the correctness of documents. **Proceed to no.9 if inspection is not required*	None	6 working days	Food Drug Regulation Officer CCHUHSRR
	6. Data Controller updates the database and forwards the application to FROO	None		Administrative Assistant VI CCHUHSRR
	7. Data Controller receives the report and update the database then forwards to CCHUHSRR Evaluator	None		
	8. Evaluator checks the correctness of documents.	None	7 working days	Food Drug Regulation Officer CCHUHSRR
	9. Checks if the recommendation is appropriate	None	30 Minutes	Food Drug Regulation Officer CCHUHSRR
	10. CCHUHSRR Director signs the final authorization	None	30 Minutes	Director IV CCHUHSRR

	(may be approved or disapproved)			
	11. Data Controller updates the database and forwards the final authorization to records section	None	30 Minutes	Administrative Assistant VI CCHUHSRR
	12. Releasing			AFS-Releasing personnel
TOTAL:		Php 1,010.00	**7 working days, 3 Hours**	

9. Sales and Promotion Permit

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

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

A. INITIAL APPLICATION

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Integrated application form	FDA website (https://ww2.fda.gov.ph/industry-corner/downloadables)
2. Information Sheet and Mechanics of the sales promotion	FDA website (https://ww2.fda.gov.ph/industry-corner/downloadables)
3. Copy of Valid LTO	FDA- CCHUHSRR
4. Copy of valid product registration/notification	FDA- CCHUHSRR
5. Copy of lay-out of any promo materials	Applicant
6. Copy of official receipt	FDA Cashier

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant requests for a schedule of submission of requirements		None		FDAC personnel
2. Pre assessment of documents	1. Checking of completeness of documents	None	30 Minutes	FDAC officer of the day
3. Applicant pays the fee through a Landbank Branch or FDA Cashier		Based on the following promo size + 1% LRF: 1. Php 300,000 and below – Php 1,000 2. Php 300,001 to Php 500,000 – Php 2,000 3. Php 500,001 to Php 1 million – Php 3,000 4. Above Php 1 million – Php 5,000	30 Minutes	FDA Cashier personnel or Landbank Personnel

4. Applicant submits requirements (electronic copies)	2. Receives complete requirements	None		FDAC officer of the day
	3. Application is forwarded to CCHUHSRR	None		FDAC personnel
	4. Data Controller receives the application and update the database	None	30 Minutes	Administrative Assistant VI CCHUHSRR
	5. Evaluator checks the correctness of documents	None	7 working days	
	6. Checks if the recommendation is appropriate	None	30 Minutes	Food Drug Regulation Officer CCHUHSRR
	7. CCHUHSRR Director signs the final authorization	None	30 Minutes	Director IV CCHUHSRR
	8. Data Controller updates the database and forwards the final authorization to records section	None	30 Minutes	Administrative Assistant VI CCHUHSRR
	9. Releasing			AFS-Releasing personnel
TOTAL:			**7 working days, 3 Hours**	

B. AMENDMENT APPLICATION

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Integrated application form	FDA website (https://ww2.fda.gov.ph/industry-corner/downloadables)
2. Letter of intent stating the type of amendment	Applicant
3. Copy of previously approved promo permit	Applicant
4. Copy of Valid LTO	FDA- CCHUHSRR
5. Copy of valid product registration/notification	FDA- CCHUHSRR
6. Copy of lay-out of any promo materials	Applicant
7. Copy of official receipt	FDA Cashier

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant requests for a schedule of submission of requirements		None		FDAC personnel
2. Pre assessment of documents	1. Checking of completeness of documents	None	30 Minutes	FDAC officer of the day
3. Applicant pays the fee through a Landbank Branch or FDA Cashier		Php 310.00	30 Minutes	FDA Cashier personnel or Landbank Personnel
4. Applicant submits requirements (electronic copies)	2. Receives complete requirements	None		FDAC officer of the day
	3. Application is forwarded to CCHUHSRR	None		FDAC personnel
	4. Data Controller receives the application and update the database	None	30 Minutes	Administrative Assistant VI CCHUHSRR

	5. Evaluator checks the correctness of documents	None	7 working days	
	6. Checks if the recommendation is appropriate	None	30 Minutes	Food Drug Regulation Officer CCHUHSRR
	7. CCHUHSRR Director signs the final authorization (may be approved or disapproved)	None	30 Minutes	Director IV CCHUHSRR
	8. Data Controller updates the database and forwards the final authorization to records section	None	30 Minutes	Administrative Assistant VI CCHUHSRR
	9. Releasing			AFS-Releasing personnel
TOTAL:		**Php 310.00**	**7 working days, 3 Hours**	

10. FIELD REGULATORY OPERATIONS OFFICER INSPECTION AGENDA

A. SIMPLE

Bureau of Customs – For Donation

Certification	Classification[1]	Type of Transaction[2]	Processing Time[3]	List of Requirements

Inspection Report with recommendation for release (Upon validation /inspection of the products)	Simple	Government-to-Business (G2B)	Upon receipt of request for inspection from the consignee	FDA Clearance issued by Centers

Legend:
[1] Classify if Simple, Complex, or Highly Technical Transaction
[2] Classify if Government-to- Citizens (G2C), Government-to-Business (G2B), and Government-to-Government (G2G)
[3] Based on Current Citizen's Charter Timeline

Bureau of Customs – For Personal Use

Certification	Classification[1]	Type of Transaction[2]	Processing Time[3]	List of Requirements
E-mail Reply (citing Joint Circular No.1)	Simple	Government-to-Business (G2B)	Upon receipt of request for inspection from the consignee	E-mail Request

Legend:
[1] Classify if Simple, Complex, or Highly Technical Transaction
[2] Classify if Government-to- Citizens (G2C), Government-to-Business (G2B), and Government-to-Government (G2G)
2 Based on Current Citizen's Charter Timeline

1. 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**	**3 Working Days**	

2. Filing 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**	

3. Filing 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:	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		

e-report@fda.gov.ph customersatisfactionteam@fda.gov.ph	3. Encodes the DTN and compliant details in the E-Report Database for tracking and monitoring.	None		
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**	

4. 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 receipt of the document/s	None	3 minutes	FDAC Information Officer II
	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**	

5. 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	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	None	10 Minutes Depending on the complexity of the issue	FDAC Phone Operators Information Officer II

8-8211162	the designated center/office e-mail address			
	TOTAL:	**None**	**10 minutes**	

6. 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.