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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3.1.INITIAL REGISTRATION OF ACTIVE INGREDIENT

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

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

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

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

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

3.2.INITIAL REGISTRATION OF FORMULATED PRODUCT

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

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

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

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

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

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

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

3.3.RENEWAL OF PRODUCT REGISTRATION

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

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

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

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

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

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

3.4.VARIATION OF PRODUCT REGISTRATION

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

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

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

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

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

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

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

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

Issued to licensed establishments that will apply for product notification.

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

4.1.INITIAL APPLICATION

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

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

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

4.2.RENEWAL APPLICATION

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

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

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

4.3.CHANGE IN CREDENTIALS APPLICATION

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

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

5.ISSUANCE OF COSMETIC PRODUCT NOTIFICATION

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

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

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

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

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

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

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

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

6.ISSUANCE OF GOOD MANUFACTURING PRACTICE (GMP) CERTIFICATE

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

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

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

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

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

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

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

7.ISSUANCE OF IMPORT CLEARANCE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE

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

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

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

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

10.ISSUANCE OF SALES AND PROMOTION PERMIT

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

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

A. INITIAL APPLICATION

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

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

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

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

B. AMENDMENT APPLICATION

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

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

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

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

11.ISSUANCE OF TOYS AND CHILDCARE ARTICLES PRODUCT NOTIFICATION

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

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

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

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

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

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