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	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.**		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. Receives the lodged application.		FDAC Personnel

	5. Forwards the application to CCHUHSRR.		FDAC Personnel
	6. Receives the application and updates the database.	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
	7. Evaluates the correctness of documents.	10 Working Days	Food-Drug Regulation Officer / Consultant CCHUHSRR
	8. Reviews the bio- efficacy study and/or toxicity study.	8 Working Days	
	9. Reviews the recommendation of the consultant and prepares the overall recommendation.	2 Working Days	
	10. Checks if the recommendation is appropriate	30 Minutes	Food-Drug Regulation Officer CCHUHSRR
	11. Renders the final decision on the recommendation.	30 Minutes	Director IV CCHUHSRR
	12. 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.	13. Releasing		AFS-Releasing Personnel
TOTAL:		**20 Working Days, 2 Hours[6]**	

[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.

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 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	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	1. Schedules the submission of application requirements for pre-assessment on **Thursdays**, except for Holidays, from **8AM to 12NN.**		FDAC Personnel

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.**		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. Receives the lodged application.		FDAC Personnel
	5. Forwards the application to CCHUHSRR.		FDAC Personnel
	6. Receives the application and updates the database.	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
	7. Evaluates the correctness of documents.	10 Working Days	Food-Drug Regulation Officer / Consultant CCHUHSRR
	8. Reviews the bio-efficacy study and/or toxicity study.	8 Working Days	

	9. Reviews the recommendation of the consultant and prepares the overall recommendation.	2 Working Days	
	10. Checks if the recommendation is appropriate.	30 Minutes	Food-Drug Regulation Officer CCHUHSRR
	9. Renders the final decision on the recommendation.	30 Minutes	Director IV CCHUHSRR
	10. 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.	11. Releasing		AFS-Releasing Personnel
TOTAL:		**20 Working Days, 2 Hours**[7]	

[7] 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.

C. RENEWAL OF PRODUCT REGISTRATION

CHECKLIST OF REQUIREMENTS[8]	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.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.**		FDAC Personnel
2. Applicant submits the application requirements for pre-assessment to FDAC	2. Forwards the received application requirements for pre-assessment to		FDAC Personnel

[8] 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.

(fdac.pacd@fda.gov.ph) on the day of the schedule, from **8AM to 12NN**.	CCHUHSRR from **1PM to 2PM.**		
	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. Receives the lodged application.		FDAC Personnel
	5. Forwards the application to CCHUHSRR.		FDAC Personnel
	6. Receives the application and updates the database.	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
	7. Evaluates the correctness of documents and prepares the recommendation.	20 Working Days	Food-Drug Regulation Officer CCHUHSRR
	8. Checks if the recommendation is appropriate.	30 Minutes	Food-Drug Regulation Officer CCHUHSRR

	9. Renders the final decision on the recommendation.	30 Minutes	Director IV CCHUHSRR
	10. 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	11. Releasing		AFS-Releasing personnel
TOTAL:		**20 Working Days, 2 Hours[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.

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	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.**		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. Receives the lodged application.		FDAC Personnel
	5. Forwards the application to CCHUHSRR.		FDAC Personnel
	6. Receives the application and updates the database.	30 Minutes	Administrative Assistant (Data Controller) CCHUHSRR
	7. Evaluates the correctness of documents and prepares the recommendation.	20 Working Days	Food-Drug Regulation Officer CCHUHSRR
	8. Checks if the recommendation is appropriate.	30 Minutes	Food-Drug Regulation Officer CCHUHSRR
	9. Renders the final decision on the recommendation.	30 Minutes	Director IV CCHUHSRR
	10. 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.	11. Releasing		AFS-Releasing Personnel
TOTAL:		**20 Working Days, 2 Hours[10]**	

[10] 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.