



### 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.

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

CHECKLIST OF REQUIREMENTS ( <i>Refer to AO 2019-0008 Annex C for the specific data on the following requirements</i> )	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

CLIENT STEPS	AGENCY ACTION	PROCESSING TIME	PERSON RESPONSIBLE
1. Applicant sends a request for schedule of submission of application requirements to	1. Schedules the submission of application requirements for pre-assessment on <b>Thursdays</b> ,		FDAC Personnel



FDAC ( <a href="mailto:fdac.pacd@fda.gov.ph">fdac.pacd@fda.gov.ph</a> ). Requests for schedule may be submitted from <b>Monday to Friday</b> .	except for Holidays, from <b>8AM to 12NN</b> .		
2. Applicant submits the application requirements for pre-assessment to FDAC ( <a href="mailto:fdac.pacd@fda.gov.ph">fdac.pacd@fda.gov.ph</a> ) on the day of the schedule, from <b>8AM to 12NN</b> .	2. Forwards the received application requirements for pre-assessment to CCHUHSRR from <b>1PM to 2PM</b> .		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 ( <a href="mailto:fdac.pacd@fda.gov.ph">fdac.pacd@fda.gov.ph</a> ).	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
<b>TOTAL:</b>		<b>20 Working Days, 2 Hours<sup>11</sup></b>	

<sup>11</sup> 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.