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

1.**ISSUANCE OF CERTIFICATE REQUESTED BY LAW ENFORCEMENT AGENCIES (LEAs) FOR VERIFICATION OF AUTHORIZATION OF PRODUCT/S AND ESTABLISHMENT/S**

A process carried out by the Product Research and Standards Development Division under the Post-Marketing Surveillance (PMS) system of the CCHUHSRR wherein the authorization of products under investigation and/or in question by the Law Enforcement Agencies (LEAs) such as cosmetics, household and urban hazardous substances (HUHS), toys and childcare articles (TCCAs), and household urban pesticides (HUPs) as well as the license to operate of the Marketing Authorization Holders are checked, verified, and reviewed to ensure continuous compliance with existing FDA laws, rules, and regulations.

Center/Office/Division	**:**	Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research – Product Research and Standards Development Division (CCHUHSRR-PRSDD)
Classification	**:**	Highly Technical Transaction
Type of Transaction	**:**	Government to Government - G2G
Who May Avail	**:**	FDA Centers- REU and FROO

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Letter of request for Verification of the Authorization of Product and Establishment emanating from Law Enforcement Agencies	Requesting Party (LEAs)
2. Referral letter with request from LEAs for verification of Authorization of Product and Establishment	FROO/REU

INTERNAL CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING DAY (Per product/ establishment basis	PERSON RESPONSIBLE
1.Requesting Party (LEAs) through FROO/ REU	1. Refers to the request for verification of authorization of products and establishments.	None	N/A	Office of the Field Regulatory Operations Office FROO/REU
2.Receives the referral and request letter	2. Receives and checks the completeness of the submitted documents then encodes it to the database then decks the referral and request forms.	None	0.5 working day	CCHUHSRR PRSDD Admin
3.Evaluation and Verification of the referral/request letter	3.1 Evaluates and verifies the notification/registration of the product and the establishment.	None	15 working days	CCHUHSRR PRSDD Evaluator
	3.2 Reviews the evaluation and recommendation by the evaluator and forwards the draft certificate or response letter to the Senior Checker and Quality assurance.	None	2 working days	CCHUHSRR PRSDD Checker

	3.3 Recommends the approval of the certificate or response letter and forwards to the Center Director.	None	1 working day	CCHUHSRR PRSDD Division Chief
	3.4 Approves the certificate or response letter for releasing to the requesting party.	None	1 working day	CCHUHSRR Center Director
4.Releasing of Certificate or Response Letter	4. The PRSDD Admin shall release the certificate or Response Letter to the Requesting Party	None	0.5 working day	CCHUHSRR PRSDD Admin
		TOTAL:	**20 WORKING DAYS**	

2. REVIEW OF POLICIES ENDORSED BY OTHER CENTERS AND OFFICES

Policy-determining issuances emanating from Other Offices (e.g., request for comments/inputs on proposed DOH Administrative Orders, FDA Orders, FDA Circulars, FDA Memorandum, Memorandum Circulars, and FDA Advisories)

Center/Office/Division	**:**	Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) - Product Research and Standards Development Division (PRSDD)
Classification	**:**	Highly technical transaction
Type of Transaction	**:**	Government to Government - G2G
Who May Avail	**:**	FDA Centers/ Offices and External Offices

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Inter-Office Memorandum* from the Proponent/Requesting Office *To aid in conducting an ample review, the following relevant information are recommended to be provided: a. Background, including overview of policy issues being addressed, legal basis b. Description and rationale of the proposed policy c. Relevant references d. Deadline of comments e. Scope of comments being sought from CCHUHSRR f. Focal person handling the proposed policy	Proponent/Requesting Office
2. Copy of the draft issuance, in word format	Proponent/Requesting Office

INTERNAL CLIENT STEP	OFFICE ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Endorses request, including attachments, to FDA-CCHUHSRR	1.1 Receives request, update document tracking system, endorse request to CCHUHSRR-OD	None	15 minutes	Administrative Assistant VI CCHUHSRR Office
	1.2 Decks request to PRSDD and provide instructions	None	4 hours	Director IV CCHUHSRR Office
	1.3 Reviews request, provides preliminary comments, deck request to Policy Section	None	4 hours	PRSDD Chief CCHUHSRR Office
	1.4 Updates policy database and endorse to Policy Section head	None	15 minutes	Administrative Assistant VI CCHUHSRR Office
	1.5 Preliminary reviews, assigns review to Policy Staff	None	4 hours	Administrative Assistant IV CCHUHSRR Office
	1.6 Conducts review, including necessary consultations, and preparation of IOM-response	None	15 working days	Food and Drug Regulation Officer CCHUHSRR Office
	1.7 Review of IOM-response and applies necessary revisions, finalizes IOM-response	None	2 working days and 3 hours	Food and Drug Regulation Officer CCHUHSRR Office
	1.8 Updates of policy database	None	15 minutes	Administrative Assistant VI CCHUHSRR Office
	1.9 Clearance of IOM-response	None	4 hours	PRSDD Chief CCHUHSRR Office
	1.10 Clearance of IOM-response	None	4 hours	Director IV CCHUHSRR Office

2. Receives IOM-response	2. Updates, document tracking system, referral to requesting/ proponent Office	None	15 minutes	Administrative Assistant VI CCHUHSRR Office
TOTAL:	None	20 working days		