XXVI. LICENSE TO OPERATE – RENEWAL APPLICATION FOR MANUFACTURERS OF HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) BASED ON ADMINISTRATIVE ORDER NO. 2019-0019 AND FDA CIRCULAR 2020-025

Issuance of Electronic Portal (E-Portal) Ver.2.0 User Account

Center/Office/Division	:	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	:	Simple
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	All Manufacturers of Household/Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be paid	:	None

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1.Proof of Ownership of Establishment (refer to Annex B and B.1 of FDA Circular No. 2020-025)	Applicant

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Request User Account credentials by accomplishing the Online User's Registration Form through the link: bit.ly/ePortal2 (refer to Annex B.1)	1. Check for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff

2. Receive username and password	2. Issue user account (username and password) to the client	None	Next Working Day	CCHUHSRR Admin. Staff
	TOTAL:	**None**	**1 Working Day and 15 minutes**	

Center/Office/Division	**:**	Center for Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	**:**	Complex
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	All Manufacturers Household Urban Hazardous Substances f Household/Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025
Fees to be Paid	**:**	**Household Hazardous Substance Manufacturer:** 1 Million and below - Php 2,000 + 10 % LRF over 1 Million but below 5 Million - Php 4,000 + 1 % LRF 5 Million but below 10 Million - Php 6,000 + 1 % LRF 10 Million but below 20 Million - Php 10,000 + 1 % LRF 20 Million but below 50 Million - Php 20,000 + 1% LRF 50 Million and above - Php 30,000 + 1% LRF **Administrative Order 50 s. 2001*** *Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs* **FDA Circular No. 2011-003** *Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856* **FDA Circular No. 2011-004**

		Computation of Surcharge or Penalty Impossible in case of Submission of Renewal Applications Covering License of Establishments and Registration of Health Products After Their Date of Expiration Pursuant to Section 3, Paragraphs (A)(2) and (B)(2) of Article I of Book II of the RA 9711 Implementing Rules and Regulations, and Other Purposes

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017 and FDA Circular No. 2020-025:	
● Accomplished e-Application Form as prescribed by FDA regulations. ● Declaration and Undertaking	FDA e-Portal V.2 (www.fda.gov.ph) Applicant / Qualified Person
2) Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	FDA Cashier/Other FDA Authorized Payment Portals or Banks
3) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	Applicant/Qualified person

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the FDA e-Portal V2 at (https://eportal2.fda.gov.ph). Log in by entering the issued username and password.		None	0	Qualified person
2. Accomplish the LTO renewal application form	1. Pre-assessment on the completeness of application and documentary requirements submitted	None	0	Applicant/Qualified person and FDA Evaluator
3. Download and print the generated Order of Payment through the ePortal and Email notification.		None	0	Qualified person

4. Pay the assessed fee as per the system generated Order of Payment Form through existing payment channels.	2. Post payment in ePortalv2 for confirmed payments. This will prompt automatic decking of application to respective Center.	See above table	0	Qualified Person and FDA Cashier Administrative and Finance Service
	3. Pre-Inspection by the Regional Field Office (RFO) Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/ Recommendation for Disapproval/ Recommendation Letter	None		Regional Field Officer/ Inspector
	4. Evaluation on the completeness and veracity of the documents submitted.	None	3 working days	FDA Evaluator (Center/Licensing and Registration)
	5. Checking of the evaluation and veracity of documents submitted.	None	2 working day	Technical Officer of specific Center of jurisdiction
	6. Final Decision on the Approval of LTO If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director of jurisdiction
5. Receive notification and copy of e-LTO for printing		None		Qualified person
TOTAL:			**7 working days**	