XXV. LICENSE TO OPERATE – INITIAL 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	:	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. Requests User Account credentials by accomplishing the Online User's Registration Form through the link: bit.ly/ePortal2 (refer to Annex B.1)	1. Checks for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff

2. Receives username and password	2. Issues 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	**:**	Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR)
Classification	**:**	Highly Technical
Type of Transaction	**:**	G2B - Government to Business
Who May Avail	**:**	All Manufacturers of Household/Urban Hazardous Substances (under Categories III and IV) based on Administrative Order No. 2019-0019 and FDA Circular No. 2020-025
Fees to be Paid	**:**	**Household Hazardous Substance Manufacturer:** 1 Million and below - Php 1,000 + 1 % LRF over 1 Million but below 5 Million - Php 2,000 + 1 % LRF 5 Million but below 10 Million - Php 3,000 + 1 % LRF 10 Million but below 20 Million - Php 5,000 + 1 % LRF` 20 Million but below 50 Million - Php 10,000 + 1 % LRF 50 Million and above - Php 15,000 + 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

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1) Basic Requirements based on the Administrative Order No. 2020-0017 and FDA Circular No. 2020-025:	FDA website (www.fda.gov.ph
Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) coordinates to be filled in the e-Application Form ● Personnel information of the Authorized Person and Qualified Person of the establishment ● Self-Declaration in the e-Application Form	FDA e-Portalv2 (https://eportal2.fda.gov.ph)
2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● For single proprietorship, the Certificate of Business Registration issued by the Department of Trade and Industry (DTI) (1 Scanned copy PDF) ● For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation (1 Scanned copy PDF) ● For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation (1 Scanned copy PDF) ● For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter (1 Scanned copy PDF) When a business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g. Mayor's Permit).	
3) Proof of income (Latest Audited Financial Statement with Balance Sheet) or Duly notarized Statement/Certification of Initial Capitalization.	
4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) Site Master File (shall be presented to the FDA inspectors during inspection).	

6) Risk Management Plan (shall be presented to the FDA inspectors during inspection)	
7) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection	

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	Applicant/Qualified person
2. In the Home tab, select New Application in the navigation pane and click e-License to Operate (Initial Application) to proceed to the LTO application form.		None	0	Applicant/Qualified person
3. Accomplish the application form as provided in parts by the application wizard. Fill-in the fields as completely as possible. Fields marked with a red asterisk (*) are required to be filled-in. Mark required fields with N/A, if not applicable.		None	0	Applicant/Qualified person
4. Upload Documents in PDF format. ● Proof of Business Name Registration, Proof of Income.Tick the box to certify all information is true and correct, then "Next".	1. Pre-assessment on the completeness of application and documentary requirements submitted	None	0	Applicant/Qualified person and FDA Evaluator

• Applicants may upload documents simultaneously.				
5. 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 RFO Posting of bank payment: LBP OnColl Payment – 5 wd Bancnet – 2 wd	See above table	0	Qualified Person FDA Cashier Administrative and Finance Service
	3. Pre-license Inspection by Regional Field Offices (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 **Not currently required since HUHS manufacturer shall also undergo PLI (based on FDA Advisory 2020-2035)*
	4. Evaluation on the completeness and veracity of the documents submitted.	None	15 working days	FDA Evaluator (Center/Licensing and Registration)
	5. Checking of the evaluation and veracity of documents submitted.	None	3 working days	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
6. Receive notification and copy of e-LTO for printing				Qualified person
TOTAL:			**20 working days**	