XXVII. LICENSE TO OPERATE – MAJOR VARIATION 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. 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	:	Highly Technical
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Manufacturers of Household/Urban Hazardous Substances (HUHS)
Fees to be Paid	:	Amendment of LTO or Re-issuance (if lost) – Php 500 +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) List of Requirements for Specific Variation based on Administrative Order No. 2020-0017: A. Transfer of Location of Manufacturing Plant Documentary Requirement: 1. Business permit reflecting the new address 2. Updated Site Master File to be presented upon inspection	Qualified Person

B. Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity Documentary Requirement: 1.Updated Site Master File to be presented upon inspection	
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. In the Home tab, select New Application in the navigation pane and click e-License to Operate (Variation Application) to proceed to the LTO application form.		None	0	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	Qualified Person
4. Upload Documents in PDF format. ● Proof of Business Name Registration, Proof of Income. Tick the box to certify	1. Pre-assessment on the completeness of application and documentary requirements submitted	None	0	Qualified Person

all information is true and correct, then "Next". ● Applicants may upload documents simultaneously.				
5. Order of payment- A computer generated document will appear reflecting the appropriate fees and charges. Applicant should save and print a copy of document as reference for payment		None	0	Qualified Person
6. Pay the assessed fee as per the system generated Order of Payment Form through existing payment channels.	2. Post payment in ePortal V.2 for confirmed payments. This will prompt automatic decking of application to respective Center	See above table	0	Qualified Person/ FDA Cashier Administrative and Finance Service (AFS)
	3. Pre-Inspection by 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 of the correctness of submitted documentary requirements.	None	15 working days	FDA Evaluator (Center/Licensing

				and Registration Division)
	5. Checking of the evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of specific Center of jurisdiction
	6. Approval of LTO If the 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
7. Receives notification and copy of e-LTO for printing		None		Qualified Person
TOTAL:			**20 working days**	