



XXVIII. LICENSE TO OPERATE – INITIAL APPLICATION FOR TRADERS, DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER) 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 Traders, Distributors (Importer, Exporter, Wholesaler) 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. Check for the completeness and appropriateness of the request	None	15 Minutes	CCHUHSRR Admin. Staff
2. Receives 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/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 Traders, Distributors (Importer, Exporter, Wholesaler) 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	<p>Household Hazardous Substances: Importer, Exporter, Wholesaler- Php 3,000+ 1 % LRF Note: The fees charged for the manufacturers and traders of products regulated by BFAD are based</p> <p>Administrative Order 50 s. 2001* <i>Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs</i></p> <p>FDA Circular No. 2011-003 <i>Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856</i></p> <p>FDA Circular No. 2011-004 <i>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</i></p>

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1)Basic Requirements based on the Administrative Order No. 2020-0017 and FDA Circular No. 2020-025: <ul style="list-style-type: none"> Location plan and Global Positioning System (GPS) coordinates to be filled in the e-Application Form 	FDA e-Portalv2 (https://eportal2.fda.gov.ph) Authorized Person Qualified Person



<ul style="list-style-type: none"> ● Personnel information of the Authorized Person and Qualified Person of the establishment ● Self-Declaration in the e-Application Form 	
<p>2) Proof of Business Registration</p> <p>Any one of the following shall be submitted as proof of business name registration:</p> <ul style="list-style-type: none"> ● 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 include Mayor's Permit or Barangay Clearance provision (1 Scanned copy PDF) <p>A copy of Business permit (i.e., Mayor's Permit or Barangay Clearance provision) will be submitted for business or establishment address with different business name registration address.</p>	Applicant/Qualified Person
<p>3) Proof of income (Latest Audited Financial Statement with Balance Sheet) or Duly notarized Statement/Certification of Initial Capitalization.</p>	Applicant/Qualified person
<p>4) Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).</p>	FDA Cashier/Other FDA Authorized Payment Portals or Banks
<p>5) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection</p>	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	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. <ul style="list-style-type: none"> ● Proof of Business Name Registration, Proof of Income. Tick the box to certify all information is true and correct, then "Next". ● Applicants may upload documents simultaneously. 	1. Pre-assessment on the completeness of application and documentary requirements submitted	None	0	Applicant/ Qualified Person FDA Evaluator
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	See above table	0	Qualified Person



	<p>prompt automatic decking of application to respective Center.</p> <p>Posting of Bank payment: LBP OnColl Payment – 5 wd Bancnet – 2 wd</p>			FDA Cashier Administrative and Finance Service
	3. Evaluation on the completeness and veracity of the documents submitted.	None	8 working days	FDA Evaluator (Center/Licensing and Registration)
	4. Checking of the evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of specific Center of jurisdiction
	5. Final Decision on the Approval of LTO	None	3 working days	Center Director of jurisdiction
	If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial.			
6. Receive notification and copy of e-LTO for printing				Qualified person
TOTAL:			14 working days	