



XXII. LICENSE TO OPERATE – INITIAL APPLICATION FOR TRADERS, DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER) OF COSMETICS, TOYS AND CHILD CARE ARTICLES (TCCAS) AND HOUSEHOLD URBAN PESTICIDES (HUPS)

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) Cosmetics, Toys and Child Care Articles (TCCAs) and Household Urban Pesticides (HUPs)
Fees to be Paid	: Cosmetics Trader: 20 Million and below -Php 3,000+ 1 % LRF over 20 Million but below 50 Million- Php 5,000+ 1% LRF 50 Million and above - Php 7,000+ 1 % LRF Cosmetics Distributors: Importer, Exporter, Wholesaler - Php 3,000+ 1 % LRF Household Hazardous Substances: Importer, Exporter, Wholesaler- Php 3,000+ 1 % LRF 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> 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>
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CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
<p>1) Basic Requirements based on the Administrative Order No. 2020-0017:</p> <ul style="list-style-type: none"> ● Accomplished e-Application Form as prescribed by FDA regulations. ● Location plan and Global Positioning System (GPS) to be filled in the eApplication Form ● Name of the Qualified Person Self-Declaration in the e-Application Form 	<p>FDA e-Portal (www.fda.gov.ph)</p>
<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>	
<p>3) Proof of income (Latest Audited Financial Statement with Balance Sheet) or Duly notarized Statement/Certification of Initial Capitalization.</p>	



4) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
5) 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. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements for e-LTO application		None	0	Qualified Person
2. Downloads and prints the generated Order of Payment through the ePortal and Email notification.		None	0	Qualified Person
3. Pays the assessed fee as per the system-generated Order of Payment Form through the existing payment channels	1. Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center. LBP OnColl Payment : 5wd Other Payment Channels : 3 wd	See above table	0	Qualified Person FDA Cashier Administrative and Finance Service (AFS)
	2. Evaluates completeness and correctness of the documents submitted.	None	5 working days	FDA Evaluator (Center/Licensing and Registration Division)
	3. Checks the veracity of documents provided	None	4 working days	Technical Officer of Center



	4. Quality assurance of the documents provided and compliance	None	3 working days	Technical Officer of Center
	5. Finalizes decision on the LTO application If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial	None	2 working days	Center Director
4. Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			14 working days	