



XIX. LICENSE TO OPERATE – INITIAL APPLICATION FOR MANUFACTURERS OF COSMETICS, TOYS AND CHILD CARE ARTICLES (TCCAS) AND HOUSEHOLD URBAN PESTICIDES (HUPS)

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	: Manufacturers of Cosmetics, Toys and Child Care Articles and Household Urban Pesticides
Fees to be Paid	<p>Cosmetics Manufacturer: 20 Million and below - Php 5,000 + 1 % LRF over 20 Million but below 50 Million - Php 10,000 + 1 % LRF 50 Million and above - Php 15,000 + 1 % LRF</p> <p>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</p> <p>Administrative Order 50 s. 2001* Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs</p>



	<p>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</p>
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CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
<p>1) Basic Requirements based on the Administrative Order No. 2020-0017:</p> <p>Accomplished e-Application Form as prescribed by FDA regulations.</p> <ul style="list-style-type: none"> ● Location plan and Global Positioning System (GPS) coordinates to be filled in the eApplication Form ● Name of the Qualified Person depending on the type of health product establishment ● Self-Declaration in the e-Application Form 	<p>FDA e-Portal System (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 (in pdf):</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 (1 Scanned copy PDF) <p>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).</p>	



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. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements (in PDF format) 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 RFO. LBP OnColl Payment: 5 wd Other Payment Channels: 3 wd	See above table	0	Qualified Person FDA Cashier Administrative and Finance Service



	<p>2. Conducts pre-licensing inspection.</p> <p><i>Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/Recommendation for Disapproval/Recommendation Letter.</i></p>	None	0	Regional Field Officer/Inspector
	<p>3. Evaluates completeness and veracity of the documents submitted.</p>	None	13 working days	FDA Evaluator (Center/Licensing and Registration)
	<p>4. Checks evaluation and veracity of the documents submitted.</p>	None	3 working days	Technical Office of Center
	<p>5. Quality assurance of the evaluation.</p>	None	1 working day	Technical Officer of Center
	<p>6. Finalizes decision on the application.</p> <p>If application is disapproved, the applicant will be notified</p>	None	3 working days	Center Director



	through email ad will receive the Letter of Denial			
4. Receives notification and link of LTO for printing				Qualified Person
TOTAL:			20 working days	