



XX. LICENSE TO OPERATE – RENEWAL 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	: Complex
Type of Transaction	: G2B - Government to Business
Who May Avail	: Manufacturers of Cosmetics, Toys and Childcare Articles and Household Urban Pesticides
Fees to be Paid	<p>Cosmetics Manufacturer: 20 Million and below - Php 10,000 + 1 % LRF over 20 Million but below 50 Million - Php 20,000 + 1 % LRF 50 Million and above - Php 15,000 + 1 % LRF</p> <p>Household Hazardous Substance Manufacturer: 1 Million and below - Php 2,000 + 10 % LRF over 1 Million but below 5 Million - Php 4,000 + 1 % LRF 5 Million but below 10 Million - Php 6,000 + 1 % LRF 10 Million but below 20 Million - Php 10,000 + 1 % LRF 20 Million but below 50 Million - Php 20,000 + 1% LRF 50 Million and above - Php 30,000 + 1% LRF</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. 2011-004</p>



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

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:	
<ul style="list-style-type: none"> ● Accomplished e-Application Form as prescribed by FDA regulations. ● Declaration and Undertaking 	FDA e-Portal (www.fda.gov.ph) Applicant /Qualified Person
2) 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. 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) 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. Pay 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/Office.	See above table	0	Qualified Person FDA Cashier Administrative and Finance Service
	2. Conducts inspection <i>Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/Recommendation for Disapproval/ Recommendation Letter</i>	None		Regional Field Officer/ Inspector
	3. Evaluates completeness and veracity of the documents submitted	None	3 working days	FDA Evaluator (Center/Licensing and Registration)
	4. Checks evaluation and veracity of documents submitted.	None	2 working day	Technical Officer of Center
	5. Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center



	6. Finalizes 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	1 working day	Center Director
4. Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			7 working days	