XIV. LICENSE TO OPERATE – RENEWAL APPLICATION FOR MEDICAL DEVICE MANUFACTURERS

Center/Office/Division	:	Center for Device Regulation, Radiation and Health Research (CDRRHR)
Classification	:	Complex
Type of Transaction	:	G2B - Government to Business
Who May Avail	:	All Manufacturers of Medical Device Products
Fees to be Paid	:	**Medical Device Manufacturer:** 20 Million and below – Php 5,000 +1% LRF over 20 Million but below 50 Million – Php 7,000 +1% LRF 50 Million and above – Php 10,000 +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. 2011-004** *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 (LRF) 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:	
• Accomplished e-Application Form as prescribed by FDA regulations. • Declaration and Undertaking	FDA e-Portal (www.fda.gov.ph)

2) Payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).	
3) 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 System (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. Pays the assessed fee as per the system-generated Order of Payment through the existing payment channels	1. Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective Center/Office **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd**	See above table	0	Qualified Person FDA Cashier Administrative and Finance Service
	2. Conducts inspection (if necessary)	None		Regional Field Officer/ Inspector

	Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/ Recommendation for Disapproval/ Recommendation Letter			
	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	1 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	2 working days	Center Director
4. Receives notification and link of LTO for printing		None		Qualified Person
TOTAL:			**7 working days**	