XIII. LICENSE TO OPERATE – INITIAL APPLICATION FOR MEDICAL DEVICE MANUFACTURERS

Center/Office/Division	:	Center for Device Regulation, Radiation and Health Research (CDRRHR)
Classification	:	Highly Technical
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. 2011-003** *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. ● 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	FDA e-Portal System

2) Proof of Business Registration Any one of the following shall be submitted as proof of business name registration (in pdf): ● 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) 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).	
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 System 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 RFO. **LBP OnColl Payment: 5 wd** **Other Payment Channels: 2 wd**	See above table		Qualified Person FDA Cashier Administrative and Finance Service
	2. Conducts pre-licensing inspection *Refer to Regional Field Office (RFO) Citizen's Charter for the issuance of Certificate of Compliance /Recommendation for*	None		Regional Field Officer/ Inspector

	Disapproval/ Recommendation Letter.			
	3. Evaluates completeness and veracity of the documents submitted.	None	13 working days	FDA Evaluator (Center/Licensing and Registration)
	4. Checks evaluation and veracity of documents submitted.	None	3 working days	Technical Officer of Center
	5. Quality assurance of the evaluation.	None	1 working day	Technical Officer of Center
	6. 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	3 working days	Center Director
4. Receives notification and link of LTO for printing				Qualified Person
TOTAL:			**20 working days**	