XV. LICENSE TO OPERATE – MAJOR VARIATION APPLICATION FOR MEDICAL DEVICE ESTABLISHMENT (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 Medical Device Manufacturers
Fees to be Paid	:	**Major Variation: Php 500 + 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 Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856*

CHECKLIST OF REQUIREMENTS (based on Administrative Order No. 2020-0017)	WHERE TO SECURE
Major Variation	FDA ePortal System (www.fda.gov.ph)
Transfer of Location of Manufacturing Plant - Accomplished e-Application Form - Business permit reflecting the new address - Updated Site Master File to be presented upon inspection - Payment of fees	

Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity - Accomplished e-Application Form - Updated Site Master File to be presented upon inspection - Payment of fees	

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 inspection *Refer to Regional Field Office (RFO) Citizen's Charter for the issuance of Certificate of*	None		Regional Field Officer/ Inspector

	Compliance /Recommendation for 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**	