



VIII. LICENSE TO OPERATE – MINOR VARIATION APPLICATION FOR MEDICAL DEVICE TRADERS AND MEDICAL DEVICE DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER)

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 Traders and Medical Device Distributors (Importer, Exporter, Wholesaler)
Fees to be Paid	: Minor Variation: Php 500 + 1% LRF 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> FDA Circular No. 2011-003 <i>Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856</i>

CHECKLIST OF REQUIREMENTS (based on Administrative Order No. 2020-0017)	WHERE TO SECURE
Minor Variation	FDA eServices (www.fda.gov.ph)
Transfer of Location of Offices <ul style="list-style-type: none"> - Accomplished e-Application Form - Business permit reflecting new location of office - Payment of fees 	



<p>Change of Distributor Activity</p> <ul style="list-style-type: none">- Accomplished e-Application Form- Contract Agreements showing change in activity- Payment of fees	
<p>Transfer/Addition of Warehouse</p> <ul style="list-style-type: none">- Accomplished e-Application Form- Business Permit reflecting new warehouse location- Payment of fees	
<p>Expansion of Office Establishments and Drug Retailers</p> <ul style="list-style-type: none">- Accomplished e-Application Form- Expansion floor plan- Payment of fees	
<p>Change of Ownership</p> <ul style="list-style-type: none">- Accomplished e-Application Form- Business name registration reflecting new ownership- Any proof on the transfer of ownership such as any of the following<ul style="list-style-type: none">• Deed of Sale or assignment or transfer of rights/ownership• Memorandum of Agreement• Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer- Payment of fees	
<p>Change of Business Name</p> <ul style="list-style-type: none">- Accomplished e-Application Form- Business permit reflecting the new name- Payment of fees	
<p>Zonal Change in Address</p> <ul style="list-style-type: none">- Accomplished e-application Form- Certificate of Zonal Change	



- Payment of fees	
Change of Qualified Person <ul style="list-style-type: none"> - Accomplished e-Application Form - Name of new qualified person - Applicable requirements as specified in ANNEX B of AO 2020-0017 - Payment of fees 	
Change of Authorized Person <ul style="list-style-type: none"> - Accomplished e-Application Form - Name of new authorized person - Updated contact details - Payment of fees 	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through http://eservices.fda.gov.ph and click “ Applications ” found on the upper right corner of the system.		None	0	Qualified person
2. Selects the product category (Food) and the type of business establishment (Food Trader, Food Distributor) before clicking “ Variations ”		None	0	Qualified Person
3. Reads the “ Declaration and Undertaking ” before proceeding with the application process. Check the box “ <i>I agree to the Declaration and Undertaking</i> ” and click on “ Start Application ”.		None	0	Qualified Person



4. Fills-out all necessary information. All fields mark with asterisk (*) are required to be filled-out.		None	0	Qualified Person
5. Uploads the required documents as indicated on the Checklist of Requirements in pdf format.		None	0	Qualified Person
6. Reviews the duly filled out form in the Self-Assessment Review . Once reviewed, click on “Confirm” to submit the application.	<p>1. Conducts pre-assessment on the submitted application and documentary requirements with regards to completeness and correctness.</p> <p>If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number via email.</p> <p>If not, the FDA shall notify the client the reason/s for non-acceptance and prompt the applicant to apply again through the eServices Portal.</p>	None	0	<p>Qualified Person</p> <p>FDA Evaluator (Center/Licensing and Registration)</p>
7. Prints the Order of Payment form with Reference Number sent through the declared e-mail address		None	0	Qualified Person



<p>8. Pays the application fee through existing payment channels</p>	<p>2. Posts payment in eServices Portal System for confirmed payments. This will prompt automatic decking of application to respective Center.</p> <p>LBP OnColl Payment: 5 wd</p> <p>Other Payment Channels: 2 wd</p> <p>Note: Acknowledgement Receipt will automatically be sent to the client once payment is posted and will signify the start of processing time of the application.</p>	<p>See above table</p>	<p>0</p>	<p>Qualified Person</p> <p>FDA Cashier Administrative and Finance Service (AFS)</p>
<p>9. Receives Acknowledgement Receipt through email</p>	<p>3. Checks and quality assurance of the documents provided</p>	<p>None</p>	<p>4 working days</p>	<p>Technical Officer of Center</p>
	<p>4. Finalizes decision on the LTO application</p> <p>If application is approved, the FDA shall send the LTO to the</p>	<p>None</p>	<p>3 working days</p>	<p>Center Director</p>



	registered email address of the applicant. If application is disapproved, the FDA shall inform the applicant through its registered email address of the reason for such action on the application.			
10. Receives notification and prints LTO if application is approved				Qualified Person
TOTAL:			7 working days	