



**VI. LICENSE TO OPERATE – MINOR VARIATION APPLICATION FOR DRUG TRADERS, DRUG DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER), DRUGSTORES, RETAIL OUTLETS FOR NON-PRESCRIPTION DRUGS (RONPD), CLINICAL RESEARCH ORGANIZATIONS AND SPONSORS**

<b>Center/Office/Division</b>	: Center for Drug Regulation and Research (CDRR)
<b>Classification</b>	: Complex
<b>Type of Transaction</b>	: G2B – Government to Business
<b>Who May Avail</b>	: All Drug Traders, Drug Distributors (Importer, Exporter, Wholesaler), Drugstores/Retail Outlets for Non-Prescription Drugs, Clinical Research Organizations and Sponsors
<b>Fees to be Paid</b>	: Minor Variation: Php 500 + 1% LRF  <b>Administrative Order 50 s. 2001</b> <i>Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs</i>  <b>FDA Circular No. 2011-003</b> <i>Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856</i>

<b>CHECKLIST OF REQUIREMENTS (based on Administrative Order No. 2020-0017)</b>	<b>WHERE TO SECURE</b>
<b>Minor Variation</b>	FDA website (www.fda.gov.ph)
<b>Transfer of Location of Offices</b> - Accomplished e-Application Form - Business permit reflecting new location of office - Payment of fees	



<p><b>Transfer of Location of Drug Retailers</b></p> <ul style="list-style-type: none"><li>- Accomplished e-Application Form</li><li>- Business permit reflecting new address</li><li>- Payment of fees</li></ul>	
<p><b>Change of Distributor Activity</b></p> <ul style="list-style-type: none"><li>- Accomplished e-Application Form</li><li>- Contract Agreements showing change in activity</li><li>- Payment of fees</li></ul>	
<p><b>Transfer/Addition of Warehouse</b></p> <ul style="list-style-type: none"><li>- Accomplished e-Application Form</li><li>- Business Permit reflecting new warehouse location</li><li>- Payment of fees</li></ul>	
<p><b>Additional Drugstore Activities</b></p> <ul style="list-style-type: none"><li>- Accomplished e-Application Form</li><li>- Additional credentials of pharmacist (as applicable)</li><li>- Other documents related or specific to the additional activity, such as but not limited to:<ul style="list-style-type: none"><li>• Adult Vaccination – Standard Operating Procedure</li><li>• Dispense Vaccines and Biologicals – Standard Operating Procedure</li><li>• Mobile Pharmacy – Standard Operating Procedure</li><li>• Online Ordering and Delivery – Standard Operating Procedure and Website Screenshot</li><li>• Sterile Compounding and Non-Sterile Complex Compounding – Standard Operating Procedure</li><li>• Other additional activities that may require appropriate regulation</li></ul></li><li>- Payment of fees</li></ul>	
<p><b>Expansion of Office Establishments and Drug Retailers</b></p> <ul style="list-style-type: none"><li>- Accomplished e-Application Form</li><li>- Expansion floor plan</li><li>- Payment of fees</li></ul>	



<p><b>Change of Ownership</b></p> <ul style="list-style-type: none"><li>- Accomplished e-Application Form</li><li>- Business name registration reflecting new ownership</li><li>- Any proof on the transfer of ownership such as any of the following<ul style="list-style-type: none"><li>• Deed of Sale or assignment or transfer of rights/ownership</li><li>• Memorandum of Agreement</li><li>• Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer</li></ul></li><li>- Payment of fees</li></ul>	
<p><b>Change of Business Name</b></p> <ul style="list-style-type: none"><li>- Accomplished e-Application Form</li><li>- Business permit reflecting the new name</li><li>- Payment of fees</li></ul>	
<p><b>Zonal Change in Address</b></p> <ul style="list-style-type: none"><li>- Accomplished e-application Form</li><li>- Certificate of Zonal Change</li><li>- Payment of fees</li></ul>	
<p><b>Change of Qualified Person</b></p> <ul style="list-style-type: none"><li>- Accomplished e-Application Form</li><li>- Name of new qualified person</li><li>- Applicable requirements as specified in ANNEX B of AO 2020-0017</li><li>- Payment of fees</li></ul>	
<p><b>Change of Authorized Person</b></p> <ul style="list-style-type: none"><li>- Accomplished e-Application Form</li><li>- Name of new authorized person</li><li>- Updated contact details</li><li>- Payment of fees</li></ul>	



CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Access the online application portal through <a href="http://eservices.fda.gov.ph">http://eservices.fda.gov.ph</a> and click “ <b>Applications</b> ” found on the upper right corner of the system.		None	0	Qualified person
2. Selects the product category (Drug) and the type of business establishment (Drug Trader, Drug Distributor, Drugstores, RONPD, CRO, Sponsor) before clicking “ <b>Variations</b> ”		None	0	Qualified Person
3. Reads the “ <b>Declaration and Undertaking</b> ” before proceeding with the application process. Check the box “ <i>I agree to the Declaration and Undertaking</i> ” and click on “ <b>Start Application</b> ”.		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 <b>Self-Assessment Review</b> . Once reviewed, click on “ <b>Confirm</b> ” 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</p>	None	0	<p>Qualified Person</p> <p>FDA Evaluator (Center/Licensing and Registration)</p>



	<p>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>			
7. Prints the Order of Payment form with Reference Number sent through the declared e-mail address		None	0	Qualified Person
8. Pays the application fee through existing payment channels	<p>2. Posts payment in eServices Portal System for confirmed payments. This will prompt automatic decking of application to respective Center.</p> <p><b>LBP OnColl Payment:</b> 5 wd</p> <p><b>Other Payment Channels:</b> 2 wd</p>	See above table	0	<p>Qualified Person</p> <p>FDA Cashier Administrative and Finance Service (AFS)</p>



	<p><b>Note:</b> 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>			
9. Receives Acknowledgement Receipt through email	3. Checks and quality assurance of the documents provided	None	4 working days	Technical Officer of Center
	<p>4. Finalizes decision on the LTO application</p> <p>If application is approved, the FDA shall send the LTO to the registered email address of the applicant.</p> <p>If application is disapproved, the FDA shall inform the applicant through its registered email address of the reason for such action on the application.</p>	None	3 working days	Center Director
10. Receives notification and prints LTO if application is approved				Qualified Person
<b>TOTAL:</b>			<b>7 working days</b>	