



## V. LICENSE TO OPERATE – RENEWAL 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>	<p><b>Drug Traders:</b> 20 Million and below – Php 9,000 + 1% LRF over 20 Million but below 50 Million – Php 15,000 + 1% LRF 50 Million and above – Php 21,000 + 1% LRF</p> <p><b>Drug Distributors:</b> Importer, Exporter, Wholesaler- Php 15,000 + 1% LRF</p> <p><b>Drug Outlets:</b> Drugstore and Retail Outlet for Non-Prescription Drugs - Php 3,000 + 1% LRF</p> <p><b>Clinical Research Organizations and Sponsors :</b> 20 Million and below – Php 9,000 + 1% LRF over 20 Million but below 50 Million – Php 15,000 + 1% LRF 50 Million and above – Php 21,000 + 1% LRF</p> <p><b>Administrative Order 50 s. 2001</b></p>



	<p><i>Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs</i></p> <p><b>FDA Circular No. 2011-004</b> <i>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</i></p> <p><b>FDA Circular No. 2011-003</b> <i>Collection of Legal Research Fee (LRF) Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856</i></p>
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<b>CHECKLIST OF REQUIREMENTS</b>	<b>WHERE TO SECURE</b>
1) Basic Requirements based on the Administrative Order No. 2020-0017:	FDA Website ( <a href="http://www.fda.gov.ph">www.fda.gov.ph</a> )
<ul style="list-style-type: none"> <li>● Accomplished e-Application Form as prescribed by FDA regulations.</li> <li>● Declaration and Undertaking</li> </ul>	FDA eServices ( <a href="http://www.fda.gov.ph">www.fda.gov.ph</a> )
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	

<b>CLIENT STEPS</b>	<b>AGENCY ACTION</b>	<b>FEES TO BE PAID</b>	<b>PROCESSING TIME</b>	<b>PERSON RESPONSIBLE</b>
1. Access the online application portal through <a href="https://eservices.fda.gov.ph">https://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, Drugstore, RONPD, CRO, Sponsor) before clicking “ <b>Renewal</b> ” application		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> ”.		See above table	0	Qualified Person
4. Fills-out all necessary information. All fields mark with asterisk (8*) are required to be filled-out.		None	0	Qualified Person
5. Updates contact numbers if necessary. Click “ <b>Next</b> ” to proceed to Self – Assessment Review		None	0	Qualified Person
6. Reviews all details in the “ <b>Self-Assessment Review</b> ”. Once reviewed, click on “ <b>Confirm</b> ” to submit application.	1. System sends the Order of Payment after receipt of the application	None	0	Qualified Person
7. Prints the Order of Payment with Reference Number sent through the declared email address		None	0	Qualified Person
8. Pays the application fee through existing payment channels	2. Posts confirmed payments. This will prompt automatic routing of application to Center	None		Qualified Person  FDA Cashier



	<p><b>LBP OnColl Payment: 5 wd</b>  <b>LBP Linkbiz: auto posting</b>  <b>Other Payment Channels:</b>  <b>2 wd</b></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>			Administrative and Finance Service
9. Receives Acknowledgement Receipt through email	<p>3. Finalizes decision on the LTO application</p> <p>If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial</p>	None	3 working days	Center Director
10. Receives notification and link of LTO for Printing		None		
<b>TOTAL:</b>			<b>3 working days</b>	