



XVII. LICENSE TO OPERATE – RENEWAL APPLICATION FOR MEDICAL DEVICE TRADERS AND MEDICAL DEVICE DISTRIBUTORS (IMPORTER, EXPORTER, WHOLESALER)

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| 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 | <p>Medical Device Trader : 20 million and below – Php 3,000 + 1% LRF Over 20 million but below 50 million – Php 5,000 + 1% LRF 50 million and above – Php 7,000 + 1% LRF</p> <p>Medical Device Distributors (Importer, Exporter, Wholesaler) : Php 4,000 + 1% LRF</p> <p>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></p> <p>FDA Circular No. 2011-004 <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>FDA Circular No. 2011-003</p> |



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 |
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| 1) Basic Requirements based on the Administrative Order No. 2020-0017: | FDA Website (www.fda.gov.ph) |
| <ul style="list-style-type: none"> ● Accomplished e-Application Form as prescribed by FDA regulations. ● Declaration and Undertaking | |
| 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 | |

| CLIENT STEPS | AGENCY ACTION | FEES TO BE PAID | PROCESSING TIME | PERSON RESPONSIBLE |
|--|---------------|-----------------|-----------------|--------------------|
| 1. Access the online application portal through https://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 (Drug) and the type of business establishment (Drug Trader, Drug Distributor, Drugstore, RONPD, CRO, Sponsor) before clicking " Renewal " application | | 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 ". | | See above table | 0 | Qualified Person |



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| 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 “Next” to proceed to Self – Assessment Review | | None | 0 | Qualified Person |
| 6. Reviews all details in the “Self-Assessment Review”. Once reviewed, click on “Confirm” 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 | <p>2. Posts confirmed payments. This will prompt automatic routing of application to Center</p> <p>LBP OnColl Payment: 5 wd</p> <p>LBP Linkbiz: auto posting</p> <p>Other Payment Channels: 2 wd</p> <p>Note: Acknowledgement Receipt will automatically</p> | None | | <p>Qualified Person</p> <p>FDA Cashier Administrative and Finance Service</p> |



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| | be sent to the client once payment is posted and will signify the start of processing time of the application. | | | |
| 9. Receives Acknowledgement Receipt through email | | | | |
| 10. Receives notification and link of LTO for Printing | | None | | |
| TOTAL: | The LTO shall be automatically generated by the system once the payment has been posted by the FDA Cashier | | | |