



XXI. LICENSE TO OPERATE – MAJOR VARIATION APPLICATION

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| Center/Office/Division | : | Center for Cosmetic and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) |
| Classification | : | Highly Technical |
| Type of Transaction | : | G2B - Government to Business |
| Who May Avail | : | Manufacturers of Cosmetics, Toys and Childcare Articles, and Household Urban Pesticides |
| Fees to be Paid | : | <p>Major Variation – Php 500 +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. 2011-003 <i>Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856</i></p> |

| CHECKLIST OF REQUIREMENTS (Based on Administrative Order No. 2020-0017) | WHERE TO SECURE |
|---|------------------------|
| Major Variation | |
| A. Transfer of Location of Manufacturing Plant <ol style="list-style-type: none"> 1. Accomplished e-Application Form 2. Business permit reflecting the new address 3. Updated Site Master File to be presented upon inspection 4. Payment of fees | Qualified Person |



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| <p>B. Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity</p> <ol style="list-style-type: none"> 1. Accomplished e-Application Form 2. Updated Site Master File to be presented upon inspection 3. Payment of fees | |
| <p>1) Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001).</p> | <p>FDA Cashier/Other FDA Authorized Payment Portals or Banks</p> |
| <p>2) Refer to FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection</p> | <p>Applicant/Qualified person</p> |

| CLIENT STEPS | AGENCY ACTION | FEES TO BE PAID | PROCESSING TIME | PERSON RESPONSIBLE |
|---|---|------------------------|-----------------|---|
| <p>1. Logs in to the e-Portal (http://eportal.fda.gov.ph) using the issued username and password, and uploads the required documentary requirements for e-LTO application</p> | | <p>None</p> | <p>0</p> | <p>Qualified Person</p> |
| <p>2. Downloads and prints the generated Order of Payment through the ePortal and Email notification</p> | | <p>None</p> | <p>0</p> | <p>Qualified Person</p> |
| <p>3. Pays the assessed fee as per the system-generated Order of Payment Form through the existing payment channels</p> | <p>1. Posts payment in ePortal for confirmed payments. This will prompt automatic decking of application to respective RFO.</p> | <p>See above table</p> | <p>0</p> | <p>Qualified Person/ FDA Cashier</p> |



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| | LBP OnColl Payment: 5wd Other Payment Channels: 2 wd | | | Administrative and Finance Service |
| | 2. Conducts inspection Refer to Regional Field Office Citizen's Charter for the issuance of Certificate of Compliance/Recommendation for Disapproval/ Recommendation Letter | None | 0 | Regional Field Officer/ Inspector |
| | 3. Evaluates completeness and veracity of the documents submitted. | None | 12 working days | FDA Evaluator (Center/Licensing and Registration) |
| | 4. Checks evaluation and veracity of documents submitted. | None | 4 working days | Technical Officer of Center |
| | 5. Quality assurance of the evaluation. | None | 2 working day | Technical Officer of Center |
| | 6. Finalizes decision on the LTO application If the application is disapproved, the applicant will be notified through email and will receive the letter of Denial | None | 2 working days | Center Director |



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| 4. Receives notification and link of LTO for printing | | | | Qualified Person |
| TOTAL: | | | 20 working days | |