## XXX. LICENSE TO OPERATE – MINOR VARIATION APPLICATION FOR HOUSEHOLD URBAN HAZARDOUS SUBSTANCES (HUHS) BASED ON ADMINISTRATIVE ORDER NO. 2019-0019 AND FDA CIRCULAR 2020-025

### Issuance of Electronic Portal (E-Portal) Ver.2.0 User Account

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| **Center/Office/Division** | : | Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR) |
| **Classification** | : | Simple |
| **Type of Transaction** | : | G2B - Government to Business |
| **Who may Avail** | : | All Manufacturers, Traders, Distributors (Importer, Exporter, Wholesaler) of Household/Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025 |
| **Fees to be paid** | : | None |

| CHECKLIST OF REQUIREMENTS | WHERE TO SECURE |
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| 1.Proof of Ownership of Establishment (refer to Annex B and B.1 of FDA Circular No. 2020-025) | Applicant |

| CLIENT STEPS | AGENCY ACTION | FEES TO BE PAID | PROCESSING TIME | PERSON RESPONSIBLE |
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| 1. Request User Account credentials by accomplishing the Online User's Registration Form through the link: bit.ly/ePortal2 (refer to Annex B.1) | 1. Check for the completeness and appropriateness of the request | None | 15 Minutes | CCHUHSRR Admin. Staff |
| 2. Receive username and password | 2. Issue user account (username and password) to the client | None | Next Working Day | CCHUHSRR Admin. Staff |
| | **TOTAL:** | **None** | **1 Working Day and 15 minutes** | |

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| **Center/Office/Division** | : | Cosmetic (and Household/Urban Hazardous Substances) Regulation and Research (CCHUHSRR) |
| **Classification** | : | Complex |
| **Type of Transaction** | : | G2B - Government to Business |
| **Who May Avail** | : | All Manufacturers, Traders, Distributors (Importer, Exporter, Wholesaler) of Household Urban Hazardous Substances (under Categories III and IV) based on AO 2019-0019 and FDA Circular No. 2020-025 |
| **Fees to be Paid** | : | Amendment of LTO or Re-issuance (if lost) – Php 500 +1% LRF<br>**Administrative Order 50 s. 2001***<br>*Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs*<br>**FDA Circular No. 2011-003**<br>*Collection of Legal Research Fee 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)List of Requirements for Specific Variation based on Administrative Order No. 2020-0017:<br><br>A. Transfer of Location Offices<br>- Physical transfer of the office of the establishment<br><br>Documentary Requirement:<br>1. Business permit reflecting new location of office<br>- Physical transfer of the office of the establishment<br><br>● For Single Proprietorship: Business Permit/ Mayor's Permit or Barangay Business Permit/ Clearance reflecting the new office location;<br>● For SEC-registered establishments:<br>a) Amended Articles of Incorporation (if transferred from one city/ municipality/province); or | Qualified Person |

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| b) Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality/province)<br>● If the establishment address is different from the address indicated in the SEC Registration, provide LGU/Mayor's Permit or Barangay Business Permit/Clearance reflecting new office location<br><br>B. Change of Distributor Activity<br>-additional/deletion or change in activity that the distributor is currently engaged<br><br>Documentary Requirement:<br>1. Contract Agreements showing change in activity<br><br>C. Transfer or Addition of Warehouse<br>-Physical transfer and addition of warehouse of the establishment<br><br>Documentary Requirement:<br>1. Mayor's Permit or Barangay Business Permit/Clearance reflecting new warehouse location<br><br>D. Expansion of Office Establishment<br>- expansion made which is adjacent to the existing location of the establishment<br><br>Documentary Requirement:<br>a) Current floor plan<br>b) Expansion floor plan | |

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| E. Change of Ownership<br>-Change in ownership of the licensed establishment<br><br>Documentary Requirement:<br>1. Business name registration reflecting new ownership<br>2. Any proof on the transfer of ownership<br>● Deed of sale or assignment or transfer of rights/ownership;<br>● Memorandum of Agreement; or<br>● Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer<br><br>F. Change of Business Name<br>-Change only in the business name of the establishment<br><br>Documentary Requirement:<br>1. Business name registration reflecting new business name.<br><br>G. Zonal Change in Address<br>-Change of the name/number of the street/building without physical transfer of the establishment<br><br>Documentary Requirement:<br>1. Certificate of Zonal Address<br>2. Certification from Local Government Unit (City/Municipality) stating no physical transfer of the establishment<br><br>H. Change of Qualified Person<br>-Change in the identified qualified person initially registered with the FDA | |

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| Documentary Requirement:<br>1. Name of new qualified person, with credentials when applicable<br>2. Valid Professional Regulation Commission (PRC) ID<br>3. Signed Letter of Resignation duly noted by the former employer, if previously connected with another pharmacy/establishment<br><br>I. Change of Authorized Person<br>-Change in the authorized person initially registered with the FDA<br><br>Documentary Requirement:<br>1. Name of new qualified person<br>2. Valid Government ID | |
| 2) Proof of payment of fees as prescribed by current FDA regulations (AO 50 s. 2001). | FDA Cashier/Other FDA Authorized Payment Portals or Banks |

| CLIENT STEPS | AGENCY ACTION | FEES TO BE PAID | PROCESSING TIME | PERSON RESPONSIBLE |
|---|---|---|---|---|
| 1. Access the FDA e-Portal V2 at (https://eportal2.fda.gov.ph). Log in by entering the issued username and password. | | None | 0 | Qualified Person |
| 2. In the Home tab, select New Application in the navigation pane and click e-License to Operate (Variation Application) to proceed to the LTO application form. | | None | 0 | Qualified Person |
| 3. Accomplish the application form as provided in parts by the application wizard. Fill-in the fields as completely as possible. Fields marked with a | | None | 0 | Qualified Person |

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| red asterisk (*) are required to be filled-in. Mark required fields with N/A, if not applicable. | | | | |
| 4. Upload Documents in PDF format.<br>● Proof of Business Name Registration, Proof of Income. Tick the box to certify all information is true and correct, then "Next".<br>● Applicants may upload documents simultaneously. | 1. Pre-assessment on the completeness of application and documentary requirements submitted | None | 0 | Qualified Person |
| 5. Order of payment- A computer generated document will appear reflecting the appropriate fees and charges. Applicant should save and print a copy of document as reference for payment | | None | 0 | Qualified Person |
| 6. Pay the assessed fee as per the system generated Order of Payment Form through existing payment channels | 2. Post payment in ePortal V.2 for confirmed payments. This will prompt automatic decking of application to respective Center | See above table | 0 | Qualified Person and FDA Cashier Administrative and Finance Service (AFS) |
| | 3. Evaluation of correctness of submitted documentary requirements. | None | 3 working days | FDA Evaluator (Center/Licensing and Registration Division) |
| | 4. Checking of the evaluation and veracity of documents submitted. | None | 2 working days | Technical Officer of specific Center of jurisdiction |
| | 5. Approval of LTO | None | 2 working days | Center Director of jurisdiction |

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| | If application is disapproved, the applicant will be notified through email and will receive the Letter of Denial | | | |
| 7. Receive notification and copy of e-LTO for printing | | None | | Qualified Person |
| **TOTAL:** | | | **7 working days** | |

Note:

1. The fees charged for manufacturers and traders of products regulated by FDA are based on the capital invested.
2. Renewal of HUHS LTO shall be valid for a maximum period of five (5) years.
3. Application for renewal shall be done within three (3) months prior to validity date of the LTO. Applications filed after the validity date of the LTO shall be subject to surcharge as prescribed in RA 9711 and its IRR.