

FDA ADVISORY

No. **2024-0543**

25 MAR 2024

TO : HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES (HUHS) STAKEHOLDERS

SUBJECT : ON-BOARDING OF THE LICENSING PROCEDURES FOR HOUSEHOLD/URBAN HAZARDOUS SUBSTANCES (HUHS) ESTABLISHMENTS ON THE FOOD AND DRUG ADMINISTRATION (FDA) E-SERVICES PORTAL SYSTEM

The Food and Drug Administration (FDA) continues its digital system enhancement through the development of online application platforms, particularly, the FDA eServices Portal System. These enhancements aim to further simplify application submissions in alignment with the principles of ease of doing business espoused in Republic Act No. 11032, otherwise known as the “Ease of Doing Business and Efficient Government Service Delivery Act of 2018”.

The FDA hereby informs all stakeholders and the general public that the following services in relation to applications for **License to Operate (LTO) for HUHS Establishments** will be on-boarded onto the FDA eServices Portal System:

On-Boarding of FDA eServices Portal System for the Licensing of HUHS Establishments	
Type of LTO Application	<ol style="list-style-type: none"> 1. Initial 2. Renewal 3. Variation
Type of HUHS Establishment	<ol style="list-style-type: none"> 1. HUHS Manufacturer <ol style="list-style-type: none"> a. HUHS Manufacturer / Toll Manufacturer b. HUHS Manufacturer-Packer / Toll Packer c. HUHS Manufacturer-Repacker / Toll Repacker 2. HUHS Distributor <ol style="list-style-type: none"> a. HUHS Distributor-Importer b. HUHS Distributor-Exporter c. HUHS Distributor-Wholesaler 3. HUHS Trader

All applications shall be exclusively filed and accepted through the eServices Portal System at <https://eservices.fda.gov.ph/> beginning on 01 July 2024.



Currently, the HUHS licensing module of the eServices Portal System is in the last stages of dry run testing. The FDA will issue a separate announcement once the FDA eServices Portal System is available and ready to receive HUHS LTO applications.

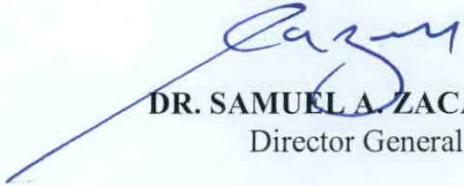
The following guidance documents on the procedure for filing applications are annexed to this Advisory:

1. **Annex A** - LTO Requirements for HUHS Establishments
2. **Annex B** - Procedure in the Submission of an Initial LTO Application
3. **Annex C** - Procedure in the Submission of Renewal LTO Application
4. **Annex D** - Procedure in the Submission of Variation LTO Application
5. **Annex E** - Procedure for Checking the Status of an Application
6. **Annex F** - Procedure for Voluntary Cancellation of an Application
7. **Annex G** – Letter Template for HUHS LTO Renewal

Further, please be clarified on the following arrangements:

1. All initial LTO applications filed via the FDA ePortal v2 System before 01 July 2024 will be processed in accordance with FDA Circular No. 2023-0006, hence, re-application through the FDA eServices Portal System is not necessary. However, should an applicant wish to apply through the new FDA eServices Portal System, the application shall be treated as new, and a separate fee shall be charged.
2. All previously-issued HUHS LTOs expiring before the availability of the system are automatically extended **until 30 June 2024 and their surcharges are waived; Provided**, that prior 15 June 2024 a letter signifying intention to submit an LTO renewal application in the FDA eServices Portal System once available, shall be submitted by the establishment through the Food and Drug Action Center (FDAC). The letter must be in the format of **Annex G**, with complete information including the declaration statement, and signed by the establishment owner/authorized representative/qualified person.

For the information and guidance of all concerned.


DR. SAMUEL A. ZACATE
Director General