

**ANNEX D**  
**Procedure in the Submission of Variation LTO Application**

**A. Procedure outline**

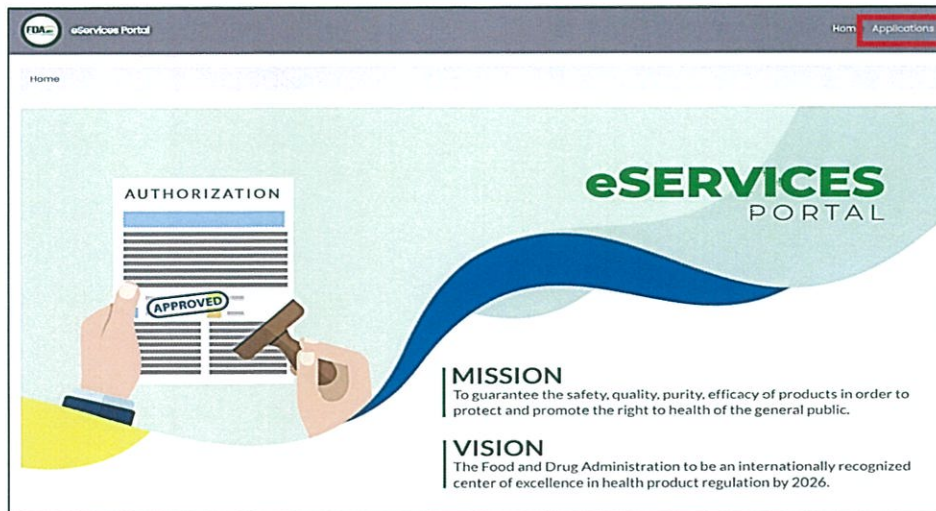
1. Accessing and navigating the FDA eServices Portal System
2. Filing an application
  - a. Page 1: Declaration & Undertaking
  - b. Page 2: License to Operate
  - c. Page 3: Contact Information
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**B. Step-by-step procedure**

Follow the steps outlined below in order to submit a renewal HUHS LTO application.

**1. Accessing and navigating the FDA eServices Portal System**










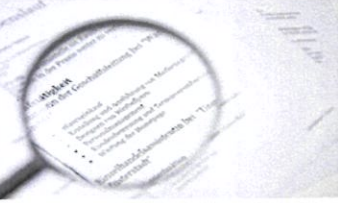





- a. Access the online portal through (<https://eservices.fda.gov.ph/>) and click “Applications” found on the upper right corner of the eServices landing page.



- b. Click the License to Operate for Household/Urban Hazardous Substances and Type of Establishment (Distributor, Trader, Manufacturer, Packer or Repacker)



## License to Operate

 <p><b>Bottled Water</b> For establishments that handle bottled water products</p>	 <p><b>Drug</b> For establishments that handle drug products</p>	 <p><b>Food</b> For establishments that handle food products</p>
 <p><b>Iodized Salt</b> For establishments that handle salt products</p>	 <p><b>Device</b> For establishments that handle device products</p>	 <p><b>Cosmetic</b> For establishments that handle cosmetic products</p>
 <p><b>Household/Urban Pesticide</b> For establishments that handle Household/Urban pesticide products</p>	 <p><b>Household/Urban Hazardous Substances</b> For establishments that handle Household/Urban Hazardous Substances products</p>	 <p><b>Toy and Child Care Article</b> For establishments that handle Toy and Child Care Article products</p>
 <p><b>Application Status</b> Check the current status of your application</p>	 <p><b>Distributor</b> License authorization for distributor establishments</p>	 <p><b>Trader</b> License authorization for trader establishments</p>
 <p><b>Manufacturer</b> License authorization for manufacturer establishments</p>	 <p><b>Packer</b> License authorization for packer establishments</p>	 <p><b>Repacker</b> License authorization for repacker establishments</p>

i. Select the primary activity the applicant intends to engage in which may be one of the following:

- Manufacturer-** An establishment that is engaged in any and all operations involved in the production of HUHS products including preparation, processing, formulating, filling, packaging, repacking, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution.
- Packer-** An establishment that packages bulk HUHS product into its immediate container with the end view of storage, distribution, or sale of the product.

- **Repacker-** An establishment that repacks a finished product into smaller quantities in a separate container and/or into secondary packaging, including but not limited to relabeling, stickering, and bundling for promo packs with the end view of storage, distribution, or sale of the product.
- **Trader-** An establishment which is a registered owner of a HUHS product and procures the raw materials and packing components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such product to a licensed manufacturer.
- **Distributor-** Any establishment that imports/exports raw materials, active ingredients and/or HUHS products for its own use or for wholesale distribution to other establishments or outlets.

### Household/Urban Hazardous Substances Manufacturer



**Initial**

Apply for a new License to Operate



**Renewal**

Renew existing License to Operate



**Variations**

Apply for changes in the existing License to Operate

## 2. Filing an application

### a. Page 1: Declaration & Undertaking

To start the application, read carefully and agree to the declaration & undertaking form. Make sure to check the box found below and click on **“Start Application”**.

### Household/Urban Hazardous Substances Manufacturer Variations

- 1 Declaration & Undertaking
- 2 License to Operate
- 3 Contact Information
- 4 Variations
- 5 Self-Assessment Review

#### Declaration & Undertaking

I, duly authorized officer/s or representative/s of the Establishment hereby voluntarily and categorically declare, undertake, and agree that all data and information contained and provided in the attached application, together with all other submissions, including amendments, are true and correct based on my knowledge and are based on existing records, legal documents and available information.

I, likewise declares, undertakes and agrees that:

- I. The said establishment shall be open during its business hours under the supervision of a PRC registered professional (e.g. Pharmacists) or authorized personnel at all times;
- II. The pharmacist/s and the other appropriate allied health professionals, upon and during employment in the establishment, is/are not and will not in any way be connected to, employed by or engaged with any other FDA-regulated establishment;
- III. The approved and valid license to Operate shall be displayed in a conspicuous place in the establishment visible to my customers;
- IV. The establishment will change its business name, and/or brand name in the case of products, in the event that there is a similar, same, or confusingly similar name registered with the Food and Drug Administration, or if the FDA rules later that such name is misleading, offensive, against the law, customs, public morals, public policy or otherwise violative of relevant rules and regulations;
- V. The electronic copy of the files, documents, or information submitted in relation to this application are the exact duplicate or scanned copy of the same and, any discrepancy, prejudicial contents, false claims or misrepresentation on any of the data therein shall be a ground for the disapproval of application, or if discovered post-

I agree to the declaration and undertaking

[Start Application](#)

**b. Page 2: License to Operate**

Provide the existing LTO Number, Validity Date, and Security Code (by scanning the QR Code from the given document). Please ensure the correctness of the data given to proceed with the change in licensing authorization. Tick **“I’m not a robot”** then click **“Next”** to proceed.

Home / Applications / License to Operate / Huhs / Manufacturer / Variations

### Household/Urban Hazardous Substances Manufacturer Variations

1 Declaration & Undertaking    License to Operate

2 License to Operate

3 Contact Information

4 Variations

5 Self-Assessment Review

\* License Number    License Number

\* Date of Validity    Date of Validity

\* Security Code    Security Code

Please scan the QR Code in the document. For previously issued LTO, enter the sequence number located at the bottom right corner of the document (e.g. FDA-123456)

I'm not a robot    reCAPTCHA

Back    Next

**c. Page 3: Contact Information**

Provide an updated contact information if applicable. Click **“Next”** to proceed.

Home / Applications / License to Operate / Huhs / Distributor / Variations

### Household/Urban Hazardous Substances Distributor Variations

1 Declaration & Undertaking    Contact Information

2 License to Operate

3 Contact Information

4 Minor Variations

5 Self-Assessment Review

\* Email Address

The owner/authorized representative shall ensure that they have access to the declared email address. The FDA shall not be held responsible or liable in any way for loss of access to the declared email address.

\* Mobile Number

Update mobile number if necessary

Landline Number    Landline Number

Update landline number if necessary

Back    Next

**d. Page 4: Variations**

- i. Choose and tick the box of the type of variation/s applicable for your LTO. More than one type of HUHS LTO variation can be applied simultaneously in a single application.

- ii. Upload the required document/s for the variation/s in accordance to FDA Circular No. 2020-025 and DOH AO 2020-0017, in pdf format by clicking “Upload Files”, then click “Next”

**e. Page 5: Self-Assessment Review**

- i. A Self-Assessment Review summary will appear that reflects all the declared information and uploaded documents.
- ii. Review and recheck the information declared and documents uploaded. If there are corrections to be made, the information and documents can directly be updated on the Self-Assessment Review page.
- iii. After the self-assessment review, the applicant shall confirm the correctness of the data and uploaded documents. Tick “I’m not a robot”, **Data Privacy Act declaration** and click the “**Confirm**” submit the application.
- iv. Auto-generated electronic email will be sent containing the Application Summary