

## ANNEX B

### Procedure in the Submission of an Initial LTO Application

#### A. Procedure outline

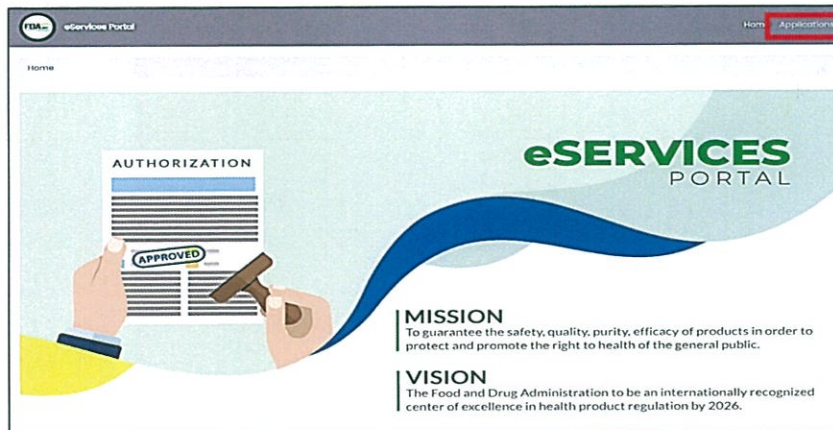
1. Accessing and navigating the FDA eServices Portal System
2. Filing an application
  - a. Page 1: Declaration and Undertaking
  - b. Page 2: General Information
  - c. Page 3: Product Line (*For Manufacturer Only*)
  - d. Page 4: Establishment Information
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  - h. Page 8: Details of Authorized Person
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#### B. Step-by-step procedure

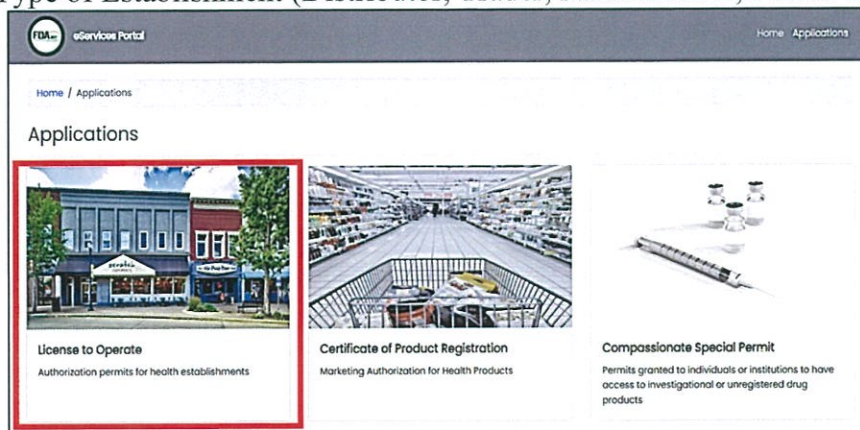
Follow the steps outlined below in order to submit an initial HUHS LTO application.

##### 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



### Bottled Water

For establishments that handle bottled water products



### Drug

For establishments that handle drug products



### Food

For establishments that handle food products



### Iodized Salt

For establishments that handle salt products



### Device

For establishments that handle device products



### Cosmetic

For establishments that handle cosmetic products



### Household/Urban Pesticide

For establishments that handle Household/Urban pesticide products



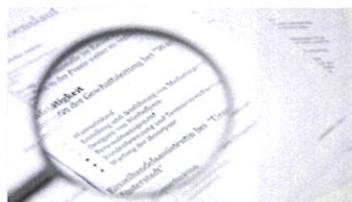
### Household/Urban Hazardous Substances

For establishments that handle Household/Urban Hazardous Substances products



### Toy and Child Care Article

For establishments that handle Toy and Child Care Article products



### Application Status

Check the current status of your application



### Distributor

License authorization for distributor establishments



### Trader

License authorization for trader establishments



### Manufacturer

License authorization for manufacturer establishments



### Packer

License authorization for packer establishments



### Repacker

License authorization for repacker establishments

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.

c. Click the Initial Application.

The screenshot shows the FDA eServices Portal interface. At the top, there is a navigation bar with 'Home Applications Downloadables FAQs'. Below it, a breadcrumb trail reads 'Home / Applications / License to Operate / Huhs / Manufacturer'. The main heading is 'Household/Urban Hazardous Substances Manufacturer'. There are three main options presented as cards:

- Initial:** Apply for a new License to Operate. The card features an image of a person writing on a document.
- Renewal:** Renew existing License to Operate. The card features an image of a clock.
- Variations:** Apply for changes in the existing License to Operate. The card features an image of a hand holding a red circular object in front of a chalkboard with the word 'UPDATE' written on it.

## 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”**.

The screenshot shows the 'Declaration & Undertaking' form within the FDA eServices Portal. The breadcrumb trail is 'Home / Applications / License to Operate / Huhs / Manufacturer / Initial'. The form title is 'Household/Urban Hazardous Substances Manufacturer Initial'. On the left, there is a vertical list of steps: 1. Declaration & Undertaking (highlighted with a red box), 2. General Information, 3. Product Line, 4. Establishment Information, 5. Office Address, 6. Warehouse Addresses, 7. Plant Address, 8. Authorized Person, 9. Qualified Personnel, 10. Documentary Requirements, and 11. Self-Assessment Review. The main content area contains the following text:

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:

- The said establishment shall be open during its business hours under the supervision of a PRC registered pharmacist/s or authorized personnel at all times.
- The registered 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.
- The approved and valid License to Operate shall be displayed in a conspicuous place in the establishment visible to my customers.
- 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.

At the bottom of the form, there is a checkbox labeled 'I agree to the declaration and undertaking' (highlighted with a red box) and a blue 'Start Application' button (also highlighted with a red box).

## b. Page 2: General Information

Fill out the necessary information accurately based on establishment's activity/ies. Make sure to properly tick the corresponding activity/ies before proceeding onto the next step.

### 1.1. Manufacturer and Trader Activities

- Importer of Raw Materials for Own Use
- Exporter of Own Products
- Wholesaler of Own Products

### 1.2. Distributor Activities

- Importer
- Exporter
- Wholesaler

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

### Household/Urban Hazardous Substances Manufacturer Initial

1 Declaration & Undertaking

2 **General Information**

3 Product Line

4 Establishment Information

5 Office Address

6 Warehouse Addresses

7 Plant Address

8 Authorized Person

9 Qualified Personnel

10 Documentary Requirements

11 Self-Assessment Review

#### General Information

\* Type of Application: Initial

\* Product Type: Household/Urban Hazardous Substances

\* Primary Activity: Manufacturer

Additional Activities:

- Importer of Raw Materials for Own Use
- Exporter of Own Products
- Wholesaler of Own Products

\* Primary Activity: Trader

Additional Activities:

- Importer of Raw Materials for Own Use
- Exporter of Own Products
- Wholesaler of Own Products

Primary Activity: Distributor

Distributor Activities:

- Importer
- Exporter
- Wholesaler

## c. Page 3: Product Line (For Manufacturer Only)

Declare all product lines that the applicant intends to manufacture based on their current production capabilities. Select the applicable product line from the dropdown list. If there is more than one (1) Product Line click “Add Product Line”, then click “Next”.

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

### Household/Urban Hazardous Substances Manufacturer Initial

1 Declaration & Undertaking

2 General Information

3 **Product Line**

4 Establishment Information

5 Office Address

6 Warehouse Addresses

7 Plant Address

8 Authorized Person

9 Qualified Personnel

#### Product Line Details

\* Type: [Please Select]

- [Category III] Bleaches
- [Category III] Cleaners (ie. corrosive, multi-purpose, surface, etc.)
- [Category III] Deodorizers
- [Category III] Dishwashing and laundry detergents/soaps
- [Category III] Disinfectants (for surfaces)
- [Category III] Fabric conditioners/softeners and ironing aids
- [Category III] Fresheners (ie. room, car, etc.), aromatics, diffusers
- [Category III] Moisture absorbing agents (ie. desiccant)
- [Category III] Polishes
- [Category III] Pool chemicals
- [Category IV] Adhesives, glues, and sealants
- [Category IV] Automotive, furniture and jewelry care, and restoring products
- [Category IV] Button batteries
- [Category IV] Coloring materials
- [Category IV] Fabric dyes, tattoo dyes
- [Category IV] Paint stripper
- [Category IV] Rust remover/degreasers
- [Category IV] Paints, varnishes, and thinners

Add Product Line

Back Next

#### d. Page 4: Establishment Information

Fill-in the necessary information. Field marked with a red asterisk (\*) are required to be filled-in.

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

### Household/Urban Hazardous Substances Manufacturer Initial

1 Declaration & undertaking

2 General Information

3 Product Line

**4 Establishment Information**

5 Office Address

6 Warehouse Addresses

7 Plant Address

8 Authorized Person

9 Qualified Personnel

10 Documentary Requirements

11 Self-Assessment Review

#### Establishment Information

\* Name of Establishment: Name of Establishment  
Business Name shall be the same name in the SEC/D11/CDA permit/Original Charter. Please ensure correctness of the declared Business Name as this will be the same name to be reflected in the License to Operate.

\* Owner of Establishment: Owner of Establishment  
For SEC/CDA registered establishments, the name of the corporation/cooperative must be used as the owner.

\* Tax Identification Number: Tax Identification Number

\* Declared Capital: Please Select

#### Contact Information

\* Email Address: 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 or damage to the declared email address.

\* Mobile Number: Mobile Number  
Please indicate an 11 digit mobile number.

Landline Number: Landline Number  
Please indicate the area code followed by the landline number.

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*The declared e-mail address shall serve as the communication channel in receiving all notifications and results generated in the e-Services portal system.*

#### e. Page 5: Office Address

Utilize the dropdown list when selecting the Region, Province and City or Town. Click the “Get GPS Coordinates” to determine the exact location of the Office Address. Pin accurately the location on the map.

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

### Household/Urban Hazardous Substances Manufacturer Initial

1 Declaration & Undertaking

2 General Information

3 Product Line

4 Establishment Information

**5 Office Address**

6 Warehouse Addresses

7 Plant Address

8 Authorized Person

9 Qualified Personnel

10 Documentary Requirements

11 Self-Assessment Review

#### Office Address

\* Region: Please Select

\* Province: Please Select

\* City or Town: Please Select

\* Street Address: Street Address  
The declared address shall be the same address indicated in the SEC/D11/CDA permit. Otherwise, the declared address must be consistent with the one indicated in the business permit.

\* GPS Latitude: GPS Latitude

\* GPS Longitude: GPS Longitude

Get GPS Coordinates

Back Next

**f. Page 6: Warehouse Address**

Utilize the dropdown list when selecting the Region, Province and City or Town. Click the “**Get GPS Coordinates**” to determine the exact location of the Warehouse Address. Pin accurately the location on the map.

1 Declaration & Undertaking

2 General Information

3 Product Line

4 Establishment Information

5 Office Address

**6 Warehouse Addresses**

7 Plant Address

8 Authorized Person

9 Qualified Personnel

10 Documentary Requirements

11 Self-Assessment Review

### Warehouse Addresses

Warehouse #1

\* Region Please Select

\* Province Please Select

\* City or Town Please Select

\* Street Address Street Address

The declared warehouse address shall be the same address indicated in the SEC/DTI/CDA permit. Otherwise, the declared address must be consistent with the one indicated in the business permit.

\* GPS Latitude GPS Latitude

\* GPS Longitude GPS Longitude

Get GPS Coordinates

Add Warehouse Address

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*If there are two or more warehouse addresses provided, it shall indicate in the application with respective GPS coordinates generated on the Geo-Coding Map.*

**g. Page 7: Plant Address (For Manufacturer Only)**

For manufacturers, one (1) plant address must be declared. Click the “**Get GPS Coordinates**” to determine the exact location of the Warehouse Address. Pin accurately the location on the map.

1 Declaration & Undertaking

2 General Information

3 Product Line

4 Establishment Information

5 Office Address

6 Warehouse Addresses

**7 Plant Address**

8 Authorized Person

9 Qualified Personnel

10 Documentary Requirements

11 Self-Assessment Review

### Plant Address

\* Region Please Select

\* Province Please Select

\* City or Town Please Select

\* Street Address Street Address

The declared address shall be the same address indicated in the SEC/DTI/CDA permit. Otherwise, the declared address must be consistent with the one indicated in the business permit.

\* GPS Latitude GPS Latitude

\* GPS Longitude GPS Longitude

Get GPS Coordinates

Back Next

### h. Page 8: Details of Authorized Person

**Authorized Person** refers to the owner, President, Chief Executive Officers (CEO) or its equivalent, or any organic or full-time employee representing the establishment in an authorized or official capacity.

FDA eServices Portal Home Applications Downloadables FAQs

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

### Household/Urban Hazardous Substances Manufacturer Initial

- 1 Declaration & Undertaking
- 2 General Information
- 3 Product Line
- 4 Establishment Information
- 5 Office Address
- 6 Warehouse Addresses
- 7 Plant Address
- 8 Authorized Person**
- 9 Qualified Personnel
- 10 Documentary Requirements
- 11 Self-Assessment Review

**10** Authorized Person refers to the owner, President, Chief Executive Officers (CEO) or its equivalent, or any organic or full-time employee representing the establishment in an authorized or official capacity.

#### Details of Authorized Person

* First Name	First Name <small>include suffix name on first name</small>
Middle Name	Middle Name
* Last Name	Last Name
* Designation	Please Select <small>select owner for sole proprietorships</small>
Government Issued Identification Document	
* Type	Please Select
* Identification Number	Identification Number

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### i. Page 9: Details of Qualified Personnel

**Qualified Person** refers to an organic or full-time employee of the establishment who possess technical competence related to the establishment's activities and health products by virtue of his profession, training or experience. A qualified person has the responsibility to comply with the technical requirements of the FDA or discuss or clarify matters with the FDA when submitting technical requirements or engage the FDA officials when conducting inspection or post-market surveillance activities. The qualified person may also be the duly Authorized Person of the establishment.

FDA eServices Portal Home Applications Downloadables FAQs

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

### Household/Urban Hazardous Substances Manufacturer Initial

- 1 Declaration & Undertaking
- 2 General Information
- 3 Product Line
- 4 Establishment Information
- 5 Office Address
- 6 Warehouse Addresses
- 7 Plant Address
- 8 Authorized Person
- 9 Qualified Personnel**
- 10 Documentary Requirements
- 11 Self-Assessment Review

**10** Qualified Person refers to an organic or full-time employee of the establishment who possess technical competence related to the establishment's activities and health products by virtue of his profession, training or experience. A qualified person has the responsibility to comply with the technical requirements of the FDA or discuss or clarify matters with the FDA when submitting technical requirements or engage the FDA officials when conducting inspection or post-market surveillance activities. The qualified person may also be the duly Authorized Person of the establishment.

#### Details of the Qualified Personnel

Personnel Details

* First Name	First Name
Middle Name	Middle Name
* Last Name	Last Name
* Designation	Please Select
Government Issued Identification Document	
* Type	Please Select
* Identification Number	Identification Number

**Add Personnel**

Back Next

*If there is more than one (1) Qualified Personnel, click "Add Personnel"*

**j. Page 10: Documentary Requirements**

Upload necessary documents in portable document file (PDF), maximum of two (2) megabytes (MB) file size.

**k. Page 11: 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