

ANNEX C

Procedure in the Submission of Renewal LTO Application

A. Procedure outline

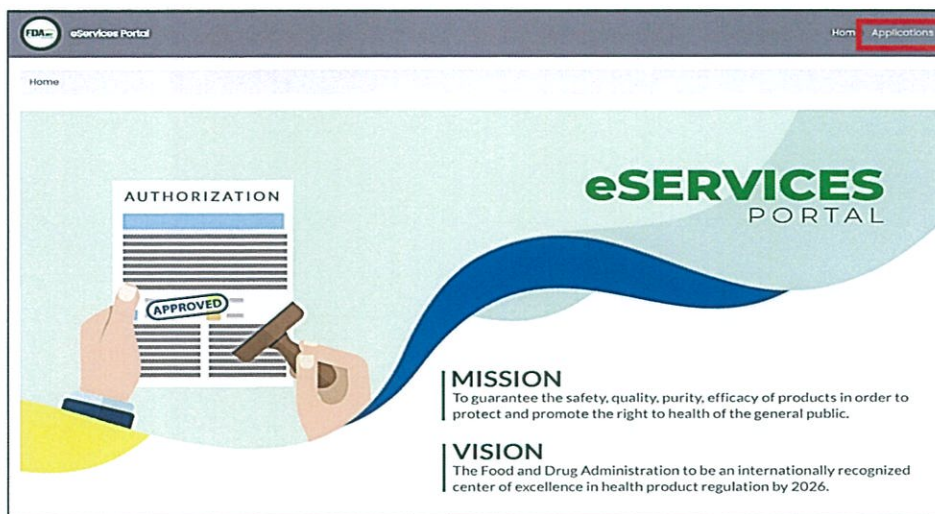
1. Accessing and navigating the FDA eServices Portal System
2. Filing an application
 - a. Page 1: Declaration & Undertaking
 - b. Page 2: License to Operate
 - c. Page 3: Contact Information
 - d. Page 4: Self-Assessment Review

B. Step-by-step procedure

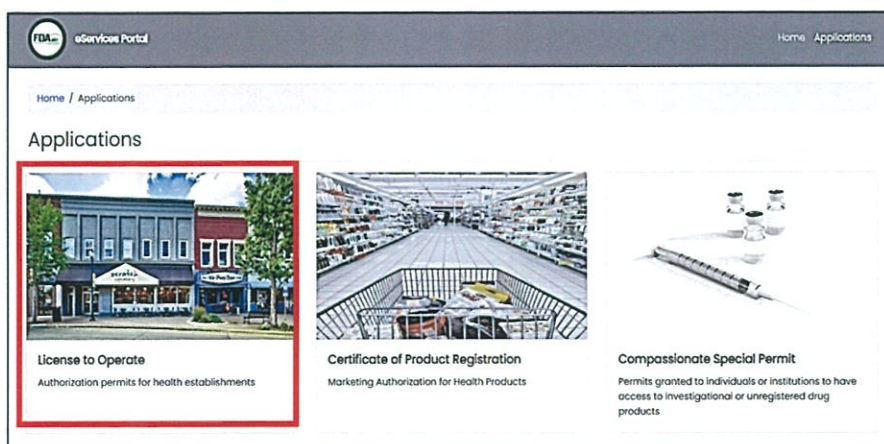
Follow the steps outlined below in order to submit a renewal HUHS LTO application.

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



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



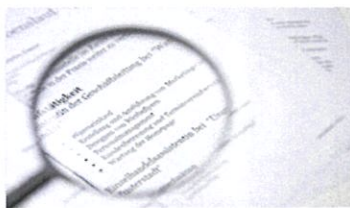
Household/Urban Pesticide
For establishments that handle Household/Urban pesticide products



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



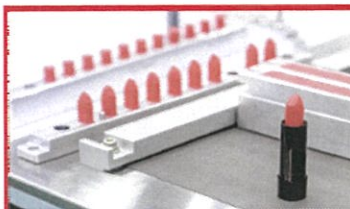
Application Status
Check the current status of your application



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 Renewal Application.

The screenshot shows the FDA eServices Portal interface. The breadcrumb trail is: Home / Applications / License to Operate / Huhs / Manufacturer. The main heading is "Household/Urban Hazardous Substances Manufacturer". Below this, there are three columns representing different application types:

- Initial:** Apply for a new License to Operate. (Image: A hand writing on a document.)
- Renewal:** Renew existing License to Operate. (Image: A hand holding a pen over a document with a red box around it.)
- Variations:** Apply for changes in the existing License to Operate. (Image: A hand holding a red pill over 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" step of the application process. The breadcrumb trail is: Home / Applications / License to Operate / Huhs / Manufacturer / Renewal. The main heading is "Household/Urban Hazardous Substances Manufacturer Renewal". On the left, there is a vertical list of steps: 1. Declaration & Undertaking (highlighted with a red box), 2. License to Operate, 3. Contact Information, and 4. 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:

- 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-

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

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.

The screenshot shows the 'License to Operate' page in the eServices Portal. The breadcrumb trail is 'Home / Applications / License to Operate / Huhs / Manufacturer / Renewal'. The page title is 'Household/Urban Hazardous Substances Manufacturer Renewal'. On the left, a progress indicator shows four steps: 1. Declaration & Undertaking, 2. License to Operate (highlighted with a red box), 3. Contact Information, and 4. Self-Assessment Review. The main form area contains three fields: 'License Number', 'Date of Validity', and 'Security Code'. Below the 'Security Code' field, there is a note: '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)'. At the bottom right, there is an 'I'm not a robot' checkbox and a reCAPTCHA logo. At the very bottom, there are 'Back' and 'Next' buttons.

c. Page 3: Contact Information

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

The screenshot shows the 'Contact Information' page in the eServices Portal. The breadcrumb trail is 'Home / Applications / License to Operate / Huhs / Distributor / Renewal'. The page title is 'Household/Urban Hazardous Substances Distributor Renewal'. On the left, a progress indicator shows four steps: 1. Declaration & Undertaking, 2. License to Operate, 3. Contact Information (highlighted with a red box), and 4. Self-Assessment Review. The main form area contains three fields: 'Email Address', 'Mobile Number', and 'Landline Number'. Below the 'Email Address' field, there is a note: '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.' Below the 'Mobile Number' field, there is a note: 'Update mobile number if necessary'. Below the 'Landline Number' field, there is a note: 'Update landline number if necessary'. At the bottom right, there are 'Back' and 'Next' buttons.

d. Page 4: Self-Assessment Review

- i. A Self-Assessment Review summary will appear that reflects all the declared information.
- ii. 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.
- iii. Auto-generated electronic email will be sent containing the Application Summary

The screenshot shows the 'eServices Portal' interface. At the top, there are navigation links: 'Home', 'Applications', 'Downloadables', and 'FAQs'. Below this is a breadcrumb trail: 'Home / Applications / License to Operate / Huhs / Distributor / Renewal'. The main heading is 'Household/Urban Hazardous Substances Distributor Renewal'. A progress indicator on the left shows four steps: 1. Declaration & Undertaking, 2. License to Operate, 3. Contact Information, and 4. Self-Assessment Review (highlighted with a red box). The 'Self-Assessment Review' section includes fields for: License Number, Date of Validity, Security Code, and a QR code area with instructions: '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-123/56)'. Below this is the 'Contact Information' section with fields for Email Address, Mobile Number, and Landline Number, each with a small explanatory note. At the bottom is the 'General Information' section.

This screenshot shows the final confirmation page, enclosed in a red border. It features a reCAPTCHA 'I'm not a robot' checkbox. Below it is a text box containing the following declaration: 'I hereby confirm that all information I have provided are true and correct to the best of my knowledge. I understand that any errors that I have committed in this online form may be considered grounds for refusal or cancellation of my application. In compliance to the Data Privacy Act 2012, I give consent to use any personal information provided herein for Government to conduct the necessary records check and verification of facts in connection with my application.' At the bottom right, there are two buttons: a grey 'Back' button and a blue 'Confirm' button.