

ANNEX B

Procedure in the Submission of an Initial HUHS License to Operate (LTO) Application

I. Procedure Outline

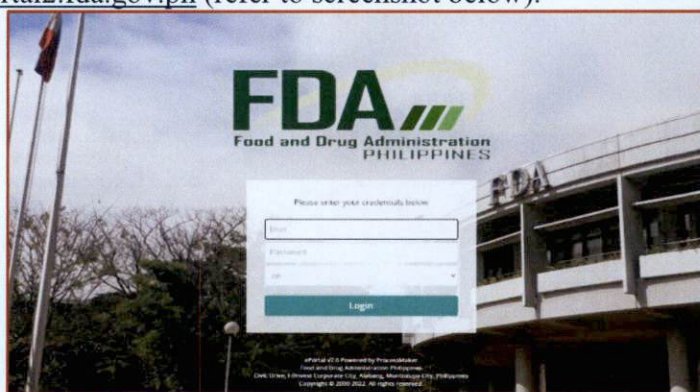
- A. Logging-in to FDA e-Portal V.2 System
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II. Step-by-step Procedure

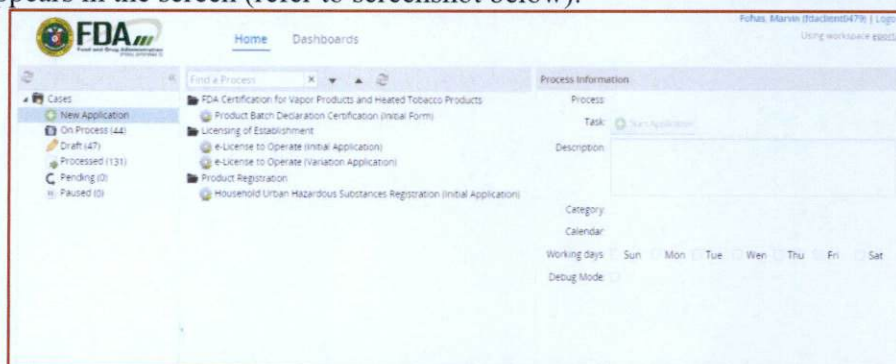
Follow the steps outlined below in order to submit an initial HUHS LTO application:

A. Logging-in to FDA e-Portal V.2 System

1. Go to the FDA website (<https://www.fda.gov.ph/>), then click the “Services” and select “ePortal2” or access the FDA e-Portal V.2 System at <https://eportal2.fda.gov.ph> (refer to screenshot below).



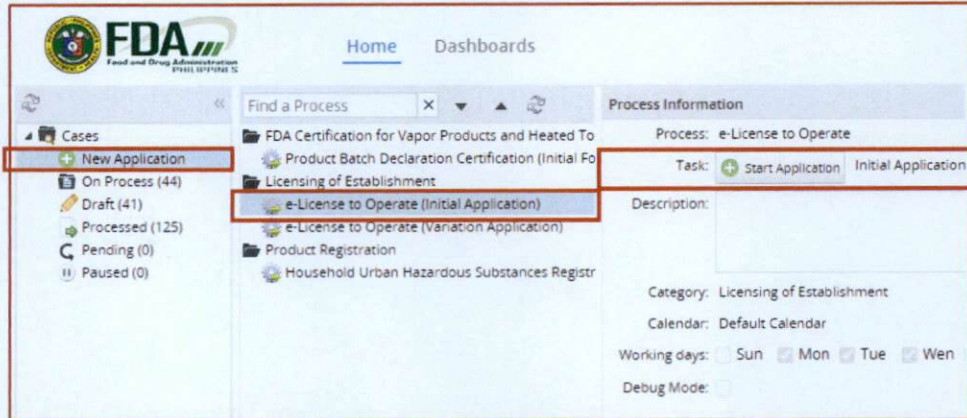
2. Log-in by entering the username and password issued by the FDA. Upon successful log-in, the FDA e-Portal V.2 System Homepage automatically appears in the screen (refer to screenshot below).



B. Preparation and Submission of Initial HUHS LTO for Pre-Assessment

1. Creating a new case application

In the HOME tab, select “New Application” in the navigation pane and click “e-License to Operate (Initial Application)” then “Start Application” or double click “e-License to Operate (Initial Application)” to proceed to the LTO application form.



2. Accomplishing the application form

Accomplish the application form as provided in parts by the application wizard. Fill-in the fields as completely as possible following the guide below:

a. Declaration of Undertaking

Carefully read the Declaration of Undertaking from start to finish before selecting a response using the dropdown menu and clicking "Next". Select "Yes, I Agree" if the applicant agrees with the items listed. Otherwise, select "No, I Disagree". Note that selecting "No, I Disagree" will automatically end the application process while choosing "Yes, I agree" will bring the applicant to the next part of the application process.

The screenshot shows the "Declaration of Undertaking" form. It contains a list of 15 items that the applicant must agree to. At the bottom, there is a dropdown menu with "Yes, I Agree" selected and a "Next" button.

b. General Information

- Select the applicable product classification the applicant intends to market - in this case, Household/Urban Hazardous Substances.

ii. 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, repackaging, 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. If the distributor sells to the general public, it shall be considered a retailer.

iii. Tick the box of all secondary activities that apply to the applicant and then declare the company's capital by selecting the price range that corresponds to the submitted proof of income. These shall be based on the selected product classification and primary activity.

iv. To continue to the next step, tick the box to certify all information is true and correct, then click 'Next'.

General Information

Type of Application: Initial Application

Classification *: Household/Urban Hazardous Substances

Primary Activity *: Manufacturer

Secondary Activity (if any) *

- Importer of Raw Materials for Own Use
- Exporter of Own Product
- Wholesaler of Own Product
- Toll Manufacturer
- Toll Packer/Repacker

Declared Capital *: 250K and Below

I attest that the provided information are true and correct.

Next

c. Establishment Information.

- i. Fill-in the necessary information. The business name, owner and company address provided shall be consistent with the submitted Proof of Business Name Registration. In cases when the address is inconsistent, a mayor's permit shall be submitted.

- ii. Tick the box to certify all information is true and correct, then click 'Next'.

d. Establishment Addresses

- i. Individually declare the office and warehouse addresses of the applicant in the "Address" field and select the type of the address that has been provided (ie. Plant, Office, Warehouse). For manufacturers, one (1) plant address must be declared. In case the declared location houses more than one type of address (i.e. plant and warehouse, or plant, office and warehouse), the applicant may tick all applicable types of address, as applicable.
- ii. Utilize the dropdown list when selecting the region, province, city and zip code.
- iii. Use the Show Map Tool to pin the exact location of the address on the map and determine the GPS coordinates. Move the arrow to the exact location of the establishments on the map and click "Submit".
- iv. Select the desired mailing address by clicking "Set this address as my mailing address" and then click 'Add Address'. For manufacturers, please provide one (1) plant address. Submission is limited to one (1) plant address per manufacturer only.
- v. Tick the box to certify all information is true and correct, then click 'Next'.

e. **Product Line (For Manufacturer Only)**

- i. 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 and click 'Add'.
- ii. Tick the box to certify all information is true and correct, then click 'Next'.

Product Line

Select [Category III] Fabric conditioners/softeners and ironing aids [Add]

- [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. rooms, 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] Paints, varnishes, and thinners
- [Category IV] Rust remover/cleaners
- [Category III] Fabric conditioners/softeners and ironing aids

I attest that I have declared all the Product Types manufactured in the declared facility.

Next

f. **List of Personnel**

- i. Declare the Authorized Representative and Qualified Personnel. Select the Type of Personnel and provide the required information. An establishment may add only **one (1) Authorized Representative** and **one (1) or more Qualified Person/s**.
 - The Authorized Representative should be the Owner, President, Chief Executive Officer (CEO) or its equivalent, or any organic or full-time employee representing the establishment.
 - Qualified Person/s must be any licensed Allied Health Professional (such as but not limited to Pharmacy, Physician, Medical Technology, Nurse, Chemistry, Chemical Engineer) with technical knowledge and/or adequate training on HUHS product safety. Other Allied Health Profession without PRC license can be qualified as QP as long as a Diploma for the Profession and Certificate of related trainings can be presented.
- ii. Click 'Add' after providing all the required information of each personnel. Tick the box to certify all information is true and correct, then click 'Next'.

List of Personnel

Authorized Representative: Owner, President, Chief Executive Officer (CEO) or its equivalent, or any organic or full-time employee representing the establishment.
Qualified Person: Any licensed Allied Health Professional (such as but not limited to Pharmacy, Physician, Medical Technology, Nurse, Chemistry, Chemical Engineer)

Type of Personnel: Authorized Representative | Qualified Person

Last Name: First Name: Middle Name:

Designation: Title: Contact Information:

Government-issued identification document:

Type: Professional Register: Number: Expiry Date:

Add

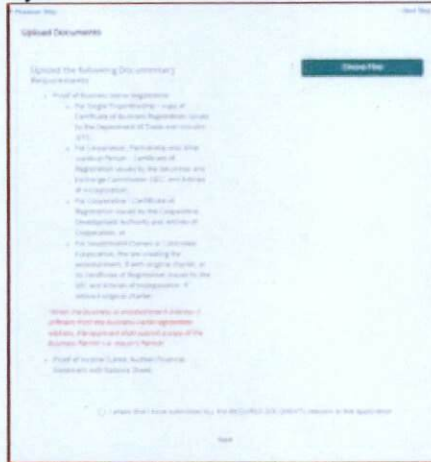
Name: Type: Designation: Title:

I attest that I have declared all the relevant personnel (Authorized and Qualified) associated with our facility.

Next

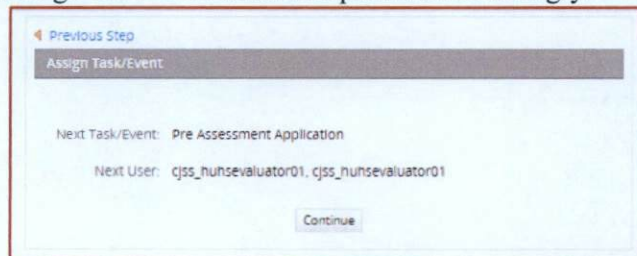
3. Uploading of the Documentary Requirements

- a. Upload the required document/s in accordance to FDA Circular No. 2020-025 and DOH AO 2020-0017, in PDF format by clicking “Choose Files”:
(1) Proof of Business Name Registration and (2) Proof of Income. In cases wherein the establishment address is different from the business name registration address, a copy of the Business Permit.
- b. Tick the box to certify all information is true and correct, then click ‘Next’.



4. Finalizing the application and submission for pre-assessment

- a. An Application Summary will appear that reflects all the declared information and uploaded documents.
- b. Review and recheck the information declared and documents uploaded. If there are corrections to be made, revisit the pages of the application form by clicking ‘Previous Steps’. Attached document/s may also be viewed by clicking its file name.
- c. After reviewing the application summary, click “Next” and then “Continue” to submit the application for pre-assessment. The application will then undergo the Pre-Assessment process accordingly.



C. Checking of Pre-Assessment Result and Payment of Fees and Charges

After the pre-assessment process, an email notification will be sent to the FDA-registered email address of the applicant containing the result of the pre-assessment which may either be approved or disapproved.



1. Pre-Assessment Disapproval (tagged as INCOMPLETE)

- a. For initial HUHS LTO applications that have been tagged as incomplete, the email notification will contain the reason/s for the pre-assessment disapproval.

- b. The result of the pre-assessment may be accessed in FDA e-Portal V.2 System by proceeding to the “On Process” folder. Click the case number of the initial HUHS LTO application and open it by double-clicking on any area within the row of the target application. The system will then show the result of the pre-assessment containing the reasons for the pre-assessment disapproval in PDF format which can be downloaded/printed.
- c. Click “Next” to access the “Application Summary” and verify the result of the pre-assessment.
- d. Once done, click “Next” and then “Finish” to end the process.
- e. The disapproval of initial HUHS LTO applications during the pre-assessment stage does not preclude the applicant from submitting a new application, provided that the deficiencies noted in the disapproved application have been addressed prior to the submission of the new application.

2. Pre-Assessment Approval (tagged as COMPLETE)

- a. For initial HUHS LTO applications that have been tagged as complete, the email notification will include the Order of Payment/Assessment Slip which contains the fees and charges that must be paid to proceed with the application.
- b. The Order of Payment/Assessment Slip can also be viewed in the FDA e-Portal V.2 System by searching the application case number under the “Processed” folder. Right-click the case number and then choose “Summary” and go to “Generated Documents”.

 Republic of the Philippines Department of Health Food and Drug Administration 	
Order of Payment	
General Information	
Account Code:	8000000128397
FDA Clearing Account Number:	0392-2220-06 (For Landbank Payment)
Product Classification:	Household/Urban Hazardous Substances
Authorization:	License To Operate
Type:	Initial Application
Primary Activity:	Manufacturer
LTO No. (If applicable):	Not Applicable
Expiry (If applicable):	Not Applicable
Establishment Information	
Company Name:	HUHS Dummy
Owner:	Juan Dela Cruz
Declared Capital:	1M to Below 5M
Address:	Type
1781 Crisp Drive, Muntinlupa (Filinvest City), Metro Manila-Muntinlupa, NCR, 1781	Plant, Office, Warehouse

List of Personnel				
Fullname	Type	Designation	Contact Information	Government ID
Juan Diego Dela Cruz	Authorized Representative	CEO/ President/ General Manager	Industrial@gmail.com	Type: Social Security System Number: 1478532
Rosey Marnel Santos	Qualified Personnel	Company Pharmacist	Industrial@gmail.com	Type: Professional Regulatory Commission Number: 1478532 Expiry: 04 March 2021

Payment Details	
Application Fee:	6,000.00
Number of Fees Applied:	3
Surcharge (if any):	0.00
Legal Research Fund (LRF):	60.00
Total Amount:	Php 6,060.00
<i>If payment is made using Bancnet Online Bills Payment Facility (www.bancnetonline.com), an additional Php15.00 should be included to the amount due.</i>	
BancNet Payment:	Php 6,075.00
Remarks:	Not Applicable

- c. Save and print a copy of the document as reference for payment and settle the appropriate fees and charges via:
 - BancNet - refer to FDA Advisory No. 2015-021 for the process,
 - Over-the-counter in any branch of the Land Bank of the Philippines - refer to Item B.6. (Payment Collection), Section IV (Guidelines) of FDA Memorandum Circular No. 2013-038. For easy reference, the clearing account number for the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research is 0392-2220-06, or
 - Link.BizPortal e-payment facility of the Land Bank of the Philippines - refer to FDA Advisory No. 2021-0246 for more information.
 - For transfer or refund of payments made - refer to FDA Circular No. 2021-027.

- d. Initial HUHS LTO applications that passed the pre-assessment stage are automatically forwarded to the FDA Cashier for posting of payment. Hence, applicants are advised to make payments as soon as possible to officially lodge the application with FDA.
- e. After the payment has been made and the FDA Cashier has posted the payment in the FDA e-portal V.2 System, the case number for the initial HUHS LTO application will then be forwarded to the assigned evaluator at the CCHUHSRR for the evaluation proper.

D. Checking of Application Result

1. Once the application has undergone the evaluation process, an email notification will be sent to the FDA-registered email address of the applicant informing that the application has been processed, and providing instructions on how to access the result. The application result may either be approved or disapproved.
2. The result may be downloaded through the “On-Process” folder of the applicant establishment in the FDA e-Portal V.2 System. Open the application case number, download and print the document (LTO or Letter of Disapproval), and then click “Finish” to end the task.
3. To view the result again, under “Processed” folder right-click on the case number and then choose “Summary” and go to “Generated Documents” tab to download and print the result.

