Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY No. 20250512

05 JUN 2025

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) ESERVICES PORTAL SYSTEM FOLLOWING DEPARTMENT OF HEALTH (DOH) ADMINISTRATIVE ORDER NO. 2024-0015**

Following the implementation of Department of Health Administrative Order (AO) No. 2024-0015 entitled, "Prescribing the Rules, Requirements, and Procedures in the Application for License to Operate of Covered Health Product Establishments with the Food and Drug Administration Repealing for the Purpose Administrative Order No. 2020-0017", it is in the exigency of service that the FDA hereby announces the on-boarding of the updated licensing procedures for HUHS establishments unto the FDA eServices Portal System. The following services shall be available beginning **2 June 2025**:

Type of License to Operate (LTO) Application	1. Initial 2. Renewal 3. Variation
Type of HUHS Establishment	1. HUHS Manufacturer 2. HUHS Distributor 3. HUHS Trader

Please be informed that data and system migration will commence from 29 May to 1 June 2025. All applications shall afterwards be exclusively filed and accepted through the FDA eServices Portal System at https://eservices.fda.gov.ph/. Applicants may be guided by the Annexes of this Advisory for the procedures for filing of applications:

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** - Procedure for the Submission of Compliance

Further, the following transitory provisions are hereby reiterated:

1. All existing and pending applications for LTO including all major and minor variation applications received **prior 2 June 2025** shall be processed according to DOH AO No. 2020-0017 and FDA Circular No. 2023-006 until all are exhausted.

a. All applicants which have been issued an Order of Payment (OP) are strongly advised to settle the fees charged to their applications within seven (7) days upon the issuance of the OP.
b. The result of such applications may be accessed and downloaded from the FDA e-Portal v.2 System by proceeding to the "On Process" folder.
c. Re-application through the FDA eServices Portal System of such applications is not necessary. However, should an applicant intend to apply through the procedures outlined in this Advisory, the application shall be treated as new, and a separate fee shall be charged.

2. For ease in transition, all previously-issued HUHS LTOs which **expired or will be expiring before 01 July 2025** may be **automatically renewed with validity period until 30 June 2025** and their surcharges may be waived; **Provided that prior 30 May 2025**, a letter of request and declaration statement, shall be submitted by the establishment through the Food and Drug Action Center (FDAC) through email at fdac@fda.gov.ph. The letter shall be in format of **Annex G of FDA Advisory No. 2024-0543**, signed by the establishment owner/authorized representative/qualified person.

   Affected establishments are reminded that filing a renewal application past this extended validity period will be charged with the appropriate fees and surcharges that may apply. Failure to submit letter of intent by 30 May 2025 will disqualify the establishment from the eligibility to automatically renew the license with waived surcharges. Applicants may refer to the renewal procedure under Annex C.

3. The requirement for the list of sources/authorized suppliers/clients for HUHS establishments shall be mandatory by **1 January 2026.**

4. For HUHS manufacturers, pre-licensing inspection shall be required upon an initial LTO or a major variation application. Meanwhile, the pre-licensing inspection for HUHS Trader, Distributor-Exporters, Importers or Wholesalers shall be required contingent to the end of the transitory period for pre-licensing inspection provided under on DOH Administrative Order No. 2024-0015 and its implementing guidelines.

   All HUHS establishments, including those with previously issued LTOs, shall be subjected to routine or post-licensing inspections for compliance with existing HUHS standards and regulations.

For the information and guidance of all concerned.

ATTY. PAOLO S. TESTON
Director General

ANNEX A

LTO Requirements for HUHS Establishments

The requirements originally provided under DOH AO No. 2024-0015 as follows must be submitted:

A. Initial Application

1. **Accomplished e-Application form with Declaration and Undertaking through the FDA eServices Portal Sysytem**

   Among other information, the applicant shall provide the following information:

   a. Global Positioning System (GPS) Coordinates; and,
   b. Name and credentials of the Qualified Person as specified in Annex C of DOH AO No. 2024-0015

2. **Proof of Business Name Registration**
   a. For Single Proprietorship, the Certificate of Business Registration and FDA-regulated activity issued by the Department of Trade and Industry (DTI);
   b. For Corporation, Partnership and other Juridical Person, the Certificate of Incorporation or License to transact business in the Philippines issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation/Partnership shall specify the activity relating to the health product/s (e.g. manufacturing, distribution [importation, exportation, wholesaling]) applied for shall be reflected in the primary or secondary purposes;
   c. For Cooperative, the Certificate of Registration issued by the Cooperative Development Authority and Articles of Cooperation; or
   d. For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter or other requirements, deemed suppletory to the application.

   Note: *When the business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit/Mayor's Permit, or Barangay Certificate with complete business address.*

   If the building is not owned by the applicant, a copy of contract of lease shall be presented during inspection.

   For establishment as a Franchisee, a ***Notarized Franchise Agreement*** *shall also be submitted. The business name of the establishment reflected in the LTO may be based on the trade name indicated in the Franchise Agreement. A copy of the applicant shall also be presented during the conduct of inspection.*

3. For MSMEs, latest audited Financial Statement with Balance Sheet (in pdf). For those that have no Financial Statement (FS) yet, Statement/Certification of Initial Capitalization (in pdf) signed by the owner or accountant.

The submitted documents shall be subject to validation by FDA during inspection and validity of the LTO. Any findings of under declaration shall be considered as mispresentation and be grounded for regulatory action

4. Risk Management Plan (RMP)

5. Site Master File (SMF) for manufacturers including packers and repackers.

6. List of Sources and Authorized Suppliers/Clients for Manufacturers including Packers/Repackers, Traders and Distributors (Importers, Exporters, Wholesalers)

   Contract of Agreement- For appropriate determination of activity that shall be indicated in the LTO, a copy of the Contract of Agreement is recommended to be submitted. The basis for the LTO activity shall depend on the legally binding contract agreement between the establishments and its client/supplier.

   The list shall identify the name of source, address, and product list (categories) whether local or imported.

   Copy(ies) of the Contract of Agreement(s) of the applicant shall be presented during inspections.

   Note: This requirement shall be mandatory by 1 January 2026, following the transitory arrangements under DOH AO No. 2024-0015.

7. Payment of appropriate fees.

B. Renewal Application

1. Accomplished eApplication Form with Declaration of Undertaking through FDA eServices Portal System

Among other information, the applicant shall provide the following information:

a) License number and its validity date;
b) Security code as provided in the QR Code of current LTO Certificate, or a sequence number located at the bottom right corner of the LTO Certificate; and
c) Contact Information

2. MSMEs, latest audited Financial Statement with Balance Sheet (in pdf). For those that have no Financial Statement (FS) yet, Statement/Certification of Initial Capitalization (in pdf) signed by the owner or accountant.

   The submitted documents shall be subject to validation by FDA during inspection and validity of the LTO. Any findings of under declaration shall be considered as mispresentation and be grounded for regulatory action

3. Payment of appropriate fees.

C. Variation Application

1. Accomplished eApplication Form with Declaration of Undertaking through FDA eServices Portal System;
2. Documentary requirements depending on the variation of circumstances of the establishment; and
3. Payment of appropriate fees.

a. Major Variation

Type of Variation	Document Requirement
Transfer of Location of Manufacturing Plant Physical transfer of the establishment and may entail changes in the previously approved address	1. Application Form 2. Payment of appropriate fees 3. Proof of business address reflecting the new plant location: a) **For Single Proprietorship**: Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location; b) **For Securities and Exchange Commission (SEC)-registered establishments**: i. Amended Articles of Incorporation (if transferred from one city/municipality/province; or, ii. Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality/province) If the establishment address is different from the address indicated in the SEC registration, provide LGU/Mayor's Permit or Barangay Business Permit/Clearance reflecting new plant location or PEZA certificate, if applicable ***If the building is not owned by the applicant, a copy of contract of lease shall be presented during inspection.*** 4. Updated Site Master File
Expansion/Reduction of Manufacturer/Packer/Repacker and/or Additional Product Line; or Change of Manufacturing Activity 1. Expansion shall refer to expansion made which is	1. Application Form 2. Payment of appropriate fees 3. Updated Site Master File (including previous and expanded floor plan)

adjacent to be existing location of the establishment 2. Additional product line shall refer to additional type or class of products produced within the same manufacturing site 3. Change in manufacturing activity shall refer to an additional/deletion activity that manufacturer engages in.	
Transfer/Additional/ Deletion of Warehouse Physical transfer and additional of the warehouse of the establishment	1. Application Form; 2. Payment of appropriate fees, and 3. Business permit reflecting new warehouse; ***In case of transfer or addition, if the building is not owned by the applicant, a copy of contract of lease shall be presented during inspection.***

b. Minor Variation

Type of Variation	Document Requirement
Transfer of Location of Offices Physical transfer of the office of the establishment	1. Application Form 2. Payment of appropriate fees 3. Proof of business address reflecting the new office location: a) **For Single Proprietorship**: Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location; **b) For Securities and Exchange Commission (SEC)-registered establishments:** i. Amended Articles of Incorporation (if transferred from one city/municipality/province; or, ii. Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality/province) 4. PEZA Certificate reflecting the new office address, if applicable; and, 5. Notarized Contract of Lease or any proof of ownership of the new office location, if applicable

	If the establishment address is different from the address indicated in the SEC registration, provide LGU/Mayor's Permit or Barangay Business Permit/Clearance reflecting new office location.
Expansion/extension of Office Establishments Shall refer to area expansion made to the existing location of the establishment within the same building	1. Application Form; 2. Payment of appropriate fees; 3. Current floor plan; and 4. Expansion floor plan
Change in ownership of the establishment	1. Application Form; 2. Payment of appropriate fees; 3. Business name registration reflecting new ownership; and 4. Proof of the transfer of ownership such as any of the following: a. Deed of Sale or Assignment or Transfer of Rights/Ownership; b. Memorandum of Agreement (MOA); or c. Notarized Affidavit: i. Previous owner, chairman or CEO (covered by appropriate board resolution) of the previously licensed establishment validating the transfer; or ii. In case of transfer to heirs due to death of previous owner, affidavit of the authorized heir
Change in the business name of the establishment	1. Application Form; 2. Payment of appropriate fees; and 3. Business name registration reflecting the new business name
Change of Distributor Activity Shall refer to an additional/deletion of/change in activity that the distributor previously engaged in.	1. Application Form; 2. Payment of appropriate fees; and 3. Appropriate Contract Agreements showing change in activity
Zonal Change in Address	1. Application Form;

Change of the name/number of the street/building without physical transfer of the establishment	2. Payment of appropriate fees; and 3. Certificate of Zonal Change from the Local Government Unit or Business Permit/Mayor's Permit/Barangay Clearance stating that there is no actual transfer of the establishment
Addition or Change of Qualified Person Addition or change in the identified qualified person initially registered with the FDA	1. Application Form; 2. Payment of appropriate fees; 3. Valid PRC, if applicable; and 4. Applicable requirements as specified[1]
Change on the Details of Qualified Person Updates/changes, but not limited to the following: 1. Validity of the government-issued ID 2. Change and/or corrections in the details of the submitted government-issued ID (e.g., marital status, print errors)	1. Application Form; 2. Payment of appropriate fees; 3. For profession with board exam: PRC ID (back-to-back) with signature at the back panel of the ID 4. For non-board: Valid government-issued ID (e.g., passport, driver's license, SSS, etc.); and 5. Other evidence corresponding to the update/change not mentioned
Change of Authorized Person Change of authorized person initially registered with the FDA	1. Application Form; 2. Payment of appropriate fees; and 3. Valid government issued ID
Change of official e-mail address of the establishment	1. Application Form 2. Payment of appropriate fees; and 3. Request Letter signed by the owner/CEO/President
Addition/Deletion of Sources and Products Notarized Valid Contract Agreement; or For foreign source(s), a copy of the contract agreement duly authenticated by the host government of the country of origin (legalized by the	1. Application Form; and 2. Payment of appropriate fees

Philippine Embassy/Consulate it from a non-Apostille country shall be available during inspection of the establishments) ***Note**: In transitory period and shall be mandatory by 1 January 2026*	

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[1]The qualification and training requirements of the Qualified Person of Manufacturer, Trader and Distributor (Wholesaler, Importer, Exporter) of Household/Urban Hazardous Substances (HUHS) shall be in accordance with the existing guidelines under DOH AO No. 2024-0015 as follows:

Qualification	**Training Requirements**
Registered professional or graduates in the field of allied health, chemistry, or chemical engineering with verifiable, recognized, and updated trainings on the safety, quality, and use of HUHS	1. PRC ID for professions with Board/Licensure Exam or Diploma for profession without Board/Licensure Exam; and, 2. Certificate and copy of program of activities as proof of attendance to seminars, trainings, learning and development activities on HUHS safety, quality, and use, given by the academe, industry organization, professional organization, National Regulatory Authorities, international organizations.

ANNEX B

Procedure in the Submission of an Initial HUHS LTO Application

A. Description

All Household/Urban Hazardous Substances (HUHS) establishments, including manufacturers, traders and distributors, shall secure a valid License to Operate (LTO) with the FDA before they may apply for a Certificate of Product Registration (CPR) and engage in any FDA-regulated activities involving HUHS products. The standards and requirements for securing an LTO are prescribed in DOH Administrative Order (AO) No. 2019-0019, DOH AO No. 2024-0015, their future amendments and implementing guidelines.

This Annex outlines the procedure for the filing and submission of an initial HUHS LTO application via the FDA eServices Portal System. This Annex covers the steps from accessing and navigating the System until the pre-assessment step where the Order of Payment is released. Guidance notes on the next steps from payment of application fees and charges, submission of compliance documents, checking of the status, and the issuance of the result of the application are also provided.

B. Procedure outline

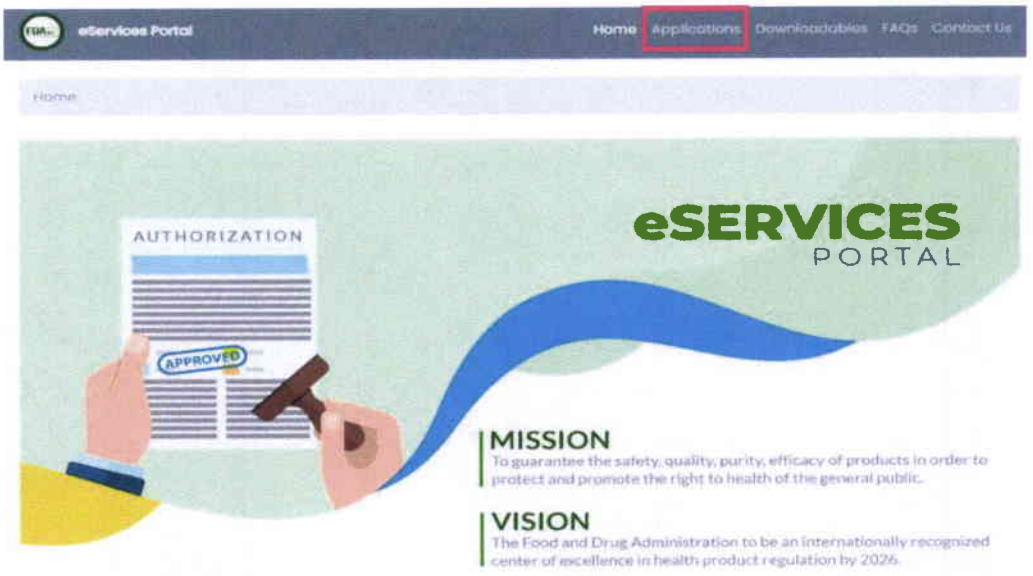
1. Accessing and navigating the FDA eServices Portal System
2. Preparation and Submission of an Initial HUHS LTO Application for Pre-Assessment
    a. Page 1: Declaration and Undertaking
    b. Page 2: General Information
    c. Page 3: Product Line *(For Manufacturer Only)*
    d. Page 4: Establishment Information
    e. Page 5: Office Address
    f. Page 6: Warehouse Address
    g. Page 7: Plant Address *(For Manufacturer Only)*
    h. Page 8: Authorized Person
    i. Page 9: Qualified Person
    j. Page 10: Self-assessment Review
3. Uploading of documents for Pre-Assessment and Payment of Fees and Charges
    a. Page 1: Application Info
    b. Page 2: Verification Code
    c. Page 3: Documents Submission
4. Pre-Assessment Result
5. Next Steps

C. Step-by-step procedure

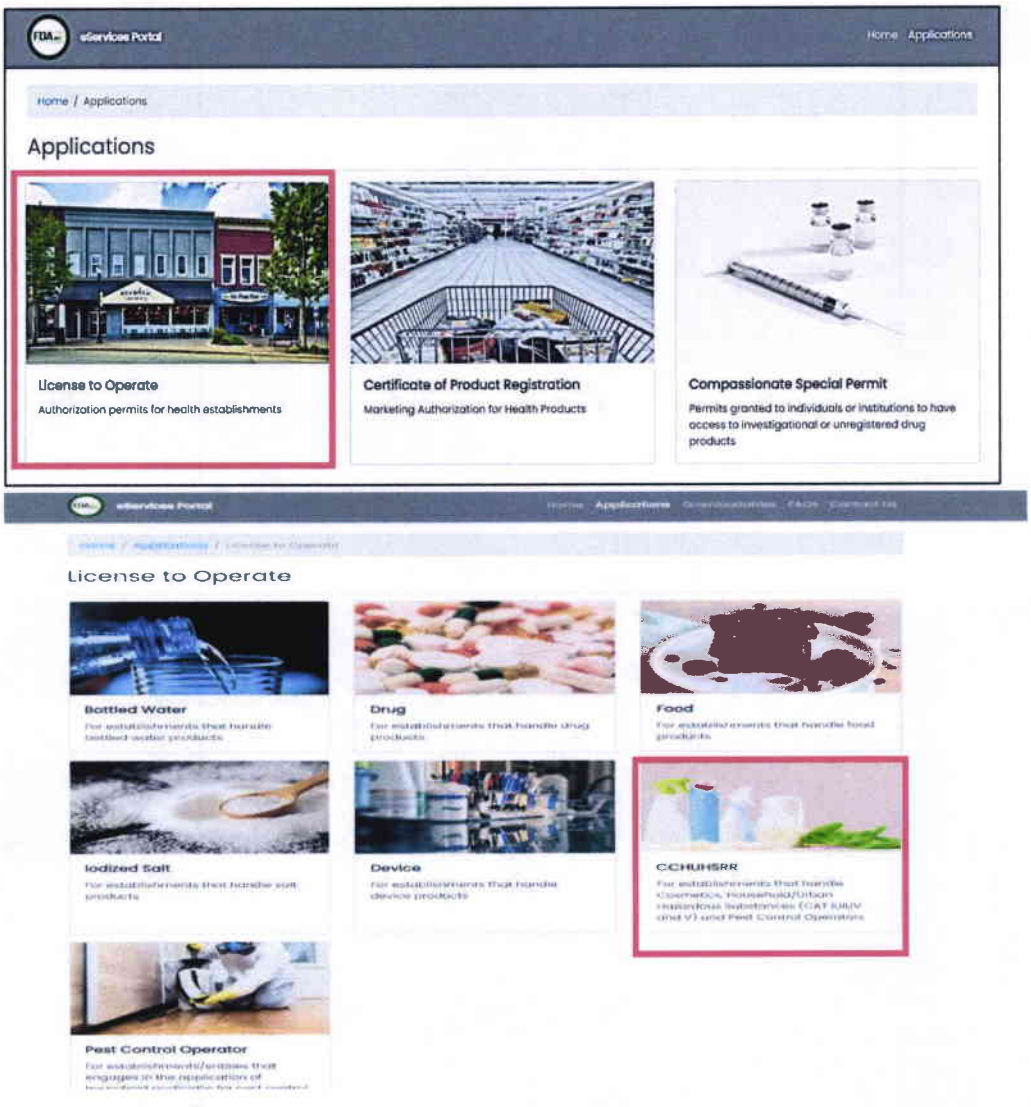
Follow the steps outlined below in order to submit an initial HUHS LTO application.

1. Accessing and navigating the FDA eServices Portal System

a. Access the online portal through https://eservices.fda.gov.ph/ and click **"Applications"** of the eServices landing page.



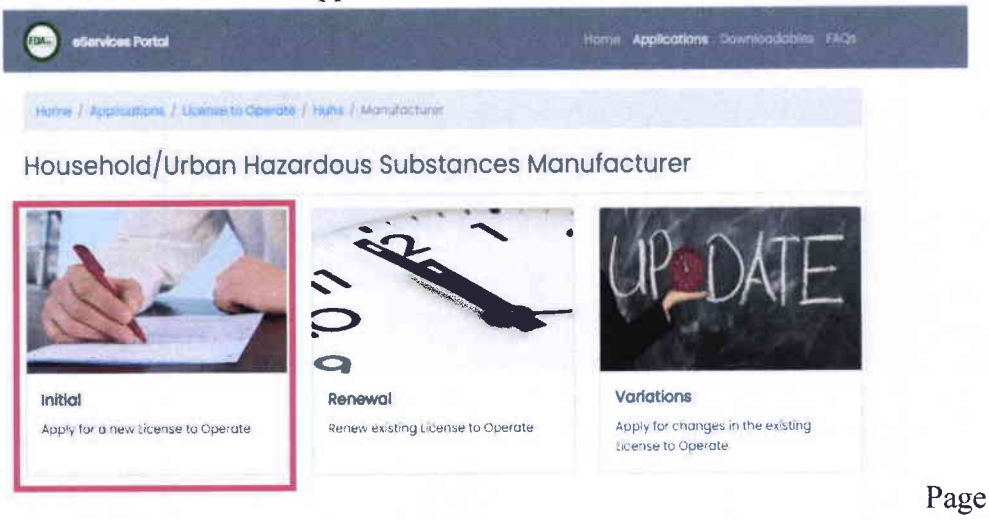
b. Click the "**License to Operate**" then select the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)



c. Among the different types of establishments, select the most appropriate based on 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.

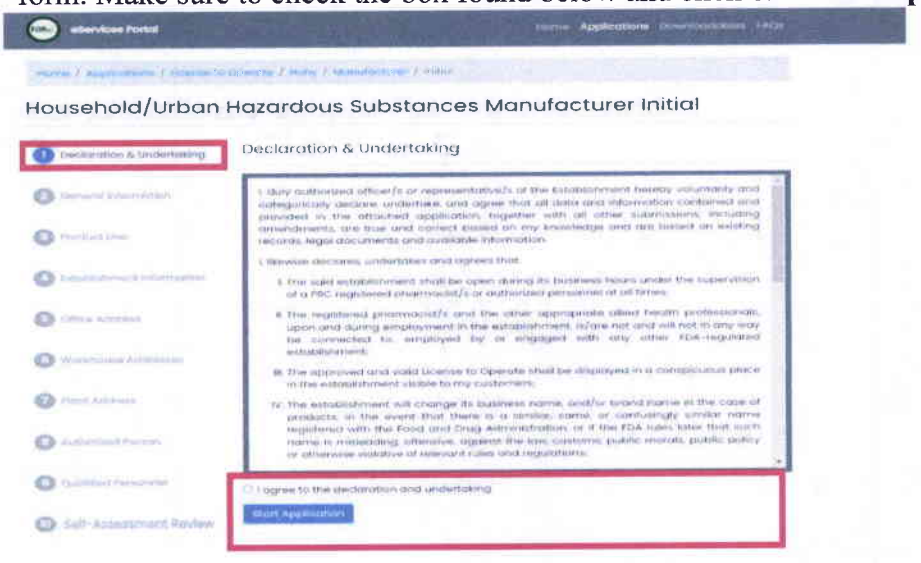
d. Click the Initial Application.



2. Preparation and Submission of an Initial HUHS LTO Application for Pre-Assessment

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"**.

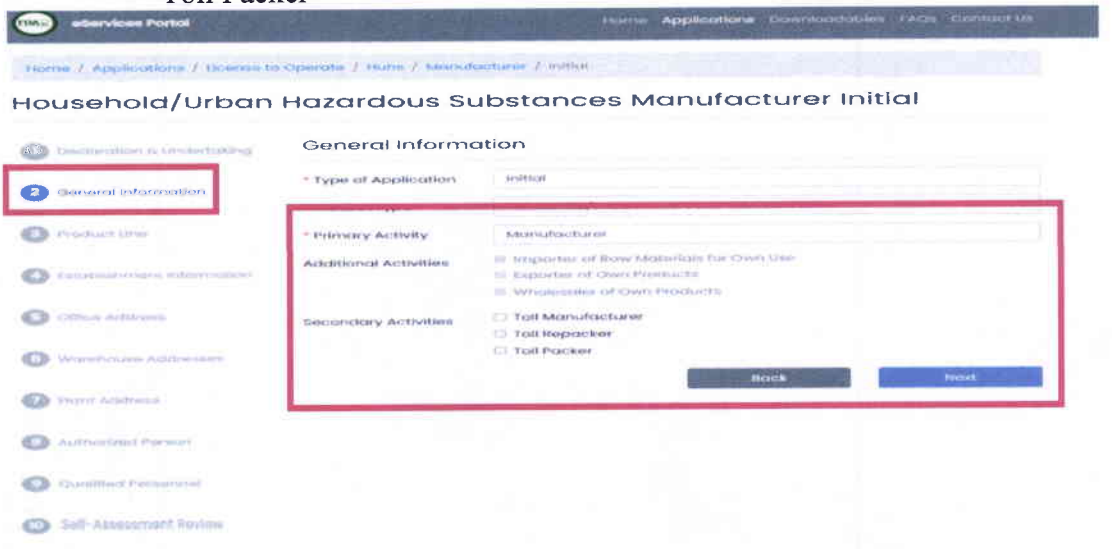


b. Page 2: General Information

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.

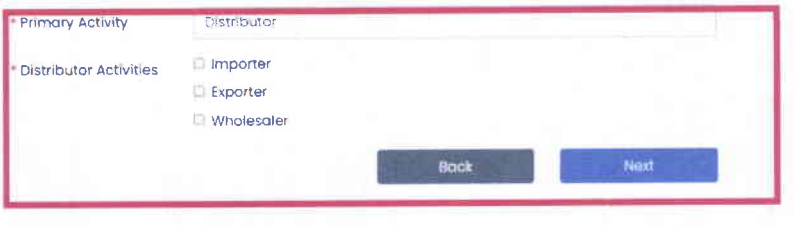
b.1. For manufacturers, select all applicable secondary activities

- Toll Manufacturer
- Toll Repacker
- Toll Packer



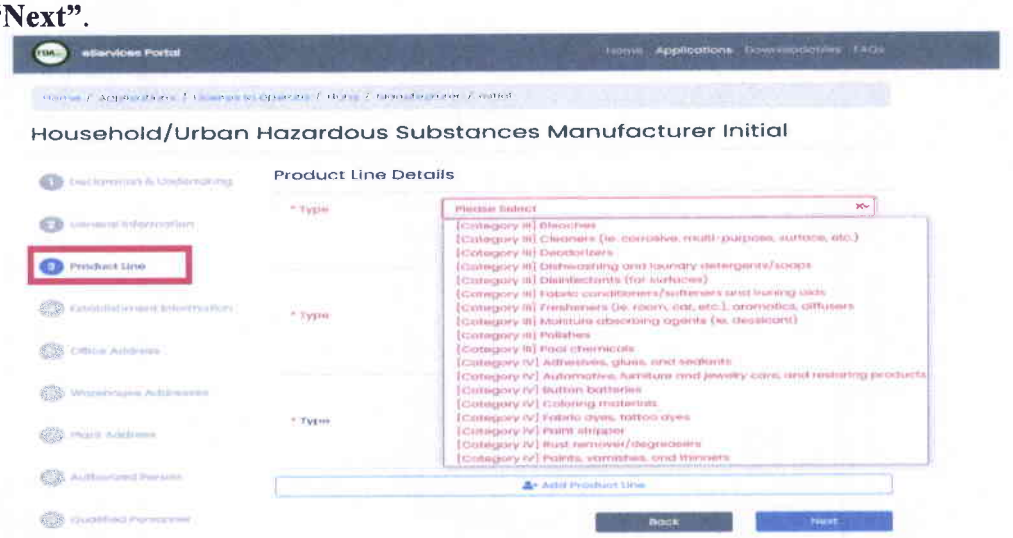
b.2. For distributors, select all applicable distributor subcategory/ies

- Importer
- Exporter
- Wholesaler



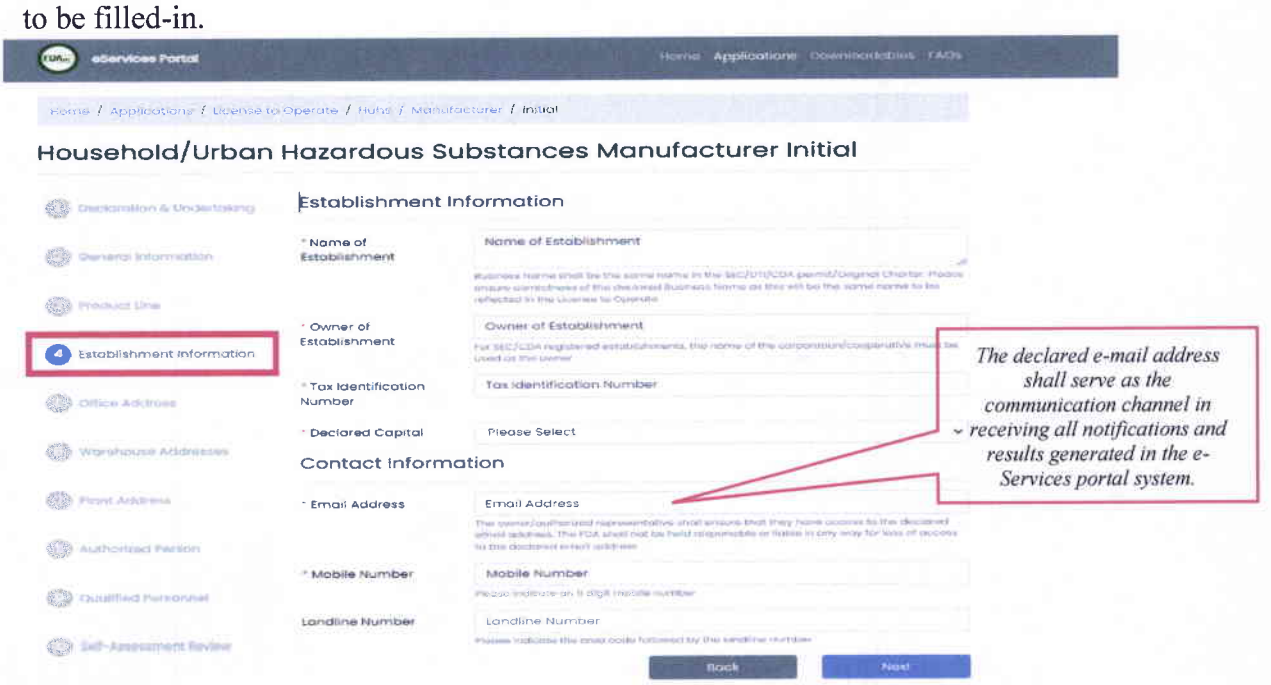
c. **Page 3: Product Line (For Manufacturer Only)**

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"**.



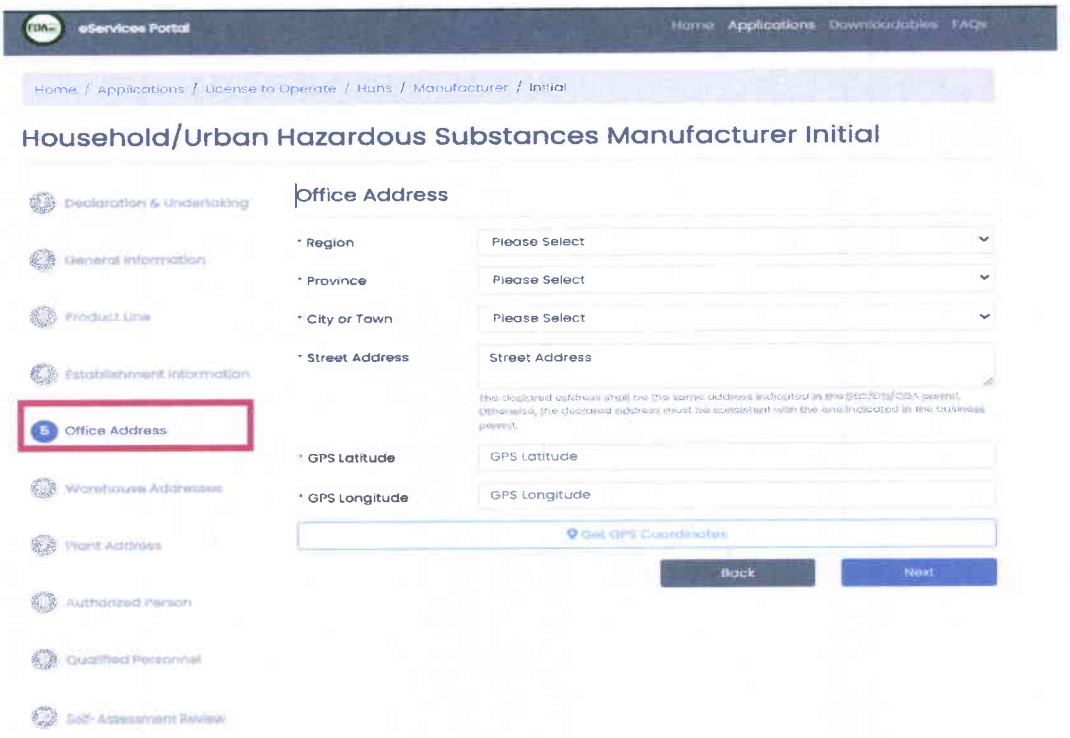
d. **Page 4: Establishment Information**

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



e. **Page 5: Office Address**

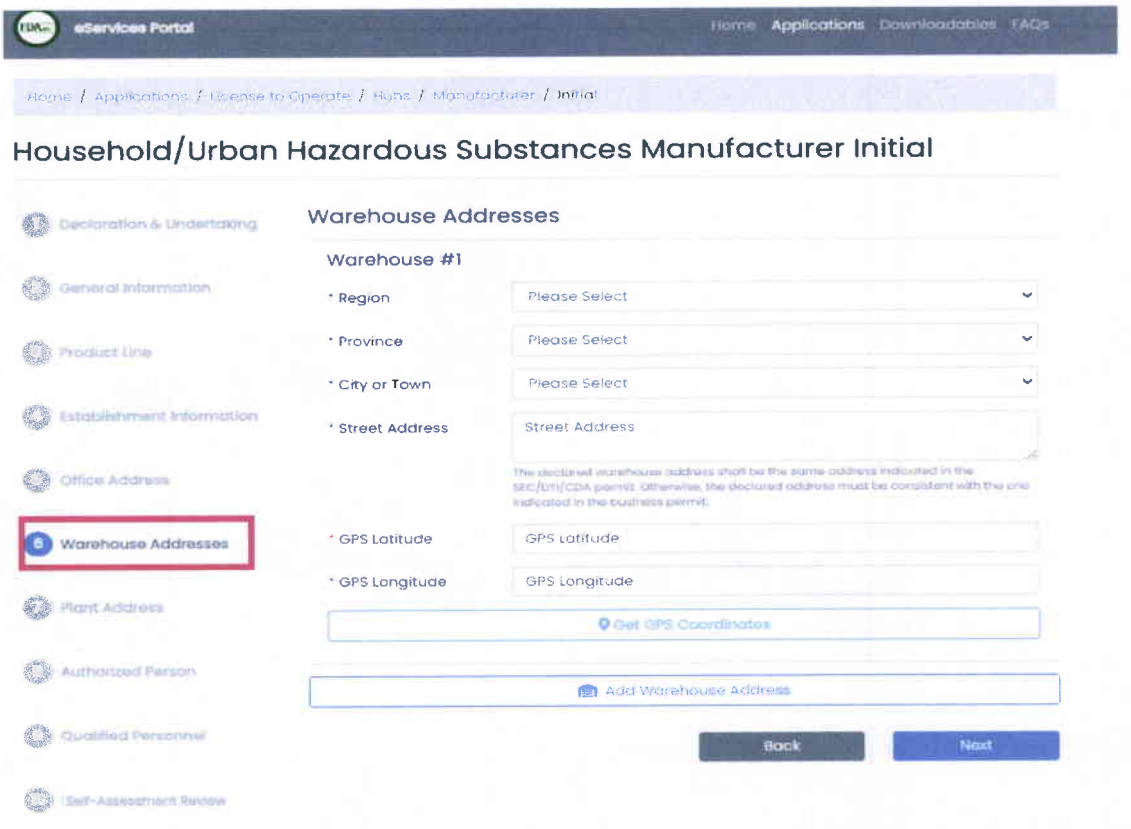
Utilize the dropdown list when selecting the Region, Province and City or Town. Click the **"Get GPS Coordinates"** to determine the exact location of the Office Address. Pin accurately the location on the map.



f. **Page 6: Warehouse Address**

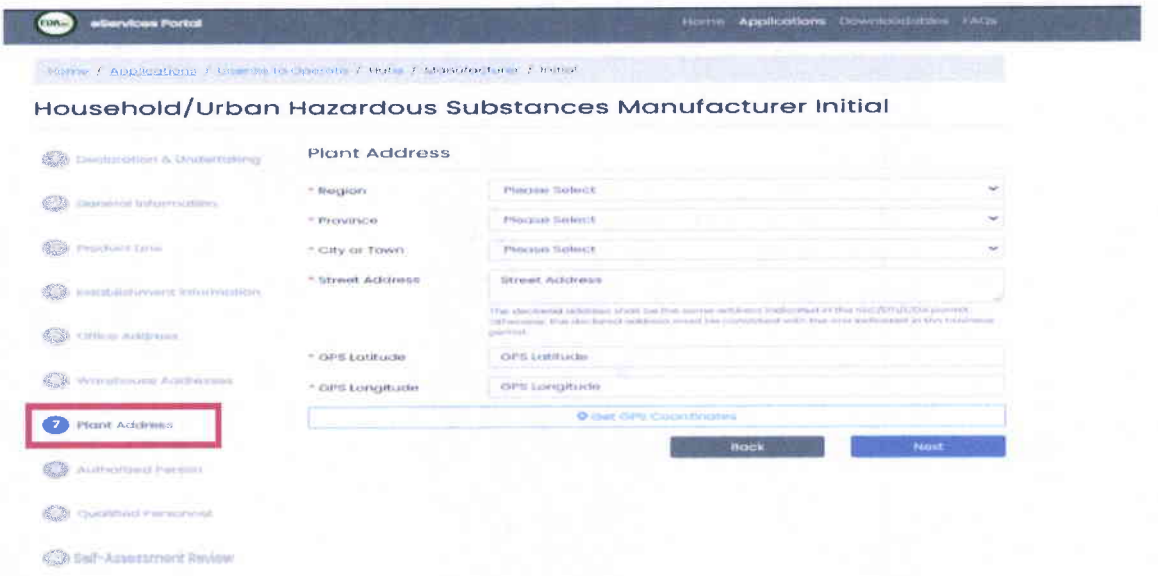
Utilize the dropdown list when selecting the Region, Province and City or Town. Click the **"Get GPS Coordinates"** to determine the exact location of the Warehouse Address. Pin accurately the location on the map.

If there are more than one (1) warehouse address, click the "**Add Warehouse Address**" button



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

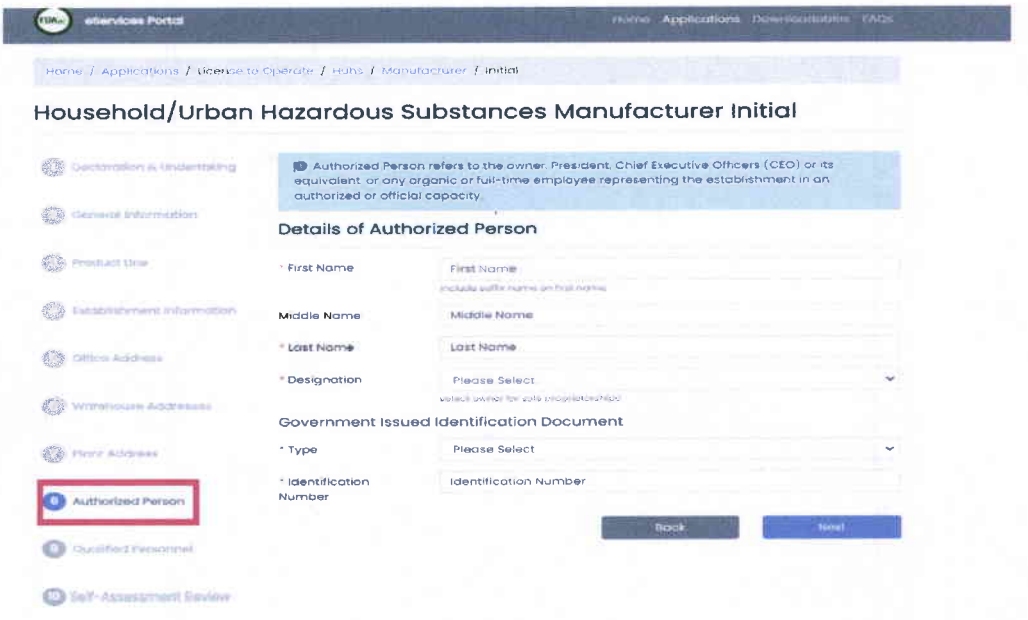
Utilize the dropdown list when selecting the Region, Province and City or Town. For manufacturers, one (1) plant address must be declared. Click the **"Get GPS Coordinates"** to determine the exact location of the Warehouse Address. Pin accurately the location on the map.



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

Fill in all the relevant information of the Authorized Person then click **"Next".** Fields marked with a red asterisk are required to be filled-up.

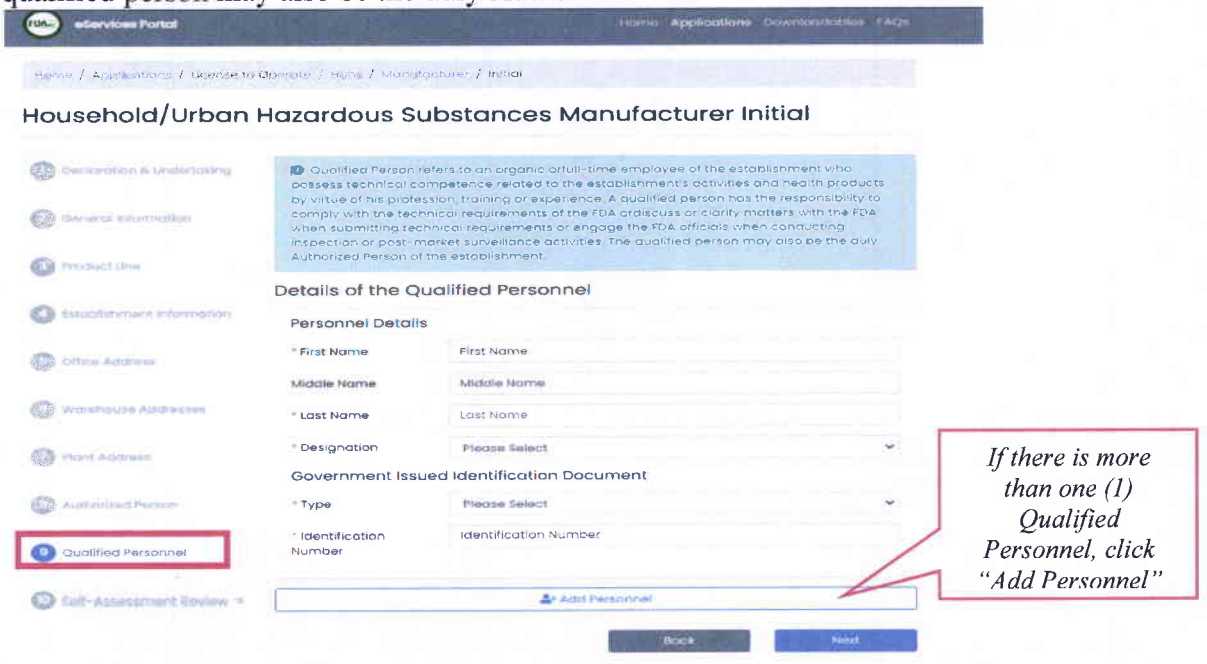
Authorized Person refers to the owner, President, Chief Executive Officers (CEO) or its equivalent, or any organic or full-time employee representing the establishment in an authorized or official capacity.



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

Fill in all relevant information of the Qualified Person the click **"Next".** Fields marked with a red asterisk are required to be filled-up.

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.

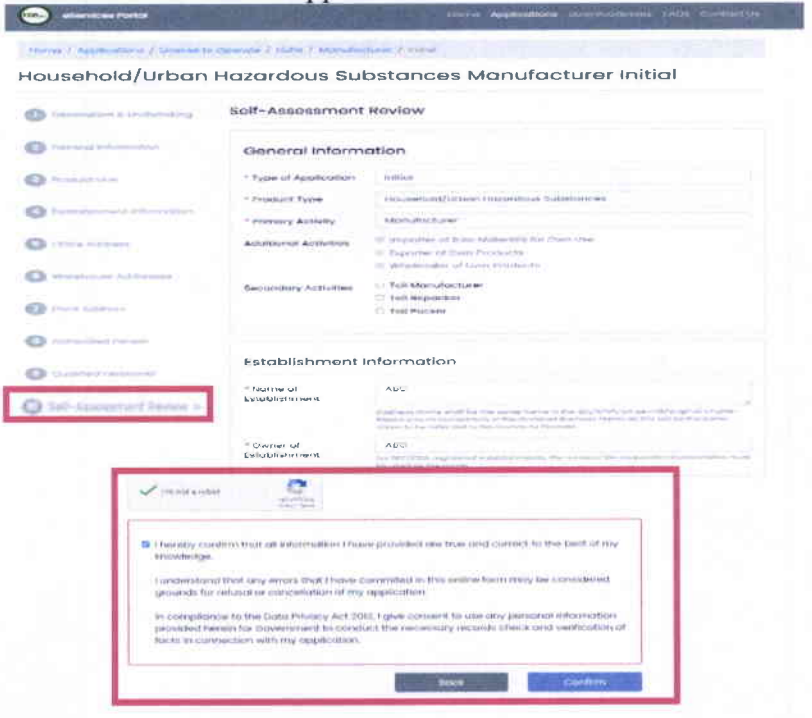


j. **Page 10: Self-Assessment Review**

i. A Self-Assessment Review summary will appear that reflects all the declared information.

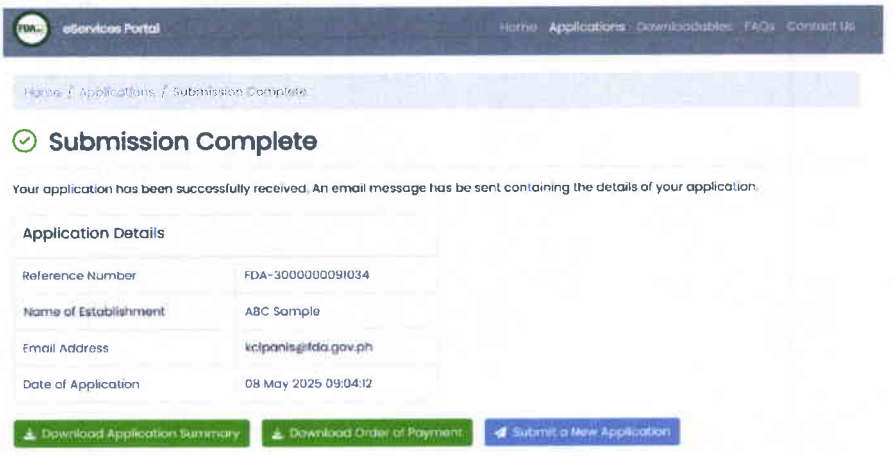
ii. Review and recheck the information declared. If there are corrections to be made, the information can directly be updated on the Self-Assessment Review page.

iii. After the self-assessment review, the applicant shall confirm the correctness of the data. Tick **"I'm not a robot"**, **Data Privacy Act declaration** and click the **"Confirm"** submit the application.



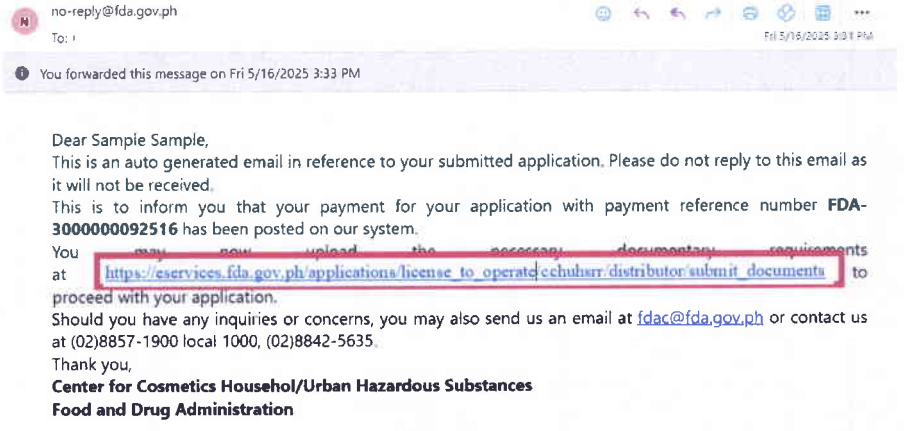
iv. Once the application is successfully submitted, a **"Submission Complete"** message will be posted showing the application details. Download the **"Application Summary"** and **"Order of Payment"**

v. A system-generated email will be sent to the applicant's registered email address in response to the filed application. The email will contain the Application Summary and Order of Payment for pre-assessment



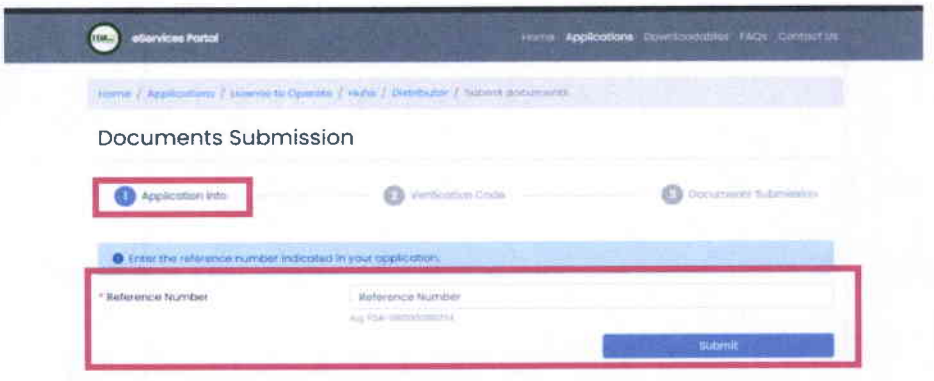
3. Uploading of Documents for Pre-Assessment and Payment of Fees and Charges

Once the Pre-Assessment Fee has been posted, a system-generated email will be sent to the applicant's registered email address containing the link and instructions for the submission of the documentary requirements. Click the link to redirect to the FDA eServices Portal System Documents Submission landing page.



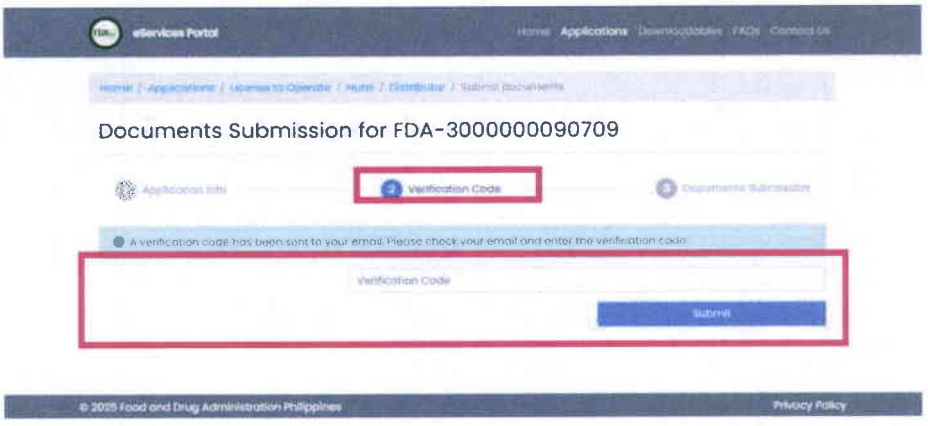
a. **Page 1: Application Info**

Provide the reference number assigned to the application and click **"Submit".** The reference number may be found in the generated email sent to the applicant's registered email address.



b. **Page 2: Verification Code**

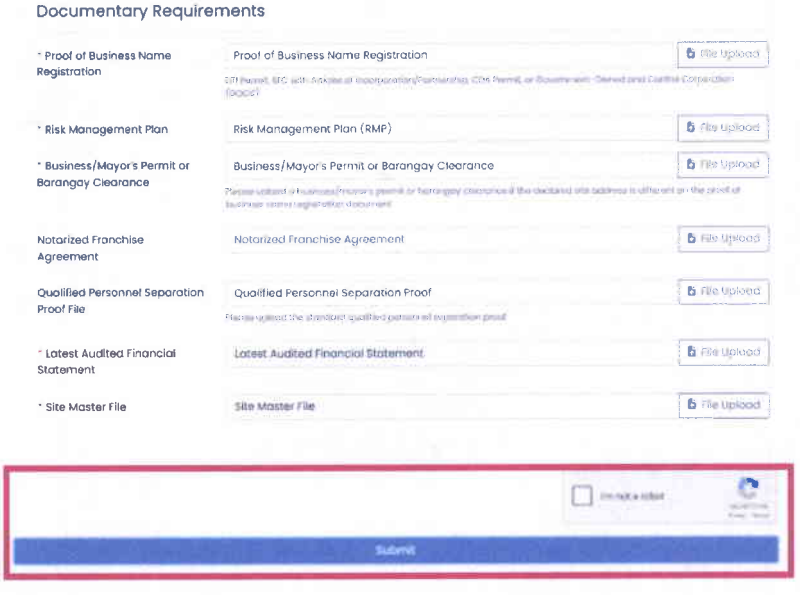
Provide verification code sent to the applicant's registered email address.



c. **Page 3: Documents Submission**

Upload necessary documents in portable document file (PDF). Once done, confirm the correctness of uploaded documents. Tick **"I'm not a robot"** and "**Submit**"

The requirement "List of Sources and Authorized Suppliers/Clients for Manufacturers including Packers/Repackers, Traders and Distributors (Importers, Exporters, Wholesalers)" shall be mandatory by 1 January 2026, following the transitory period provided under DOH AO No. 2024-0015.



4. Pre-Assessment Result

Following the pre-assessment of the submitted documents, the applicant may receive either of the following in its registered email address:

a. Order of Payment for successful pre-assessed applications. The Order of Payment shall reflect the total application fee due, less the paid pre-assessment fee. Once the payment has been posted, the application shall be forwarded to the FDA Field Regulatory Office for the Regulatory Inspection step.

b. Letter containing the list of reason/s why the application did not pass the pre-assessment. In such case, the applicant is not precluded from filing a new application with complete documentary requirements subject to applicable pre-assessment fee

5. Next Steps

a. After receiving the Order of Payment, the applicant has (10) working days to make the necessary payments through any of the following payment channels:
    - BancNet – refer to FDA Advisory No. 2015-021, and its amendments for the process.
    - Link.BizPortal e-payment facility of the LandBank of the Philippines- refer to FDA Advisory No. 2021-0246, or its amendments for more information.

b. Applicants may monitor their applications through the FDA eServices Portal System. Please refer to Annex E of this Advisory for the procedure for checking the status of an application.

c. For applications requiring the submission of a corresponding responsive Corrective and Preventive Action (CAPA), compliance documents may be submitted through the FDA eServices Portal System. Please refer to Annex G of this Advisory.

d. Results of applications will be sent to the e-mail address indicated in the application form.

ANNEX C

Procedure in the Submission of Renewal HUHS LTO Application

A. Description

A License to Operate (LTO) shall be eligible for automatic renewal when the following conditions are satisfied:

1. The application shall be filed through the FDA eServices Portal System made within ninety (90) calendar days prior to the expiration of the validity date of the LTO.
2. The prescribed renewal fee is paid upon filing of the application; and,
3. A sworn statement indicating no change or variation whatsoever in the product is attached to the application.
4. Exceptions to the application for Automatic Renewal are enumerated under Annex E of DOH AO No. 2024-0015.

All Marketing Authorization Holders (MAHs) with LTOs automatically renewed until 30 June 2025 based on the interim procedure under FDA Advisory No. 2024-0543, its amendment and this Advisory must secure their renewal applications and pay the prescribed fees and charges before this date. Surcharges shall apply to applications filed and paid beyond the validity date of the authorization, subject to the rules on Renewal Applications under Section VII(F) of DOH Administrative Order (AO) No. 2024-0015.

This Annex outlines the procedure for the filing and submission of a renewal HUHS LTO application via the FDA eServices Portal System. This Annex covers the steps from accessing and navigating the System until the pre-assessment step where the Order of Payment is released. Guidance notes on the next steps from payment of application fees and charges, submission of compliance documents, checking of the status, and the issuance of the result of the application are also provided.

B. Procedure outline

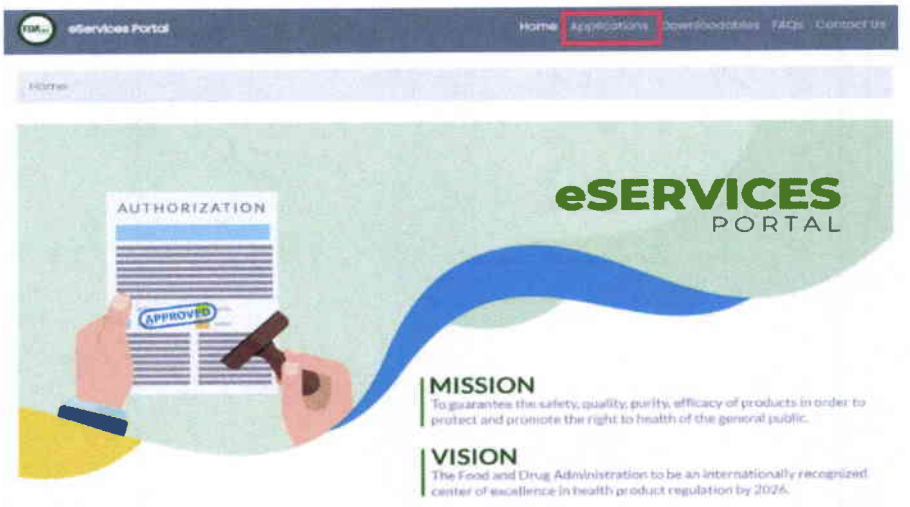
1. Accessing and navigating the FDA eServices Portal System
2. Filing an application
   a. Page 1: Declaration & Undertaking
   b. Page 2: License to Operate
   c. Page 3: Contact Information
   d. Page 4: Self-Assessment Review
3. Uploading Documents
4. Next Steps

C. Step-by-step procedure

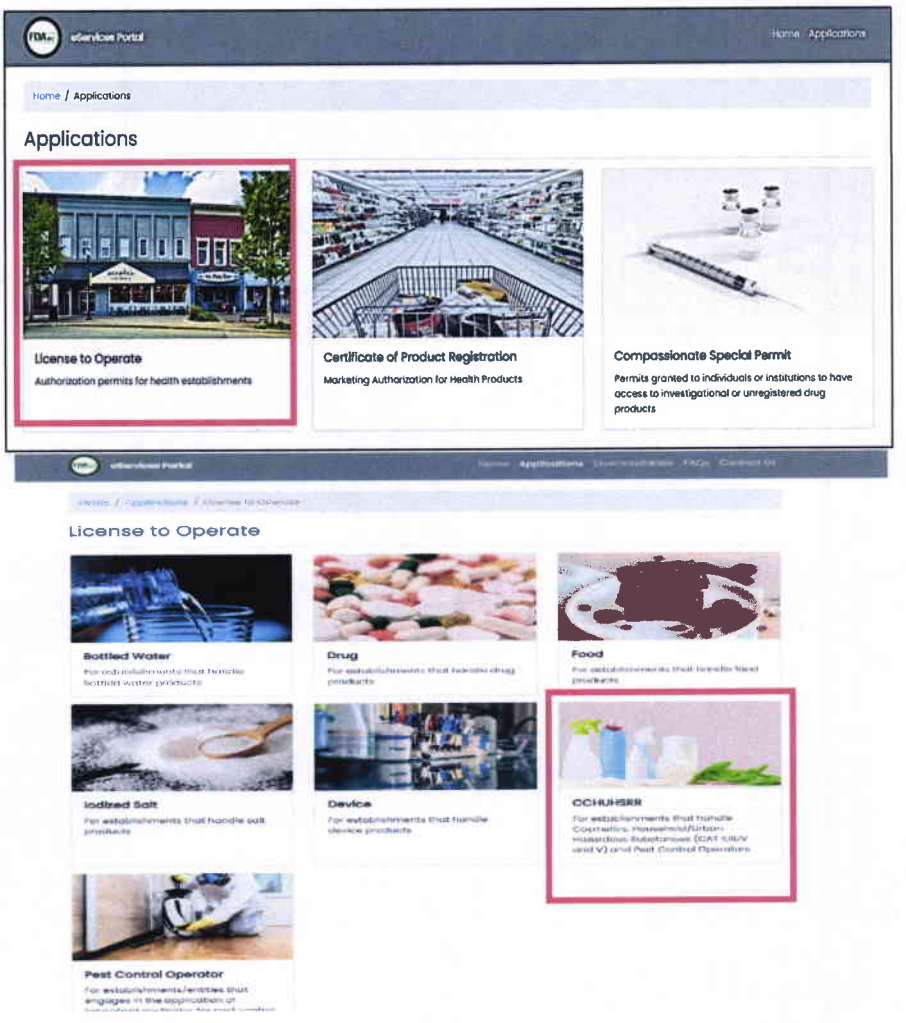
Follow the steps outlined below in order to submit a renewal HUHS LTO application.

1. Accessing and navigating the FDA eServices Portal System

a. Access the online portal through https://eservices.fda.gov.ph/ and click **"Applications"** of the eServices landing page.



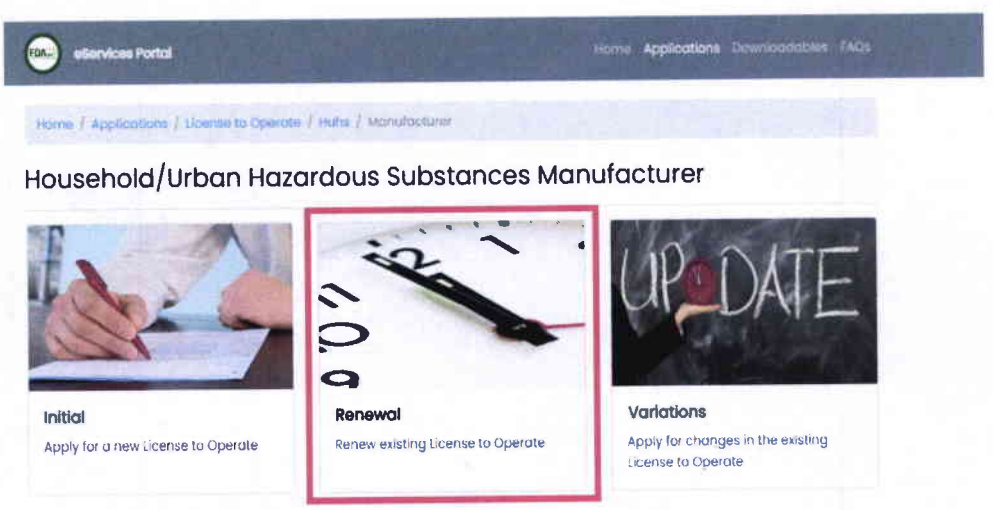
b. Click the **"License to Operate"** for Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)



c. Among the different types of establishments, select the most appropriate based on 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.

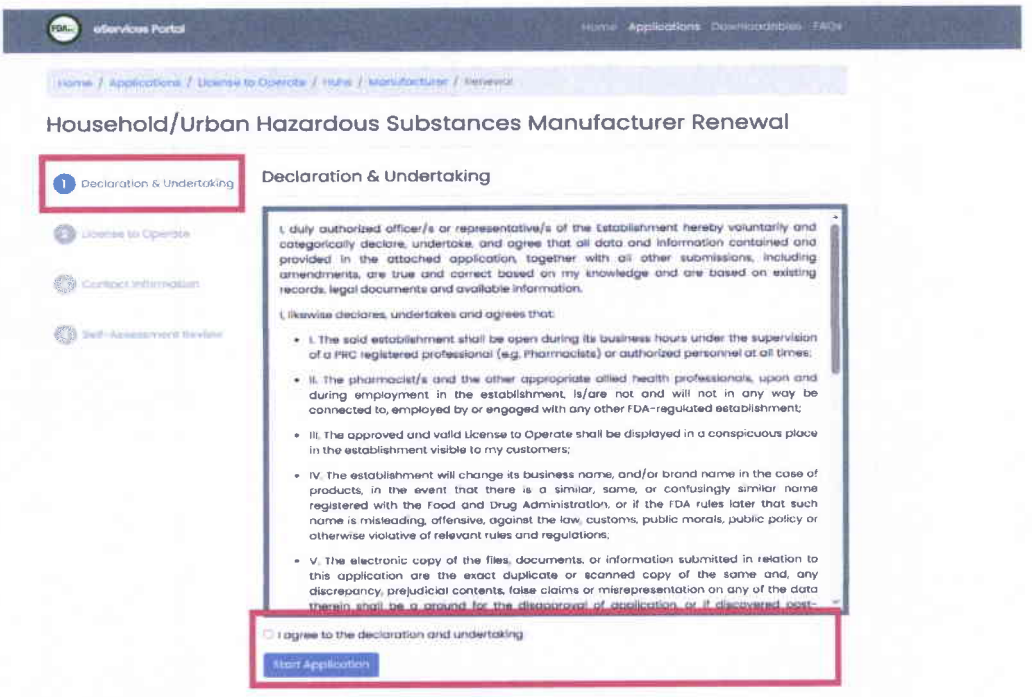
d. Click the Renewal Application.



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"**.

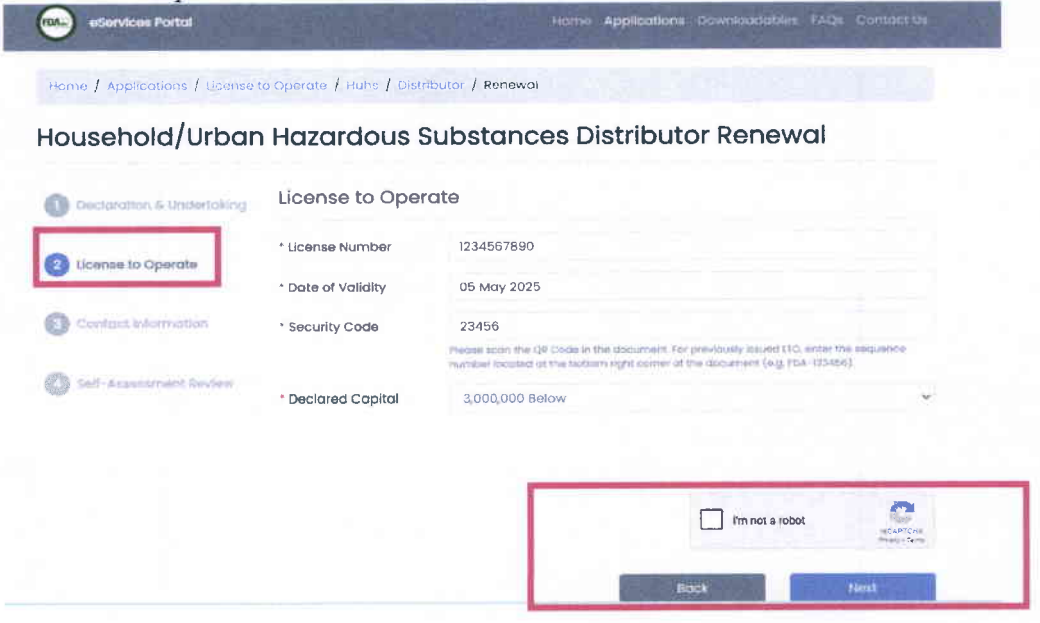


b. Page 2: License to Operate

Provide the existing LTO Number, Validity Date, Security Code*

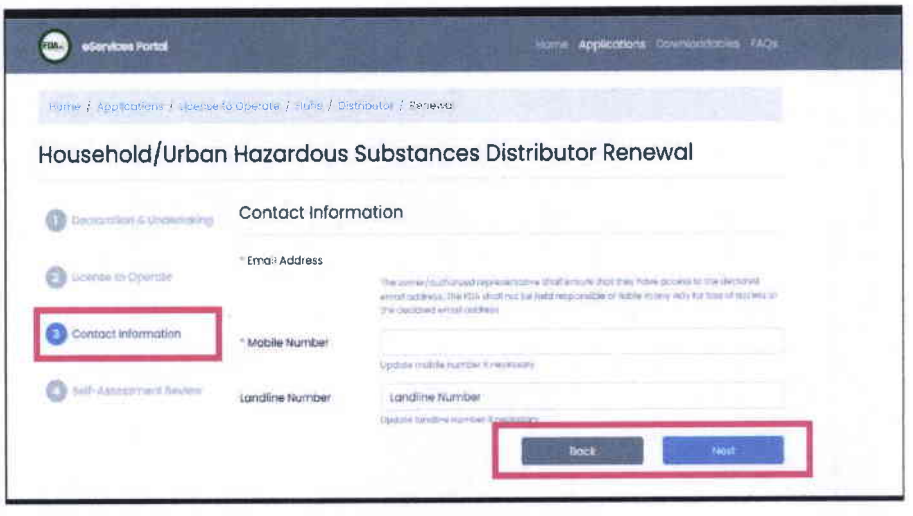
Note: The Security Code can be found in: (a) the e-mail sent to holders of LTOs issued through FDA ePortal System v.2; or, (b) the LTO issued through FDA eServices Portal System by scanning the QR Code from the given document.

Please ensure the correctness of the data given to proceed. Tick "**I'm not a robot**" then click "**Next**" to proceed.



c. **Page 3: Contact Information**

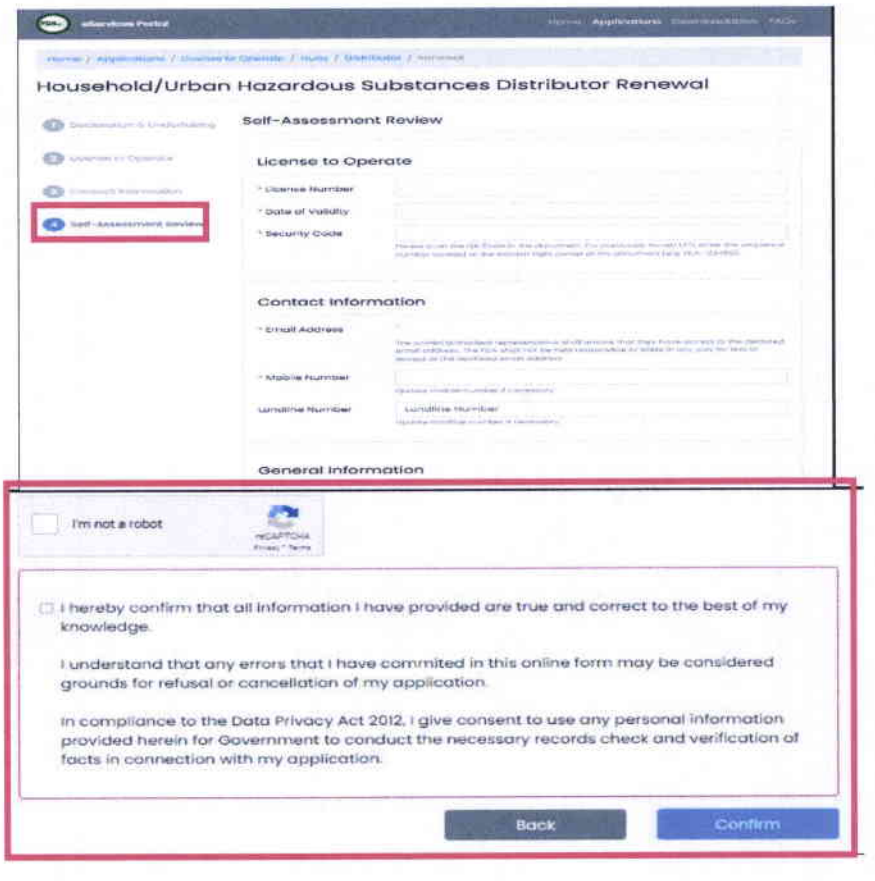
Provide an updated contact information. Click **"Next"** to proceed.



d. **Page 4: Self-Assessment Review**

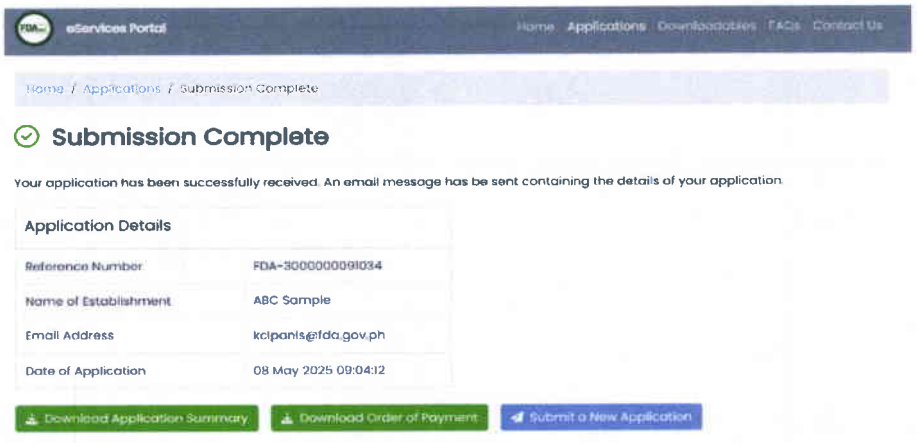
i. A Self-Assessment Review summary will appear that reflects all the declared information.

ii. After the self-assessment review, the applicant shall confirm the correctness of the data Tick **"I'm not a robot"**, **Data Privacy Act declaration** and click the **"Confirm"** submit the application.



iii. Once the application is successfully submitted, a **"Submission Complete"** message will be posted showing the application details. Download the **"Application Summary"** and **"Order of Payment"**

iv. A system-generated email will be sent to the applicant's registered email address in response to the filed application. The email will contain the Application Summary and Order of Payment for pre-assessment



3. Pre-Assessment Result

Following the pre-assessment, the applicant may receive either of the following in its registered email address:

a. Order of Payment for successful pre-assessed applications. The Order of Payment shall reflect the total application fee due, less the paid pre-assessment fee. Once the payment has been posted, the application shall be forwarded to the FDA Field Regulatory Office for the Regulatory Inspection step.

b. Letter containing the list of reason/s why the application did not pass the pre-assessment. In such case, the applicant is not precluded from filing a new application with complete documentary requirements subject to applicable pre-assessment fee

4. Next Steps

a. After receiving the Order of Payment, the applicant has (10) working days to make the necessary payments through any of the following payment channels:
   - BancNet – refer to FDA Advisory No. 2015-021, and its amendments for the process.
   - Link.BizPortal e-payment facility of the Land Bank of the Philippines- refer to FDA Advisory No. 2021-0246, or its amendments for more information.

b. Applicants may monitor their applications through the FDA eServices Portal System. Please refer to Annex E of this Advisory for the procedure for checking the status of an application.

c. For MSMEs, the latest audited Financial Statement with Balance Sheet or a Statement/Certification of Initial Capitalization signed by the owner of accountant, may be requested during pre-assessment and evaluation stages for the purposes of the computation of fees and charges. Additionally, the same document/s are subject to validation by FDA during inspection.

d. For applications requiring the submission of a corresponding responsive Corrective and Preventive Action (CAPA), compliance documents may be submitted through the FDA eServices Portal System. Please refer to Annex G of this Advisory.

e. Results of applications will be sent to the e-mail address indicated in the application form.

ANNEX D

Procedure in the Submission of Variation HUHS LTO Application

A. Description

Changes in the circumstances of an LTO of an establishment shall require a variation application, which are classified as either major or minor variations. The list of the types of variation applications and the corresponding requirements are indicated in Annex D of DOH Administrative Order No. 2024-0015, also reiterated in Annex A of this Advisory. Applicants should note that the minor variation application for the "Addition/ Deletion of Sources and Products" shall be mandatory by 1 January 2026, following the transitory arrangements under DOH AO No. 2024-0015.

This Annex outlines the procedure for the filing and submission of a variation application via the FDA eServices Portal System. This Annex covers the steps from accessing and navigating the System until the pre-assessment step where the Order of Payment is released. Guidance notes on the next steps from payment of application fees and charges, submission of compliance documents, checking of the status, and the issuance of the result of the application are also provided.

B. Procedure outline

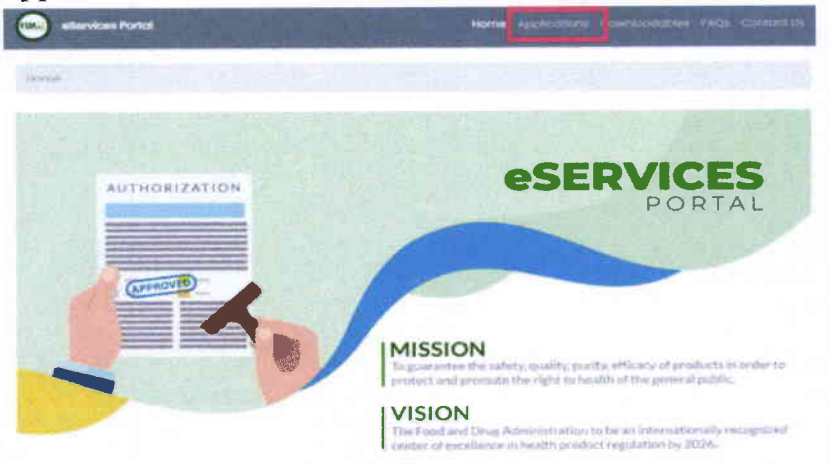
1. Accessing and navigating the FDA eServices Portal System
2. Filing an application
   a. Page 1: Declaration & Undertaking
   b. Page 2: License to Operate
   c. Page 3: Contact Information
   d. Page 4: Type of Variation
   e. Page 5: Self-Assessment Review
3. Uploading Documents
4. Next Steps

C. Step-by-step procedure

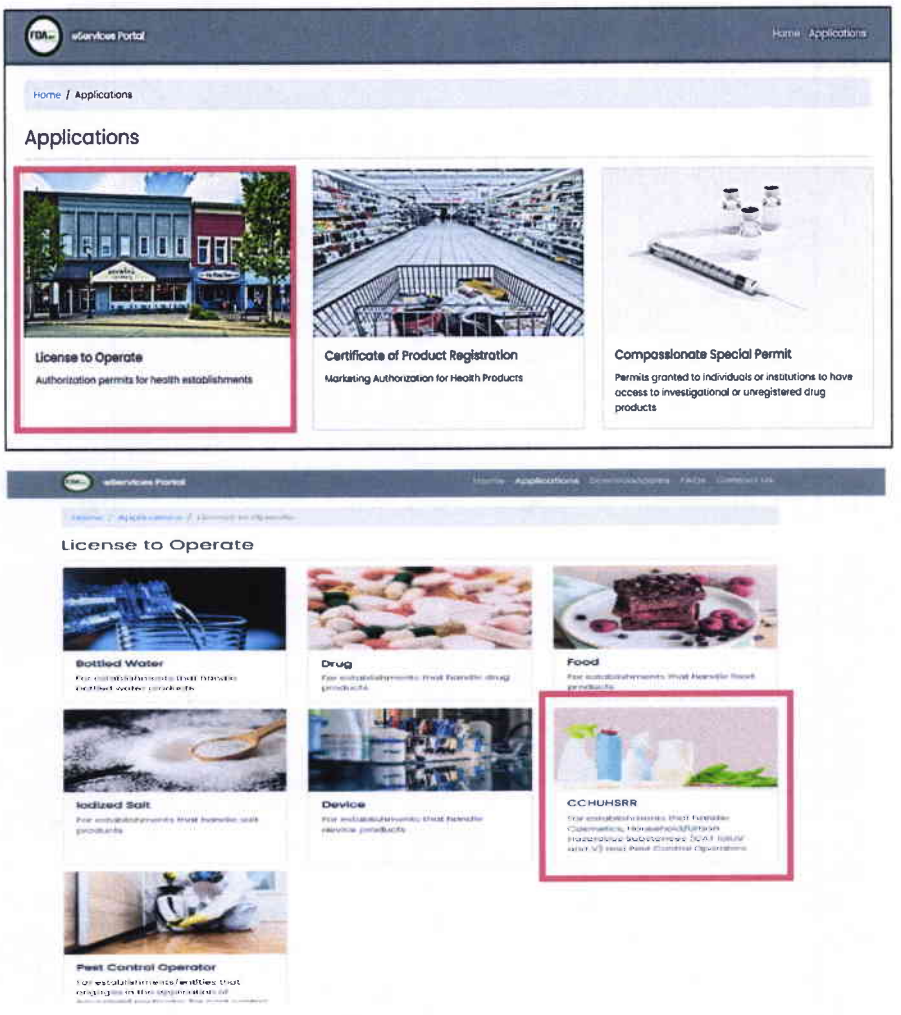
Follow the steps outlined below in order to submit a variation HUHS LTO application.

1. Accessing and navigating the FDA eServices Portal System

a. Access the online portal through https://eservices.fda.gov.ph/ and click **"Applications"** of the eServices landing page.

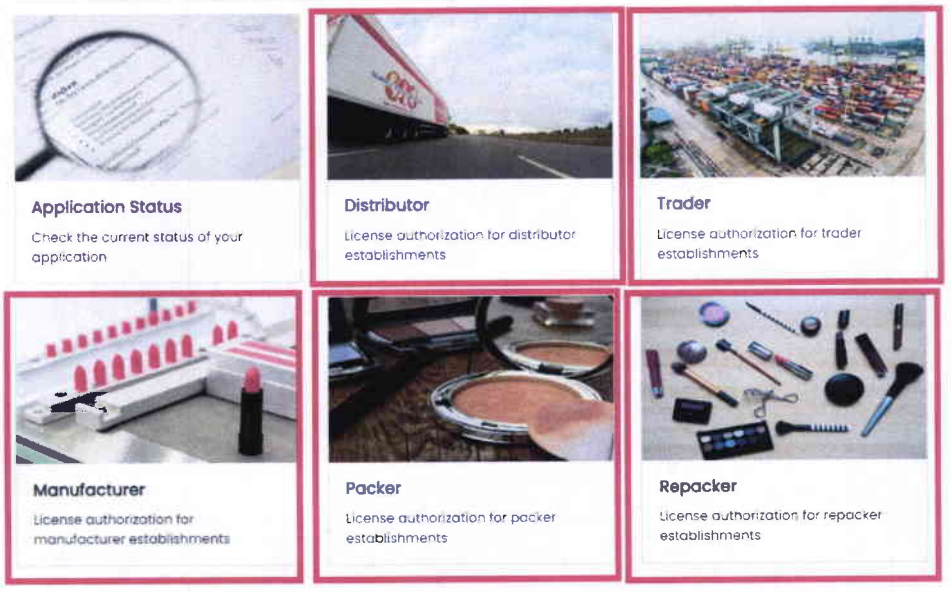


b. Click the "**License to Operate**" for Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)

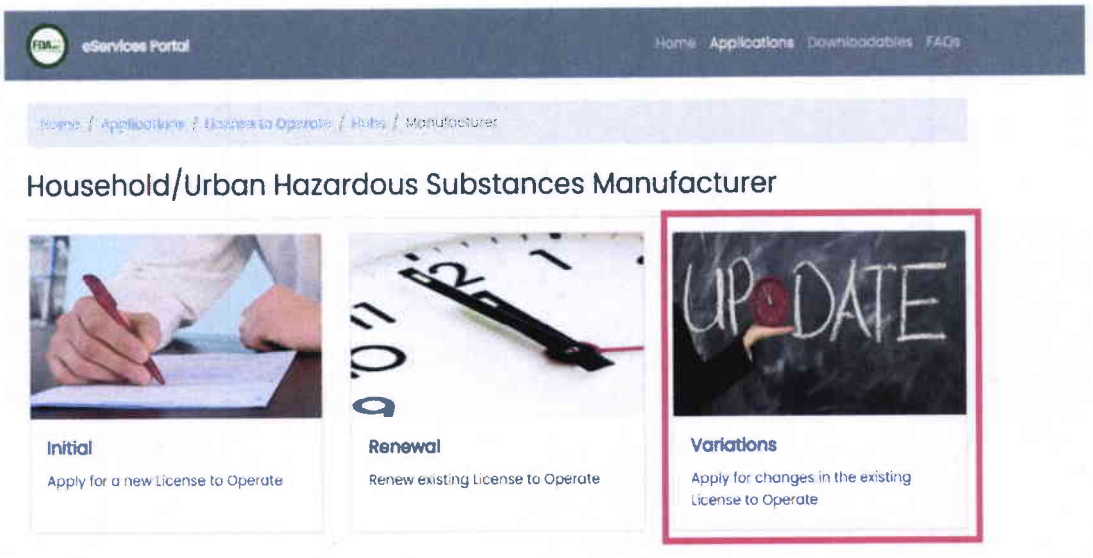


c. Among the different types of establishments, select the most appropriate based on primary activity the applicant intends to engage in which may be one of the following:

- **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.



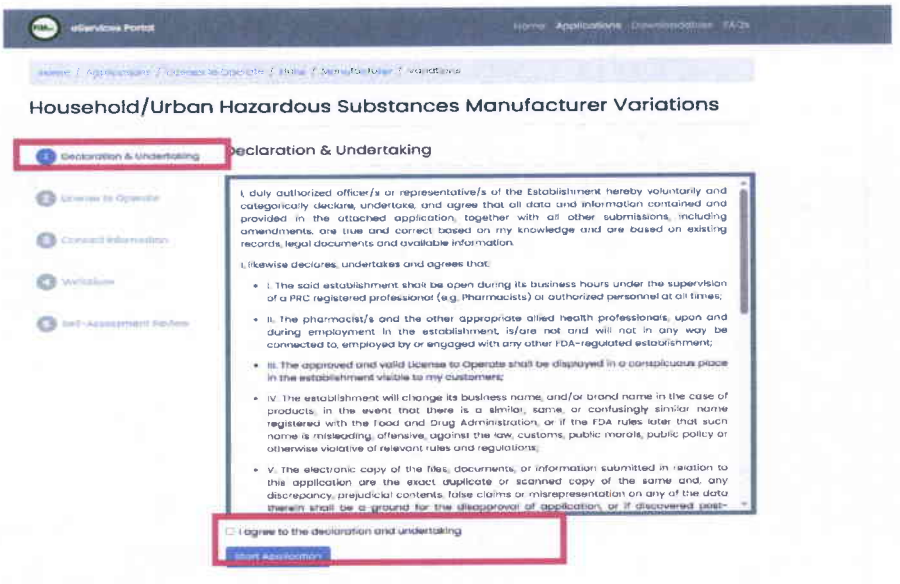
d. Click the Variation Application



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"**.

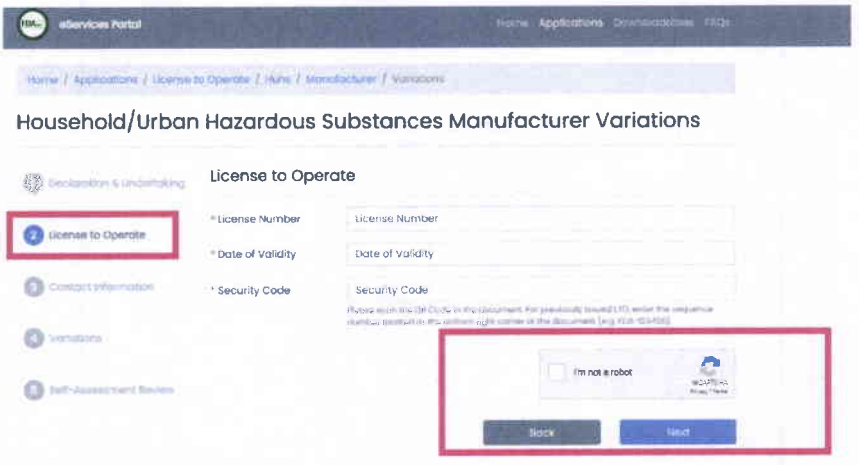


b. **Page 2: License to Operate**

Provide the existing LTO Number, Validity Date, Security Code*

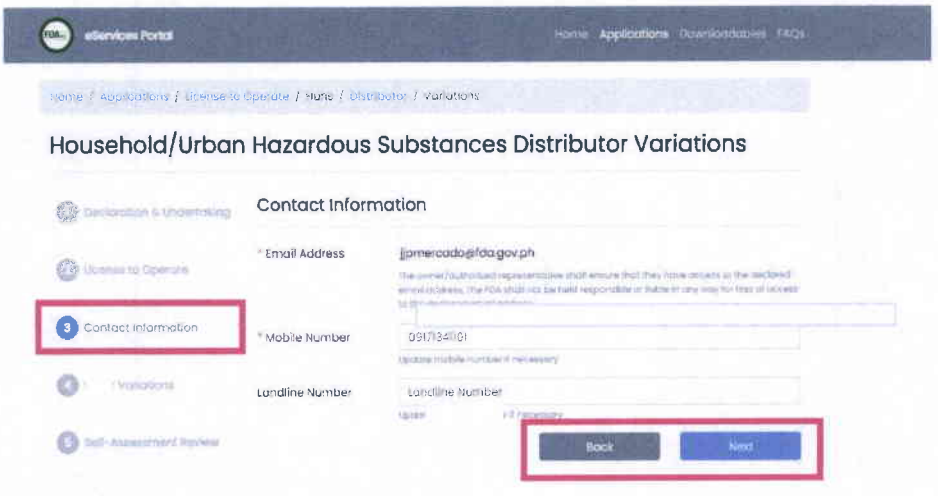
Note: The Security Code can be found in: (a) the e-mail sent to holders of LTOs issued through FDA ePortal System v.2; or, (b) the LTO issued through FDA eServices Portal System by scanning the QR Code from the given document.

Please ensure the correctness of the data given to proceed. Tick "**I'm not a robot**" then click "**Next**" to proceed.



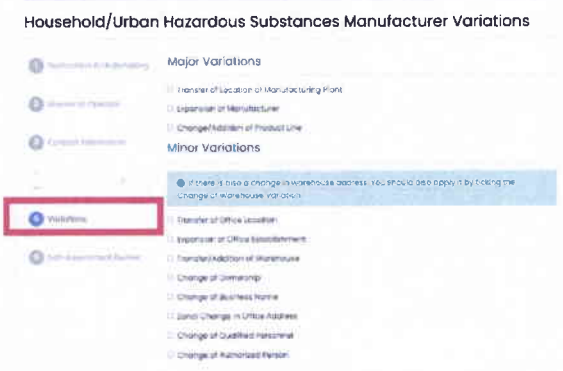
c. **Page 3: Contact Information**

Provide an updated contact information. Click **"Next"** to proceed.



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.

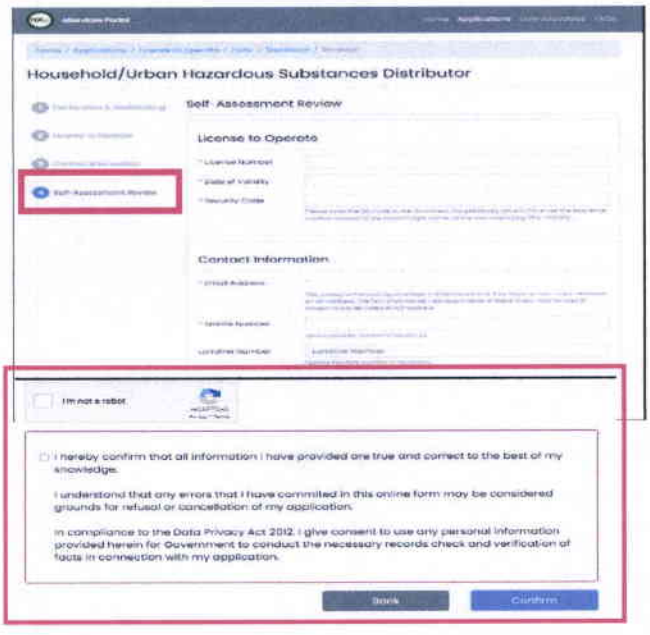


e. **Page 5: Self-Assessment Review**

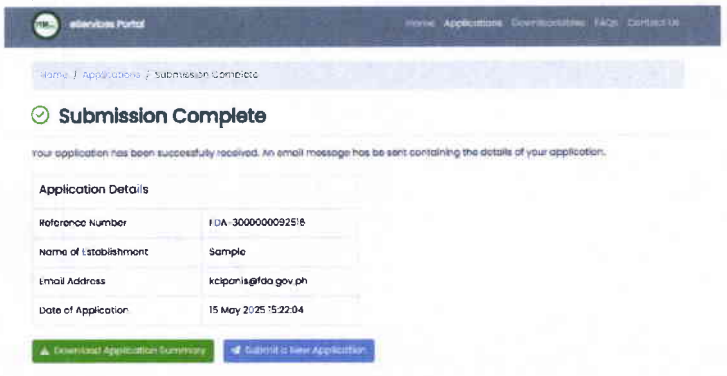
i. A Self-Assessment Review summary will appear that reflects all the declared information

ii. Review and recheck the information declared. 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. Tick **"I'm not a robot"**, **Data Privacy Act declaration** and click the **"Confirm"** submit the application.

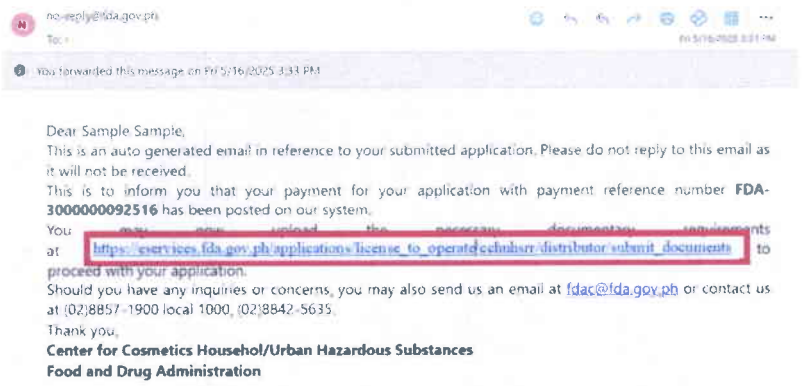


iv. Once the application is successfully submitted, a **"Submission Complete"** message will be posted showing the application details. Download the **"Application Summary"**



3. Uploading of Documents

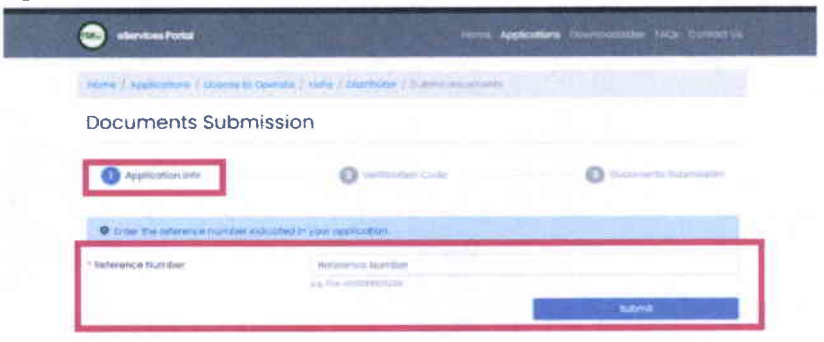
Once the Pre-Assessment Fee has been posted, a system-generated email will be sent to the applicant's registered email address containing the link and instructions for the submission of the documentary requirements. Click the link to redirect to the FDA eServices Portal System Documents Submission landing page.



Dear Sample Sample,
This is an auto generated email in reference to your submitted application. Please do not reply to this email as it will not be received.
This is to inform you that your payment for your application with payment reference number **FDA-3000000092516** has been posted on our system.
You may now upload the necessary documentary requirements at https://eservices.fda.gov.ph/applications/license_to_operate/cosmhsrr/distributor/submit_documents to proceed with your application.
Should you have any inquiries or concerns, you may also send us an email at fdac@fda.gov.ph or contact us at (02)8857-1900 local 1000, (02)8842-5635.
Thank you,
Center for Cosmetics Household/Urban Hazardous Substances
Food and Drug Administration

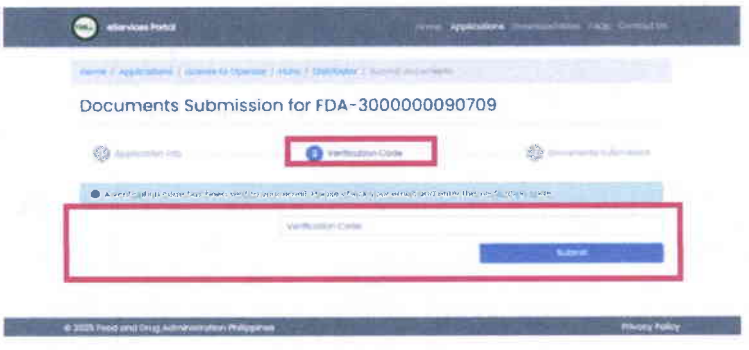
a. **Page 1: Application Info**

Provide the reference number assigned to the application and click **"Submit".** The reference number may be found in the generated email sent to the applicant's registered email address.



b. **Page 2: Verification Code**

Provide verification code sent to the applicant's registered email address.



c. **Page 3: Documents Submission**

Upload necessary documents in portable document file (PDF). Once done, confirm the correctness of uploaded documents. Tick **"I'm not a robot"** and "**Submit**"

4. Next Steps

a. After receiving the Order of Payment, the applicant has (10) working days to make the necessary payment through any of the following payment channels:

- BancNet – refer to FDA Advisory No. 2015-021, and its amendments for the process.
- Link.BizPortal e-payment facility of the Land Bank of the Philippines- refer to FDA Advisory No. 2021-0246, or its amendments for more information.

b. Applicants may monitor their applications through the FDA eServices Portal System. Please refer to Annex E of this Advisory for the procedure for checking the status of an application.
c. For applications requiring further compliance, compliance documents may be submitted through the FDA eServices Portal System. Please refer to Annex G of this Advisory for the procedure for submitting compliance documents.
d. Results of applications will be sent to the e-mail address indicated in the application form.

ANNEX E

Procedure for Checking the Status of an Application

A. Description

Updates on an application are sent to the registered email address of the company provided in the application form. Applicants may expect a notification e-mail at every stage of the application process. Further, at the option of the applicant, real-time monitoring of applications via the FDA eServices Portal System is also available and may be done directly through the website. The information and documents which will be shown include, the pre-assessment status and result, Order of Payment, LTO for approved application and a Denial Letter for disapproved application.

B. Procedure outline

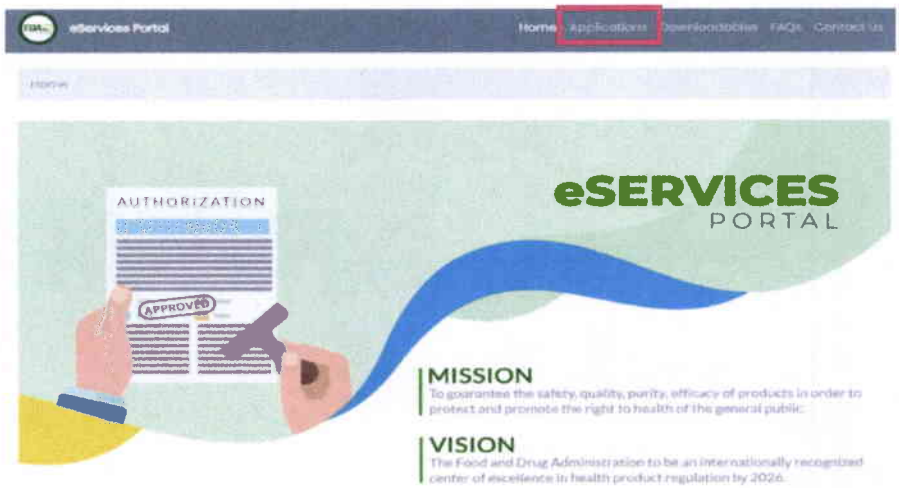
1. Accessing and navigating the FDA eServices Portal System
2. Checking the Status of an Application
    a. Page 1: Reference Number
    b. Page 2: Verification Code
    c. Page 3: Application Status

C. Step-by-step procedure

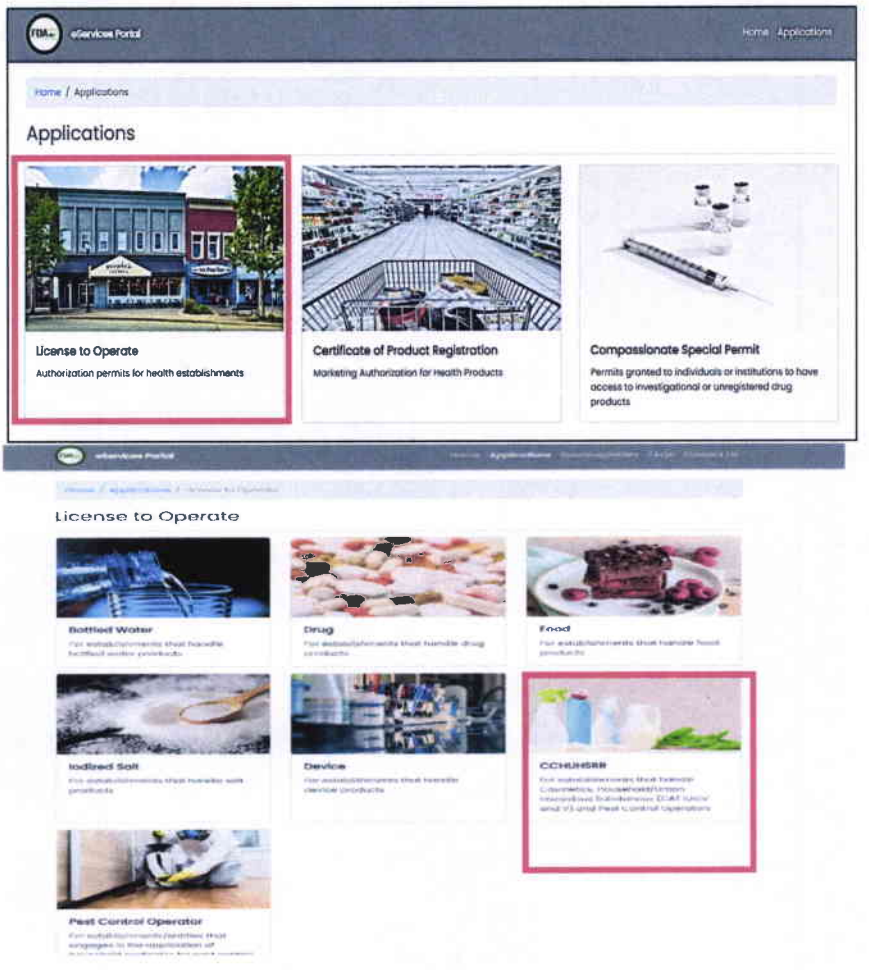
Follow the steps outlined below in order to check the status of an application.

1. Accessing and navigating the FDA eServices Portal System

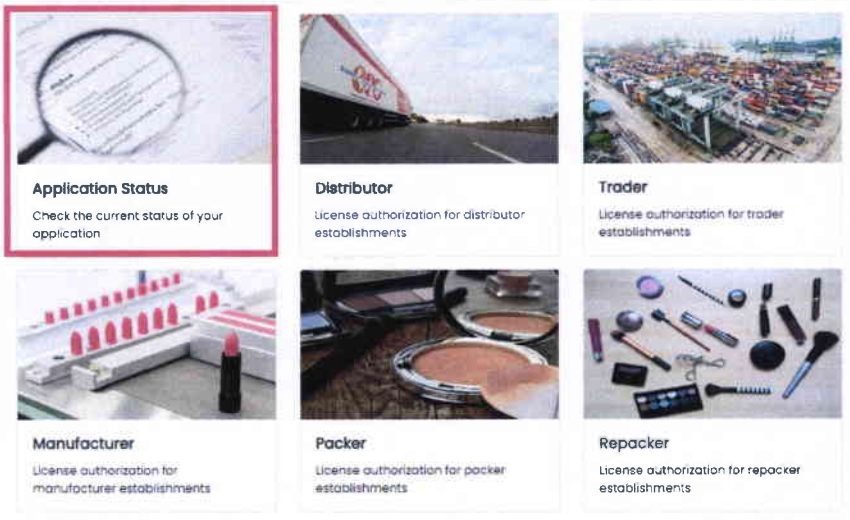
i. Checking of the application may also be accessed through the eServices webpage. Access the online portal through https://eservices.fda.gov.ph/ and click **"Applications** of the eServices landing page.



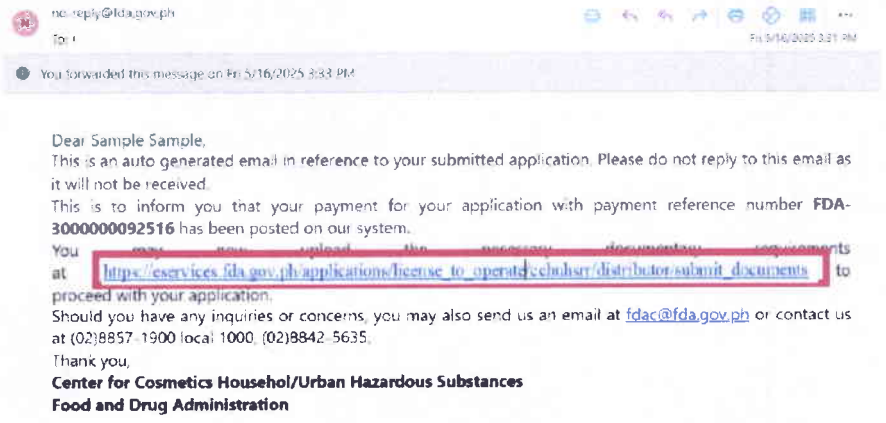
ii. Click the "**License to Operate**" for Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)



iii. To check the status of the application, click **"Application Status".**



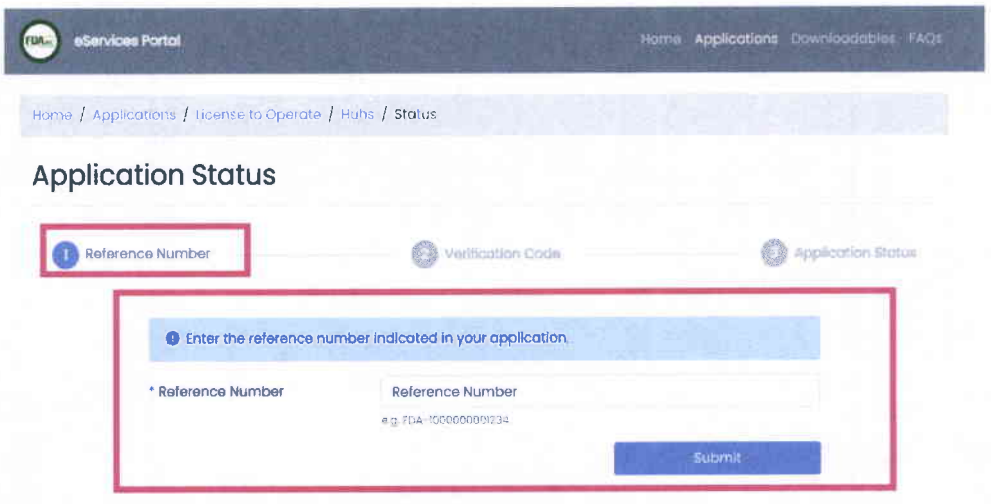
It may also be access through the link provided in the notification email sent to the registered email address



2. Checking the Status of an Application

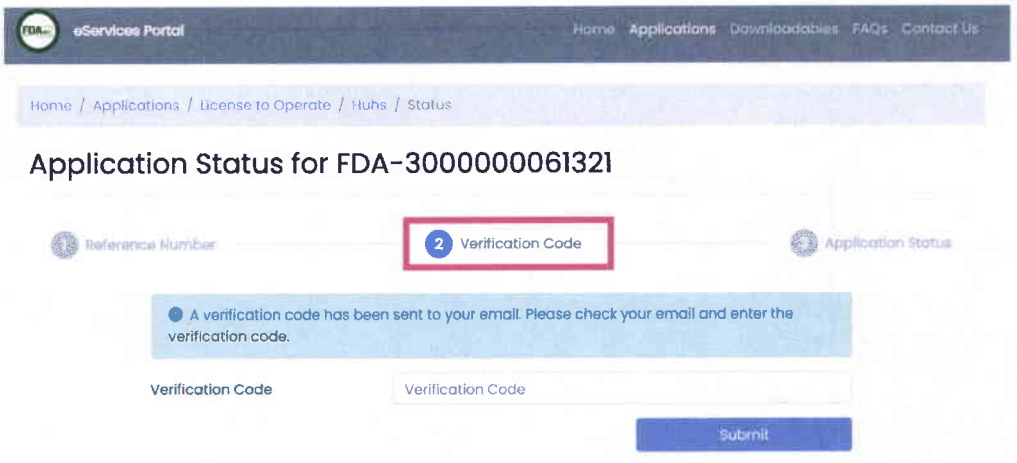
a. Page 1: Reference Number

Provide the reference number assigned to the application and click on **"Submit"**



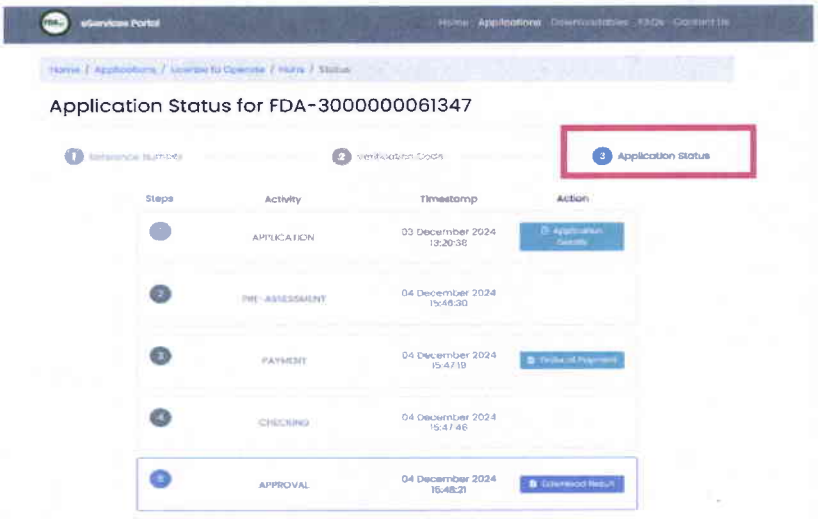
b. Page 2: Verification Code

Provide verification code sent to the applicant's registered email address.



c. Page 3: Application Status

The applicant will be directed to the **"Application Status"** which reflects the real-time status of the application. The applicant may download the Order of Payment and the Result of the application.



ANNEX F

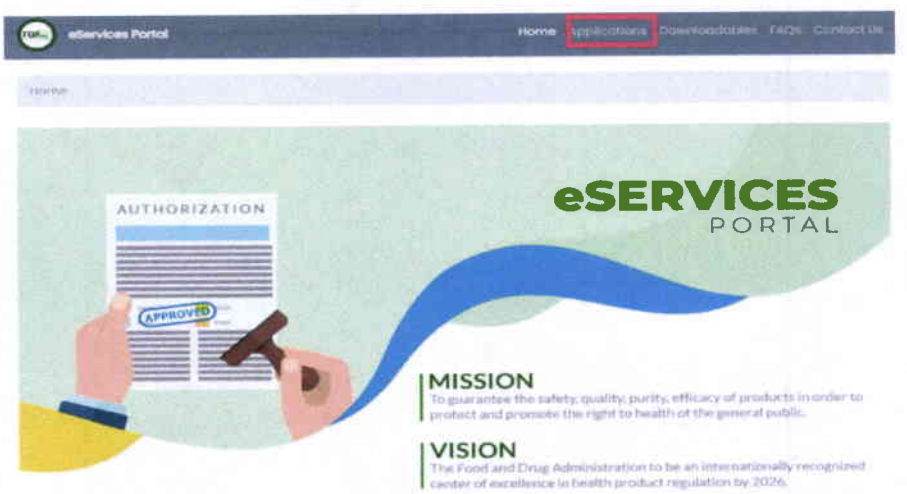
Procedure for Voluntary Cancellation of an Application

A. Description

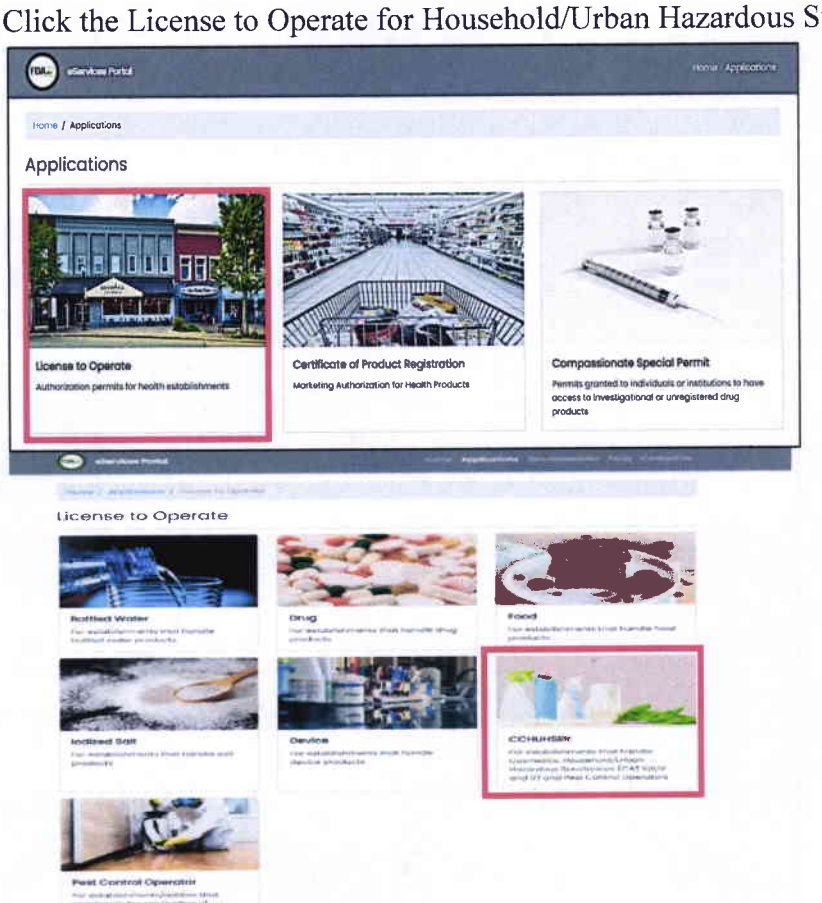
Voluntary cancellation may be done at the option of the applicant. It must be noted that the cancellation of an application shall forfeit the payment made for the said application. The same facility is available via the FDA eServices Portal System.

B. Step-by-step Procedure

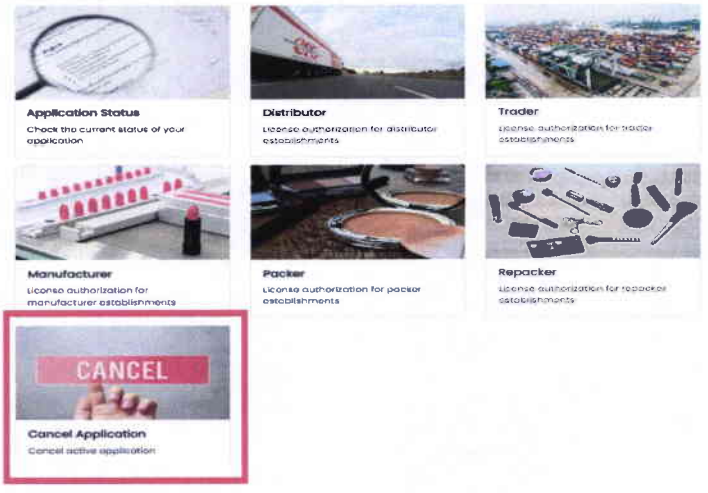
1. Access the online portal through https://eservices.fda.gov.ph/ and click **"Applications"** of the eServices landing page.



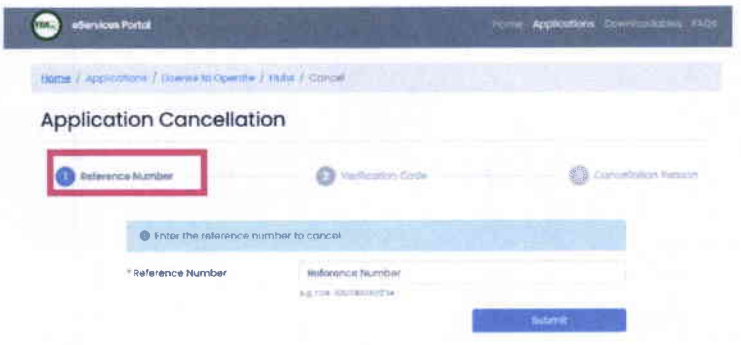
2. Click the License to Operate for Household/Urban Hazardous Substances



3. To cancel the application, click **"Cancel Application".**

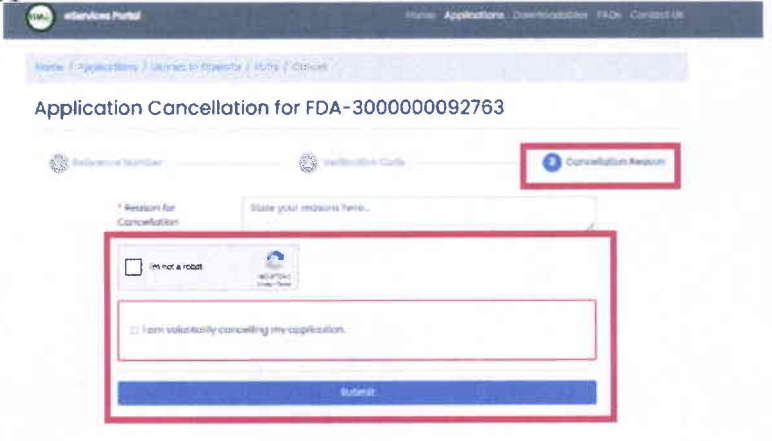


4. Provide the reference number assigned to the application and click on **"Submit"**



5. Provide the verification code sent to the applicant's registered email address.

6. State the reason for cancellation, click **"I'm not a robot"**, **"I am voluntary cancelling my application"** and "**Submit**" A generated email will be sent by the FDA to the applicant's email account in response to the cancelled application.



ANNEX G

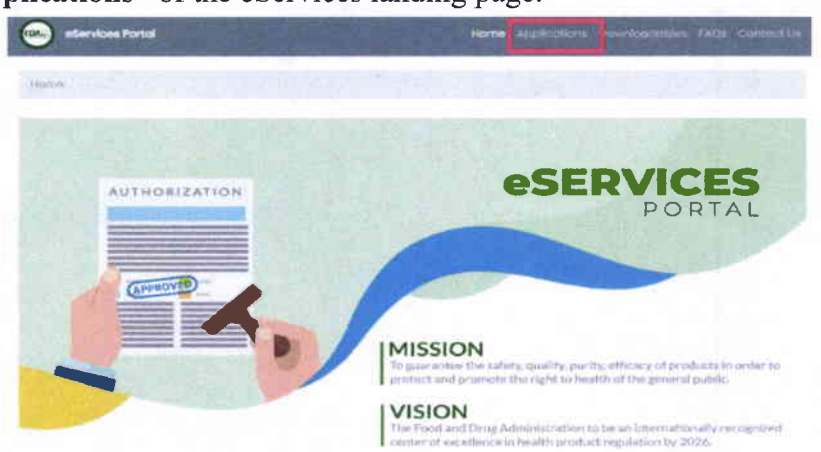
Procedure for the Submission of Compliance

A. Description

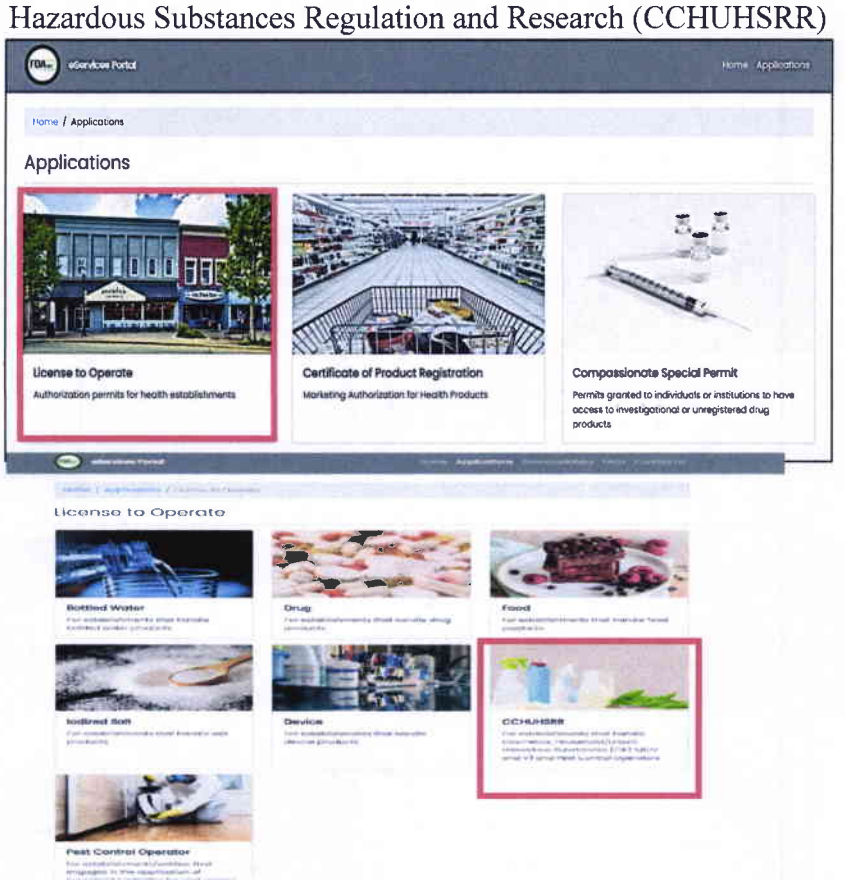
Verification for compliance of the establishments with technical requirements and applicable standards shall be conducted according to existing procedures and timelines of the FDA. Findings during licensing inspection requiring the submission of a corresponding responsive Corrective and Preventive Action (CAPA) follows the rules under Section VIII.D.1.f of DOH AO No. 2024-0015, it's implementing guidelines and future amendments. Submission of said CAPA may be done via the FDA eServices Portal System.

B. Step-by-step Procedure

1. Access the online portal through https://eservices.fda.gov.ph/ and click **"Applications"** of the eServices landing page.

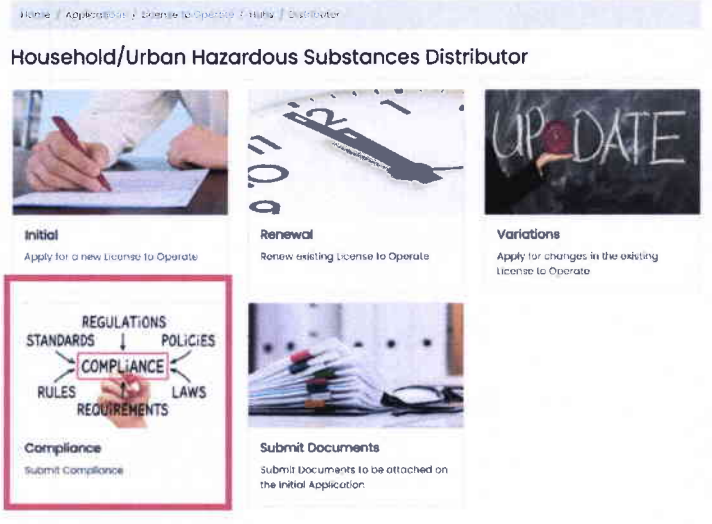


2. Click the "**License to Operate**" for Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR)

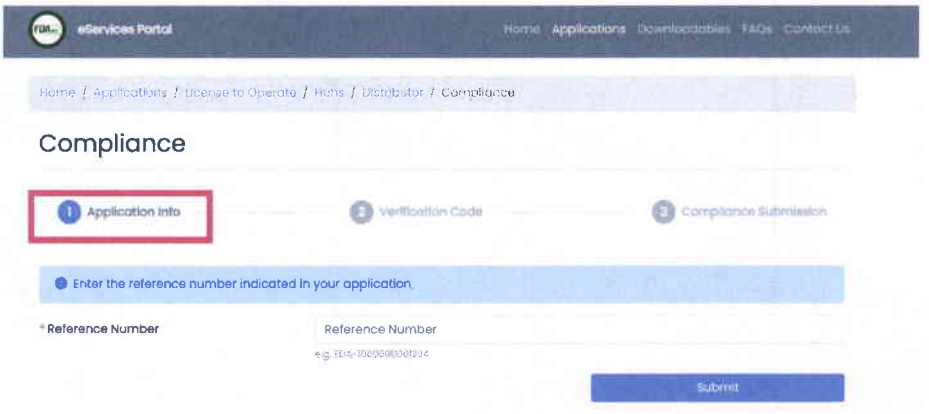


3. Among the different types of establishments, select the most appropriate based on the primary activity the applicant intends to engage in which may be one of the following

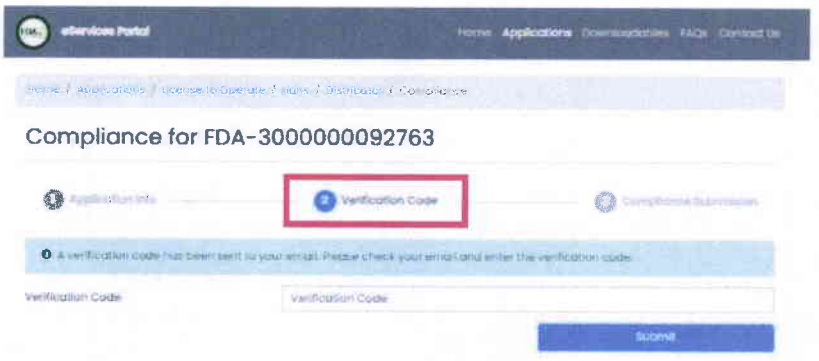
4. To submit compliance, click **"Compliance".**



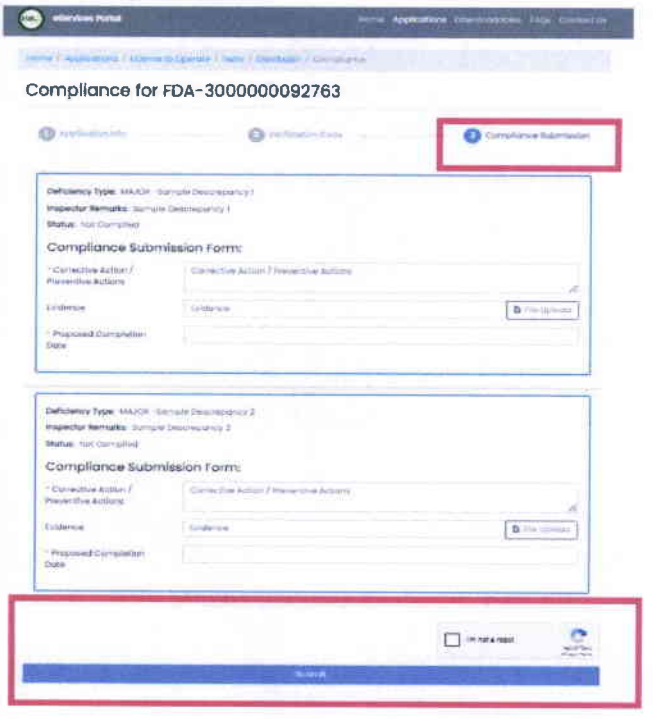
5. Enter the Reference Number assigned to the application and click on **"Submit"**



6. Provide verification code sent to the applicant's registered email address.



7. Fill-in the necessary information. Fields marked with a red asterisk (*) are required to be filled-in. Upload documents for compliance. Click **"I'm not a robot**" and "**Submit**" to confirm



8. A generated email will be sent by the FDA to the applicant's email account in response to the submission of compliance.