Note: This draft is only intended as a copy for comments during the stakeholder consultation period of the proposed guidelines. The content of this draft may change and does not prejudge any policy nor decision of the FDA. Citation of any text in this draft, for purposes other than the submission of comments as indicated in the issued announcement, is not recommended.

FDA CIRCULAR
No. _____

SUBJECT : Guidelines on the Filing and Submission of Applications for the Licensing of Household/Urban Hazardous Substances (HUHS) Establishments through the Food and Drug Administration (FDA) eServices Portal System

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I. RATIONALE

In pursuit of the principles under Republic Act No. 8792, otherwise known as the "Electronic Commerce Act of 2000", and Republic Act No. 11032, otherwise known as the "Ease of Doing Business and Efficient Government Service Delivery Act of 2018", national government agencies transitioned into operating electronic systems to promote efficient delivery of government services. In the Food and Drug Administration (FDA), digitalization efforts were initiated beginning in 2013 through the establishment of an electronic application system for cosmetic product notification, followed later on by the online systems for the notification/registration of household/urban hazardous substances (HUHS), toys and childcare articles, food products, and medical devices, and the licensing of health product establishments.

During the course of the digitalization of FDA licensing and registration services, several systems were gradually built. More recently, regulatory services of the FDA are moving towards a single platform, namely, the FDA eServices Portal System. This platform is envisioned to be a user-friendly and simpler platform to file and submit applications, intended to reduce inefficiency and redundancy presented by multiple application systems. This is also in line with the initiatives which aimed to harmonize and streamline procedures as in Department of Health (DOH) Administrative Order (AO) No. 2020-0017 of the Department of Health entitled, "Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003". Through this Circular, the FDA eServices Portal is hereby updated to include License to Operate (LTO) applications of HUHS establishments.

II. OBJECTIVE

This Circular aims to provide the procedural guidelines for the filing and submission of LTO applications of HUHS establishments through the FDA eServices Portal System

III. SCOPE

This Circular shall cover the following LTO applications:

A. Types of Establishments

1. HUHS Manufacturer
    a. HUHS Manufacturer / Toll Manufacturer
    b. HUHS Manufacturer-Packer / Toll Packer
    c. HUHS Manufacturer-Repacker / Toll Repacker

2. HUHS Distributor
    a. HUHS Distributor-Importer
    b. HUHS Distributor-Exporter
    c. HUHS Distributor-Wholesaler

3. HUHS Trader

B. Types of LTO Applications

1. Initial
2. Renewal
3. Variation

IV. DEFINITION OF TERMS

The terms used in this Circular shall have the same definition as prescribed in Republic Act No. 9711 and its Implementing Rules and Regulations (IRR), DOH Administrative Order (AO) No. 2020-0017, DOH AO No. 2019-0019, FDA Circular No. 2020-025, and other applicable laws and regulations

V. GUIDELINES

A. The procedural guidelines on the filing and submission of an FDA eServices LTO application for establishments enumerated under Section III of this FDA Circular shall be expounded herein. Whereas, the technical requirements and guidelines relative to the licensing and inspection of HUHS establishments are provided in DOH AO No. 2020-0017 and FDA Circular No. 2020-025.

B. By applying for an FDA LTO, the establishment understands and abides by the rules and regulations set forth by the Agency. The establishment shall have the ultimate responsibility in ensuring compliance with applicable national and/or international standards of safety, quality, purity, and efficacy developed and/or adopted by the FDA for of HUHS products which are manufactured, imported, exported, distributed, sold, offered for sale, promoted, and/or advertised under the authorization granted through their LTO and other marketing authorizations issued by the FDA.

C. **Application Process.** The applicant shall follow the updated procedure, as provided in this Circular, in the submission and filing of applications, amending the procedure

originally prescribed under FDA Circular No. 2023-006. Applications shall be in accordance with the following guidelines:

1. **Application Requirements and Procedure.** The application requirements and procedure are specified in the following Annexes of this Circular:

   a. Annex A – LTO Requirements for HUHS Establishments
   b. Annex B – Procedure in the Submission of an Initial LTO Application
   c. Annex C – Procedure in the Submission of a Renewal LTO Application
   d. Annex D – Procedure in the Submission of a Variation Application
   e. Annex E – Procedure for Checking the Status of an Application
   f. Annex F – Procedure for Voluntary Cancellation of an Application

2. **Filing of an Application**

   a. **Accessibility of the FDA eServices Portal System.** Applications shall be filed online through the FDA eServices Portal System website (https://eservices.fda.gov.ph). A valid company e-mail address is required to file and submit an application.

   b. **Declaration and Undertaking Upon Submission of the Application.** Agreement to the "Declaration and Undertaking" is required in order to proceed with the application. Such conveys a binding agreement of the applicant company with the FDA to provide true and accurate information in support of the application, to affirm the primary responsibility of the LTO holder over the HUHS products, and to undertake compliance with all applicable FDA standards, rules and regulations contingent with their authorization, including full cooperation with FDA licensing, inspection, and post-marketing surveillance activities.

      Any misrepresentation of the information in this application shall be subjected to administrative and criminal liabilities, provided by Republic Act No. 9711, which includes, but are not limited to disapproval of application, suspension, cancellation, or revocation of the LTO.

   c. **Security of the Declared E-mail Address.** All transactions with the FDA shall be communicated to the applicant company though the declared e-mail address during the application.

      The applicant company shall bear the responsibility of ensuring the accessibility, security and integrity of such e-mail address to their respective Authorized Person/s, Qualified Personnel, and/or owner of the establishment. The FDA shall not be held liable or responsible in any way for the loss and/or any compromise of access to the declared e-mail address.

      In the event that the applicant company wishes to change the declared e-mail address during the initial application, the applicant may send a request addressed to the FDA – Food and Drug Action Center at fdac.pacd@fda.gov.ph.

   d. **Quality of Declared Information and Uploaded Documents**

i. In filling-up the fields in the electronic application (e-Application) form, the applicant shall ensure that the declared information is consistent with the uploaded supporting documents, such as the name and address of the establishment, name of owner, among others.

ii. Documents required to be uploaded, in support of the e-Application, shall be in accordance with the following specifications:
   1. Portable document file (PDF) format; and,
   2. Maximum of 2 megabytes (MB) file size.

iii. Once the e-Application Form is completed, applicants can review the duly filled out form in the Self-Assessment Review. By agreeing to the terms and conditions, the applicant confirms the correctness of information provided and data privacy terms.

iv. The application summary shall be automatically sent to the applicant's valid e-mail address to indicate the successful submission of the application in the eServices Portal. Upon submission, the information declared in the e-Application is considered final.

e. **Timing and submission of applications**

i. Applications are processed one at a time, such that renewal applications and each variation application must be filed separately. No application for variation of LTO shall be made and granted when an establishment has a pending application for renewal of LTO, or vice versa.

ii. An applicant may only file for a renewal application of an LTO within three (3) months prior its expiry. Applications filed after the validity date of the LTO shall be subject to a surcharge as prescribed in Republic Act No. 9711 and its IRR.

iii. Applications shall be accepted in accordance with the existing guidelines on the schedule of receiving. Further, applications filed after the prescribed working/office hours or during weekends and holidays shall be considered filed on the next working day.

f. **Monitoring of the Status of Applications.** The status of the application may be monitored by the applicant through the FDA eServices Portal System website. A reference code will be sent to the registered e-mail address specified in used for the e-Application to validate the request to view the status.

g. **Voluntary Cancellation of Applications.** The application may be cancelled by the applicant voluntarily stating the reason for cancellation through FDA eServices Portal System website. A reference code will be sent to the

registered e-mail address specified in used for the e-Application to validate the request for cancellation.

Applications cancelled during the evaluation stage or after the payment has been made shall mean the outright forfeiture of the payment. Resubmission of applications thereafter shall be subject to new fees.

3. **Pre-assessment.** All HUHS licensing applications shall undergo the pre-assessment step, following Republic Act No. 11032, which covers the determination of the completeness of information and documents submitted. The pre-assessment of applications shall be guided by the following.

   a. The pre-assessment of applications shall be done within the prescribed working days and office hours of the FDA.

   b. Applications with incomplete data entries and document submissions shall not be accepted for further evaluation and the application will not proceed to the next step of the process.

   c. The FDA shall inform the applicant through the registered email address of the result of the pre-assessment. If the application passed the pre-assessment step, the applicant shall receive the Order of Payment with Reference Number through email indicating the fees to be paid. However, if the application did not pass the pre-assessment step, the FDA shall notify the reason/s for non-acceptance e.g., deficiency/ies found and prompt the applicant to file a new application.

   d. A successfully pre-assessed application is not equivalent to an approved application. The evaluation of the correctness and sufficiency of the submitted documentary requirements with reference to existing administrative and technical standards, rules, and regulations shall be conducted only during the evaluation and inspection steps as determined by the FDA.

4. **Payment of Fees.** The procedure for the payment of fees and charges shall be as follows. Any updates, changes and/or additions to the existing FDA payment channels shall be announced through separate issuances.

   a. Payment of prescribed fees as indicated in the Order of Payment shall be done through the following available payment channels based on existing FDA issuances:

      i. Over-the Counter at the Landbank of the Philippines (LBP) using the LBP Oncoll Payment Slip based on FDA Memorandum Circular No. 2013-046 through this link, https://bit.ly/36ChH4X

         The Oncoll Payment Slip shall reflect the following information:
         1. Account Number (per category of the product/center)
         2. Reference No. 1 – Account Code (reflected in the Order of Payment)
         3. Reference No. 2 – Company Name

4. Merchant Name – Food and Drug Administration

ii. Online through:

1. LBP Online Payment Link.Biz Portal based on FDA Advisory No. 2021-0246 (https://bit.ly/3DmdPRv)
2. BANCNET online (https://bit.ly/3uB8PEL)

Online payments should indicate the reference number reflected in the Order of Payment.

b. Once payment has been made, LBP or Bancnet will process the payment and send a transaction report to FDA which usually takes a minimum of two (2) days. Upon receipt of the report, the Cashier Section of the FDA shall check the details, confirm if the payment has been made in full, and posts the payment in the FDA eServices Portal System. Posting of payment may take a maximum of two (2) days, depending on the volume of paid applications received.

c. Applicants will receive a system-generated message through the registered e-mail address on the status of the payment made once posted or if there is a need to further settle the remaining balance. An Acknowledgment Receipt will be issued if a full payment has been made. Otherwise, a notification on payment deficiency will be issued in cases of incomplete payments.

d. Applications with complete documentary requirements and payment shall receive an Acknowledgement Receipt from FDA, containing the number or code of the FDA employee who received the application, the reference number, agency logo, the date and time of application, payment, and the statement of completeness of the documents submitted. An application is considered filed once the applicant receives the Acknowledgement Receipt.

5. Evaluation of the Application. A filed application will undergo evaluation of the correctness and sufficiency of the submitted documentary requirements with reference to existing administrative and technical standards, rules, and regulations. Inspection will be conducted as determined by the FDA, in accordance with the guidelines under DOH AO No. 2020-0017, FDA Circular No. 2020-025, and their future amendments.

An approval of the application shall be based on the satisfactory compliance to the administrative and technical requirements reviewed during evaluation and, if applicable, inspection.

6. Grounds for Disapproval. The grounds for disapproval of LTO application may be any of the following, as provided in DOH AO No. 2020-0017:

a. The documentary requirements submitted show that the establishment does not meet the required technical requirements and/or appropriate standards;
b. Absence of physical office upon inspection, without permission or approval from FDA;

c. The applicant made misrepresentations, false entries, withhold relevant data contrary to the provisions of the law or appropriate standards;
d. The owner has violated any of the terms and conditions of its license; and,
e. Such other analogous grounds or causes as determined by the FDA.

The disapproval of an application is without prejudice to re-application provided the deficiencies listed in the Letter of Disapproval (LOD) have been addressed before submitting the new application. As the disapproval of the application means the outright forfeiture of the payment made, re-submitted applications shall be subject to new fees.

7. Releasing of the Results of the Application

a. If the application is approved, the FDA shall send the LTO for initial and renewal applications or the updated LTO for variation applications to the registered e-mail address of the applicant. The LTO may also be accessed through the FDA eServices Portal System.

Issued LTOs processed filed through this FDA Circular under the FDA eServices Portal System shall be provided an updated LTO number in the following format:
Old: **300000XXXXXX**
New: **CCHUHSRR- (Region)- HUHS- (Activity)- (Sequence Number)**

Upon receipt of the LTO, the establishment shall print the LTO on a standard A4 size (21 cm x 29.7 cm) paper, on full-colored page and in portrait orientation. It shall be positioned in the most conspicuous place within the business establishments.

b. If the application is disapproved, the FDA shall inform the applicant through its registered e-mail address of the reason for such action on the application.

VI. SEPARABILITY CLAUSE

The provisions of this FDA Circular are hereby declared separable and in the event of any such provision/s is/are declared invalid or unenforceable, the validity of enforceability of the remaining portions or provisions which are not affected, shall remain in full force and in effect.

VII. TRANSITORY PROVISIONS

All applications shall be filed online through the eServices Portal System upon the effectivity of this Circular. Applications filed through the FDA ePortal System prior the effectivity of this Circular shall be processed in accordance with DOH AO No. 2020-0017, FDA Circular No. 2023-006, and other applicable guidelines. Establishments with a valid LTO issued via FDA ePortal System shall be honored for the duration of its validity.

VIII. REPEALING CLAUSE

This Circular hereby repeals Section IV Items A (on licensing), E.1, E.2, Annex B and Annex C of FDA Circular No. 2023-006 entitled, "Updated Guidelines on the Filing and Submission of Applications for the Licensing and Registration of Household/Urban Hazardous Substances (HUHS) Establishment and Products, Respectively, through the FDA E-Portal V.2 System". Other related issuances inconsistent or contrary to the provisions of this Circular are hereby amended or modified accordingly.

IX. EFFECTIVITY

This FDA Circular shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing with the University of the Philippines – Office of the National Administrative Register (UP-ONAR). The provisions stipulated in this FDA Circular shall remain in effect unless otherwise revoked or repealed.

DR. SAMUEL A. ZACATE
Director General

ANNEX A
LTO Requirements for HUHS Establishments

The requirements originally provided under DOH AO No. 2020-0017 and FDA Circular No. 2020-025 as follows must be submitted:

A. Initial Application

1. Accomplished e-Application form with Declaration and Undertaking
    a. Proof of income (Latest Audited Financial Statement with Balance Sheet or Sworn Statement of Capital)
    b. Location Plan;
    c. Global Positioning System (GPS) Coordinates; and,
    d. Credentials of the Qualified Person
        i. PRC ID issued for professions with Board/Licensure Examination, or Diploma for profession without Board/Licensure Examination
        ii. Certificate of Attendance to seminars, training, learning and development activities on HUHS safety, quality and use

2. Proof of Business Name Registration
    a. For Single Proprietorship, Certificate of Business Registration issued by the Department of Trade and Industry (DTI)
    b. For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Security and Exchange Commission (SEC) and Articles of Incorporation
    c. For Government owned and Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the SEC and articles of Incorporation, if without original charter
    d. For Cooperatives, proof of Business Name Registration issued by the Cooperative Development Authority

3. Payment of Fees based on the latest FDA issuance

4. Business Permit (e.g., LGU/Mayor's Permit, Barangay Business Clearance/Permit) - if the business establishment address is different from the business name registration address.

5. Additional documents for HUHS establishments that maybe further request shall be presented to FDA specifically to all inspectorates during inspection, including the Risk Management Plan (RMP) and Site Master File (SMF).

B. Renewal Application

1. Accomplished e-Application Form with Declaration of Undertaking; and,
2. Payment of Fees based on the latest FDA issuance

C. Variation Application

1. Accomplished e-Application Form with Declaration of Undertaking;
2. Payment of fees; and,
3. Documentary requirements depending on the variation of circumstances of the establishment or the product:

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. Business Permit reflecting the new address 2. Updated Site Master File to be presented upon inspection
Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity • Expansion shall refer to expansion made which is adjacent to be existing location of the establishment • Additional product line shall refer to additional type or class of products produced within the same manufacturing site • Change in manufacturing activity shall refer to an additional activity that manufacturer engages in. (e.g. LTO as Repacker to Manufacturer)	Updated Site Master File to be presented upon inspection

b. Minor Variation

Type of Variation	Document Requirement
Transfer of Location of Offices • Physical transfer of the office of the establishment	Proof of business address reflecting the new office location: 1. For Single Proprietorship: Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location; 2. For Securities and Exchange Commission (SEC)-registered establishments: a. Amended Articles of Incorporation (if transferred from one city/municipality/province; or, b. Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality/province) 3. 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

Change of Distributor Activity • Shall refer to an additional/deletion of/change in activity that the distributor engage in	Contract Agreements showing change in activity
Transfer/addition of Warehouse • Physical transfer and addition of warehouse of the establishment	Mayor's Permit or Barangay Business Permit/Clearance reflecting new warehouse location
Expansion of Office Establishments • Shall refer to expansion made which is adjacent to the existing location of the establishment	Expansion floor plan
Change of Ownership • Change in ownership of the licensed establishment	1. Business name registration reflecting new ownership 2. Any proof on 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; or c. Notarized Affidavit of the owner, proprietor, Chairman or Chief Executive Officer (CEO) of the establishment validating the transfer
Change of Business Name • Change only in the business name of the establishment	Business name registration reflecting new business name
Zonal Change in Address • Change of the name/number of the street/building without physical transfer of the establishment	1. Certificate of Zonal Change 2. Certification from Local Government Unit (LGU) (City/Municipality) stating no physical transfer of the establishment
Change of Qualified Person[1] • Change in the identified qualified person initially registered with the FDA	1. Name of new Qualified Person 2. Valid Professional Regulation Commission (PRC) ID 3. Signed Letter of Resignation duly noted by the former employer, if previously connected with another pharmacy/establishment
Change of Authorized Person • Change of authorized person initially registered with the FDA	1. Name of new Authorized Person 2. Valid Government ID 3. Updated contact details

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[1]The qualification and training requirements of the Qualified Person shall be in accordance with the existing guidelines under DOH AO No. 2020-0017 as follows:

Qualification	Training Requirements
Any licensed allied health professional	1. PRC ID for professions with Board/Licensure Exam or Diploma for profession without Board/Licensure Exam; and,

	2. Certificate 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 (World Health Organization, International Organization for Standardization), FDA Academy

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ANNEX B
Procedure in the Submission of an Initial LTO Application

A. Procedure outline

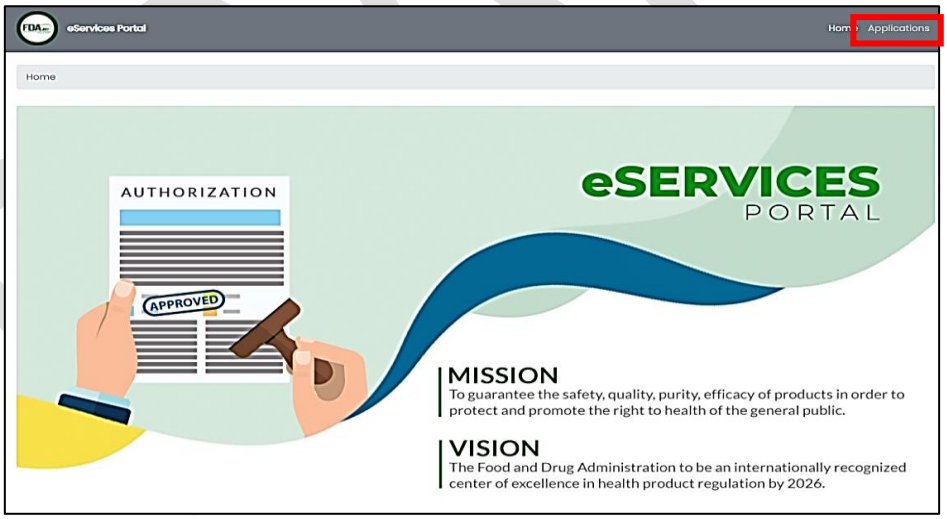
1. Accessing and navigating the FDA eServices Portal System
2. Filing an application
   a. Page 1: Declaration and Undertaking
   b. Page 2: General Information
   c. Page 3: Product Line *(For Manufacturer Only)*
   d. Page 4: Establishment Information
   e. Page 5: Office Address
   f. Page 6: Warehouse Address
   g. Page 7: Plant Address *(For Manufacturer Only)*
   h. Page 8: Details of Authorized Person
   i. Page 9: Details of Qualified Person
   j. Page 10: Documentary Requirements
   k. Page 11: Self-assessment Review

B. Step-by-step procedure

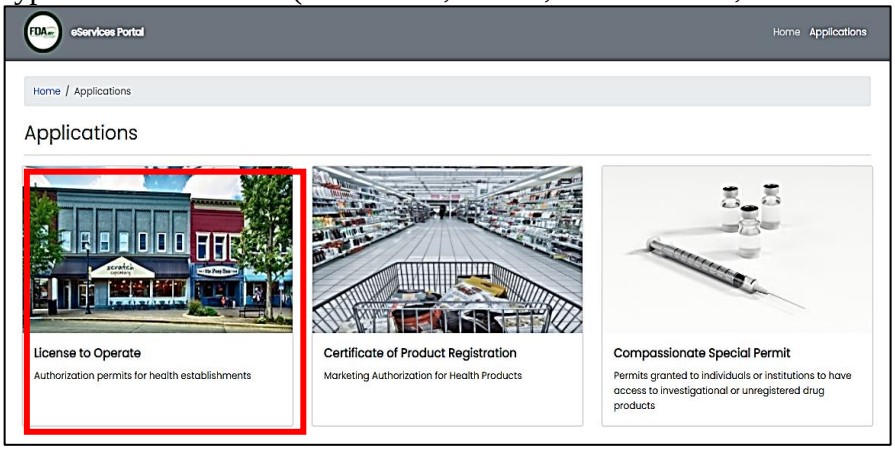
Follow the steps outlined below in order to submit an initial HUHS LTO application.

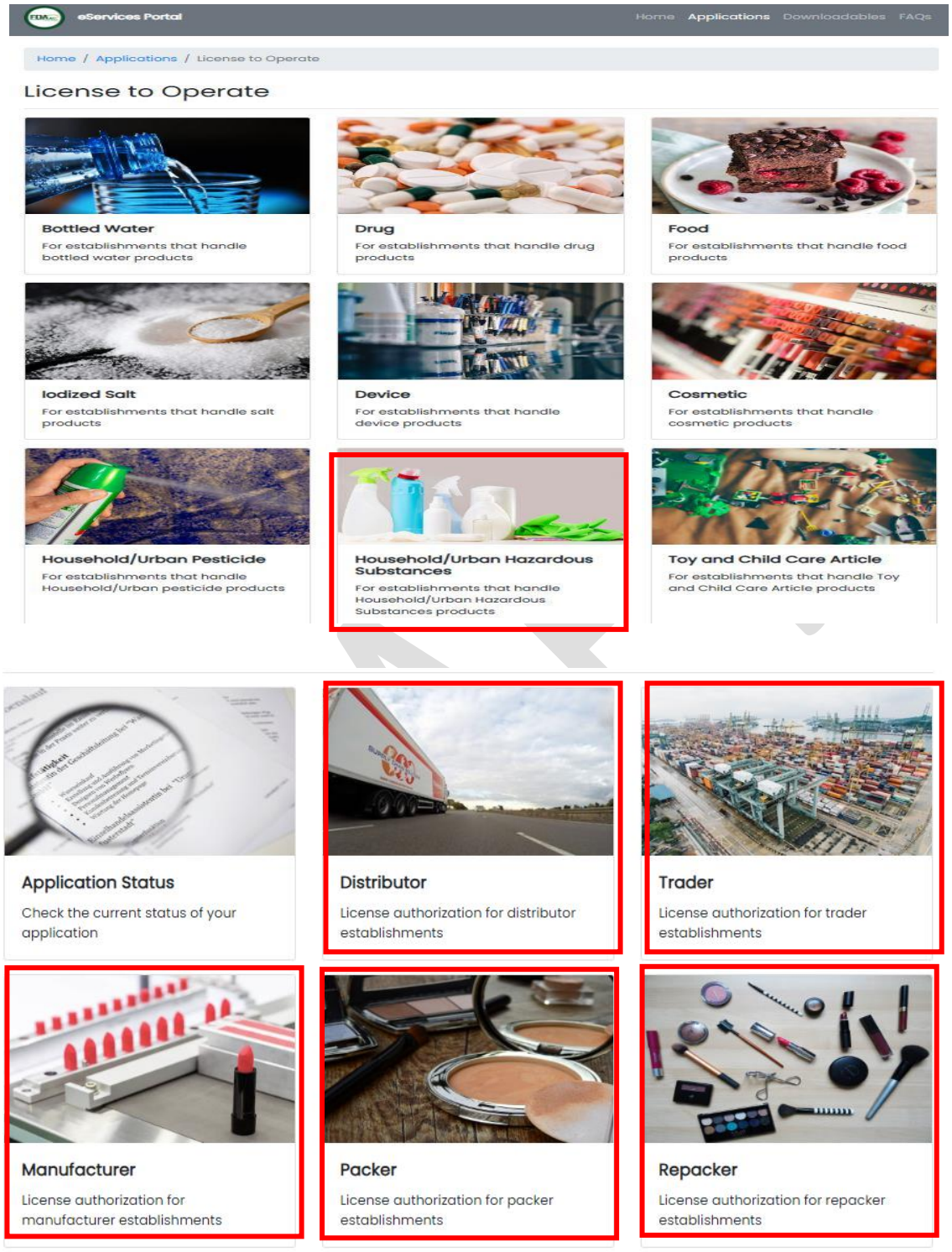
1. Accessing and navigating the FDA eServices Portal System

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)



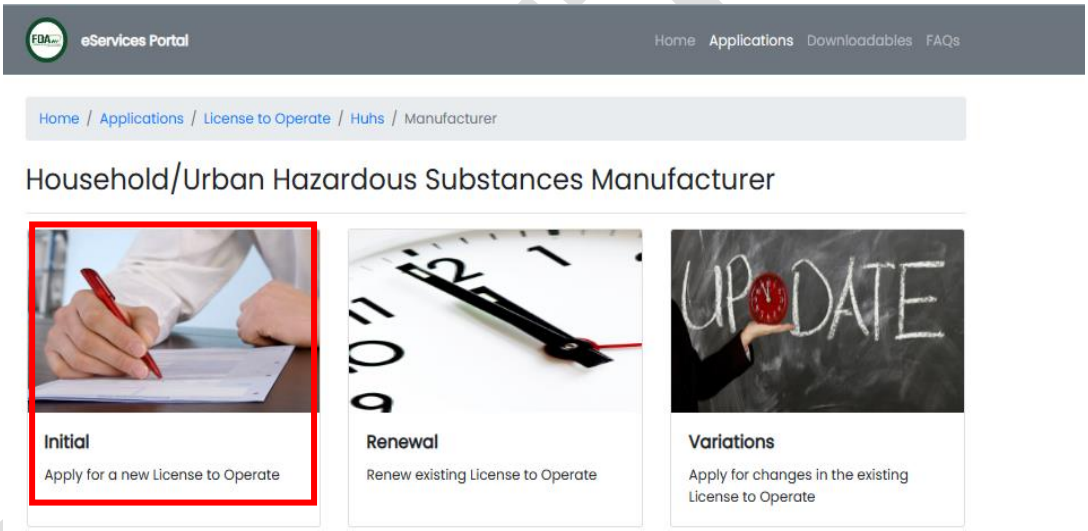


i. Select the primary activity the applicant intends to engage in which may be one of the following:

- **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. If the distributor sell to the general public, it shall be considered a retailer.

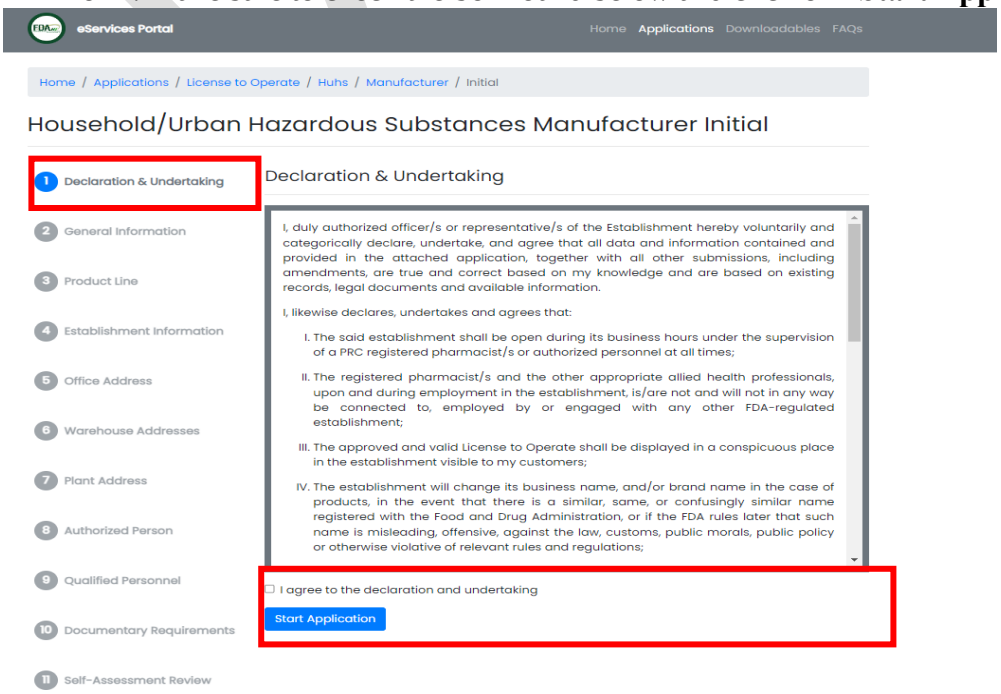
c. Click the Initial Application.



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: General Information**

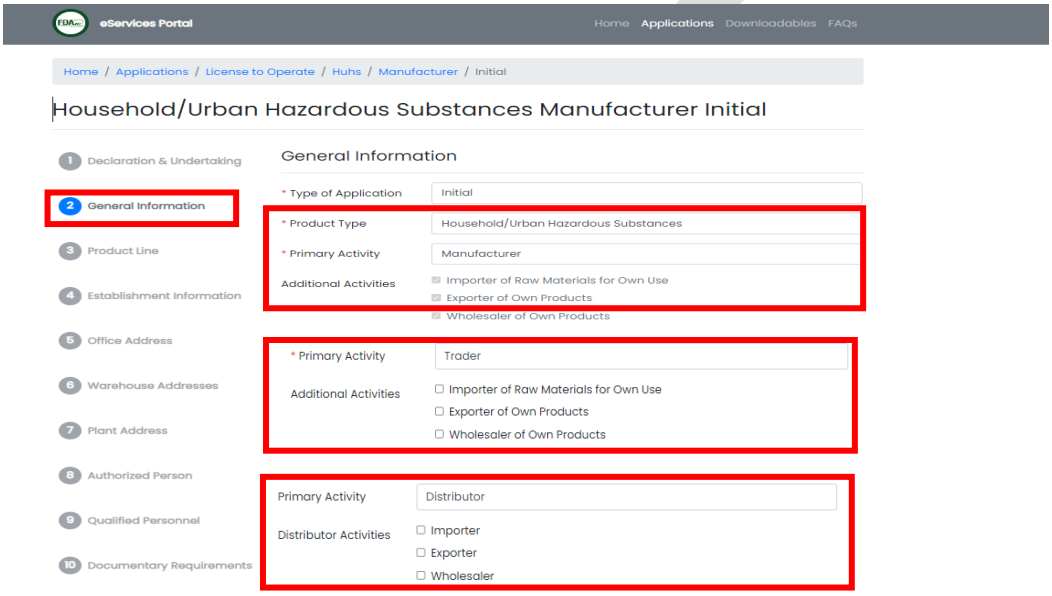
Fill out the necessary information accurately based on establishment's activity/ies. Make sure to properly tick the corresponding activity/ies before proceeding onto the next step.

1.1. Manufacturer and Trader Activities

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

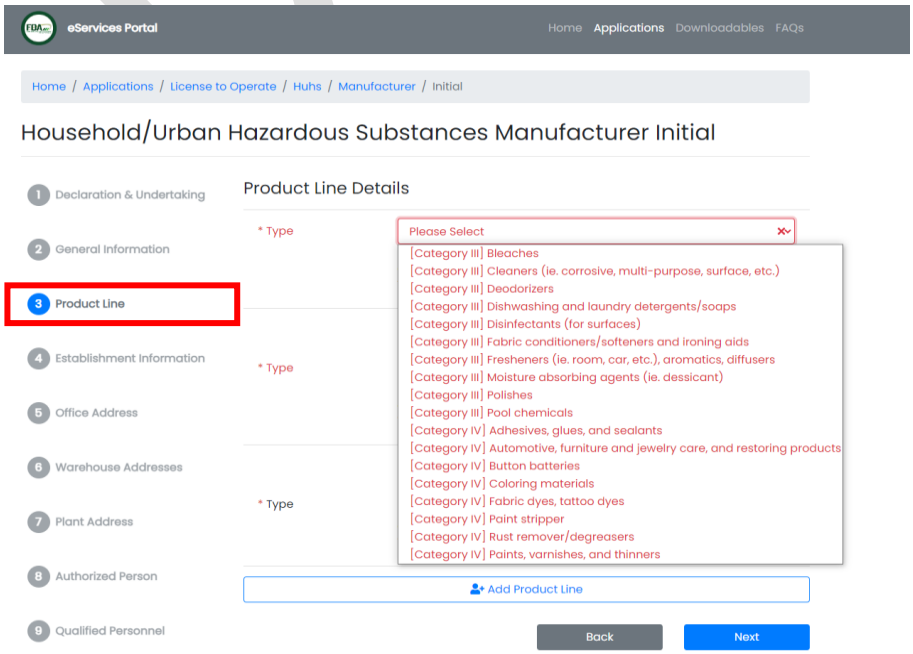
1.2. Distributor Activities

- Importer
- Exporter
- Wholesaler



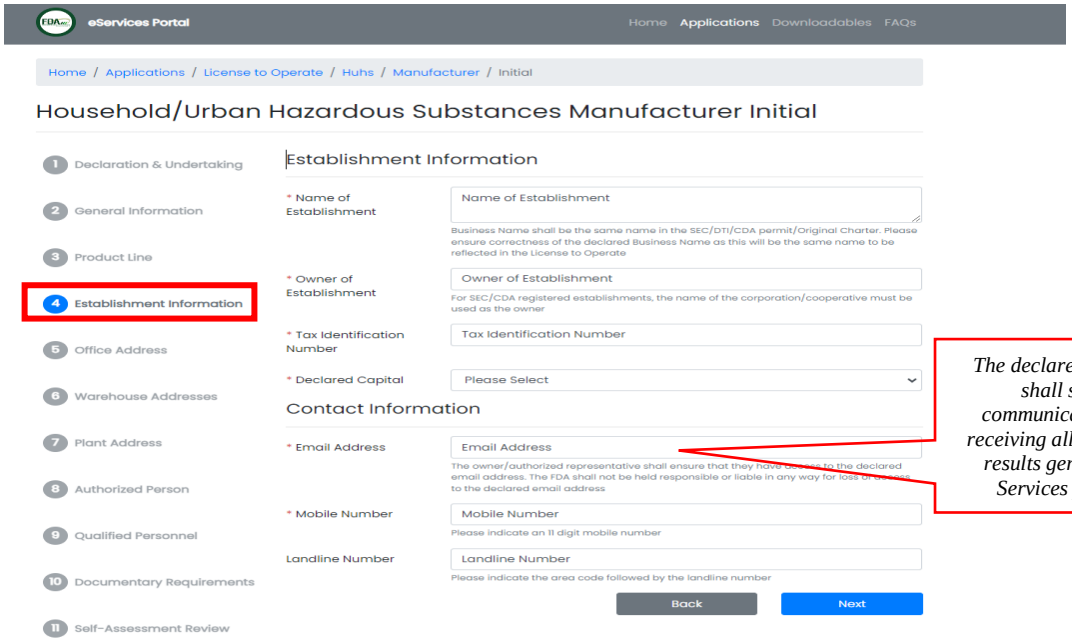
c. **Page 3: Product Line (For Manufacturer Only)**

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 that one (1) Product Line click "**Add Product Line",** then click **"Next"**.



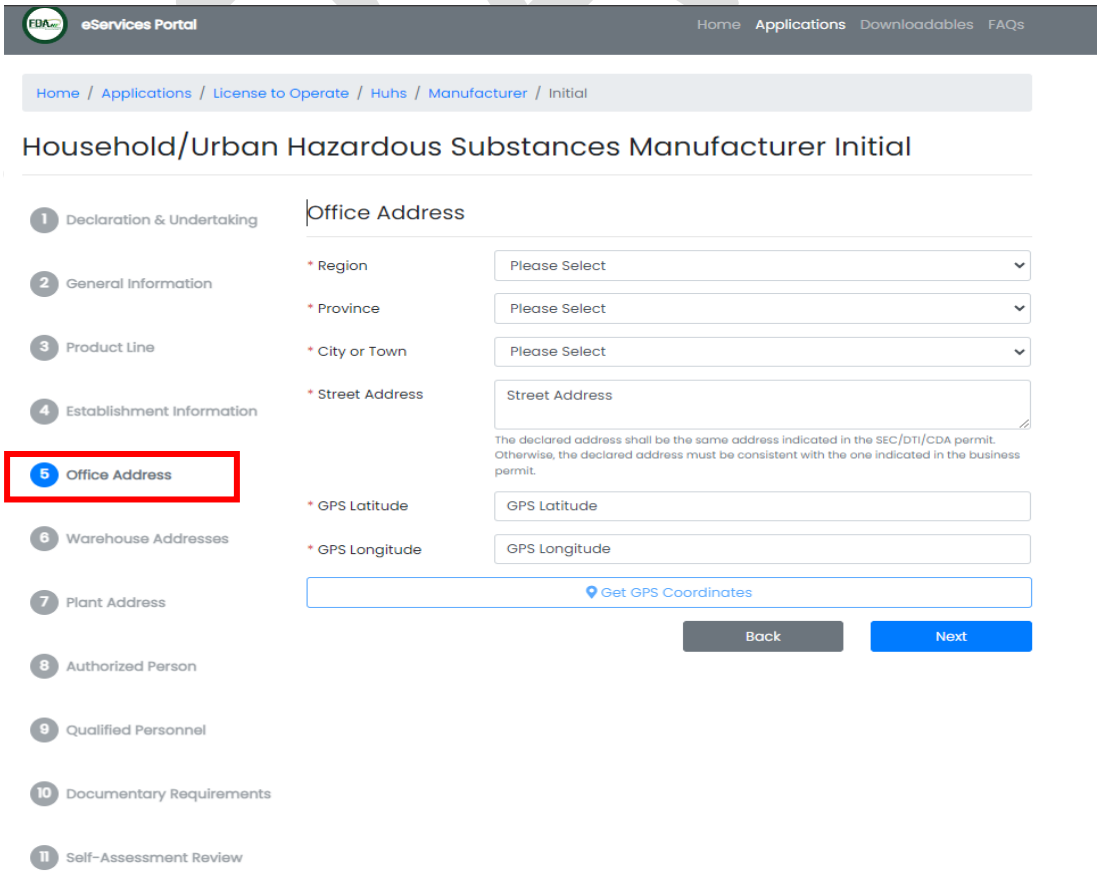
d. **Page 4: Establishment Information**

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



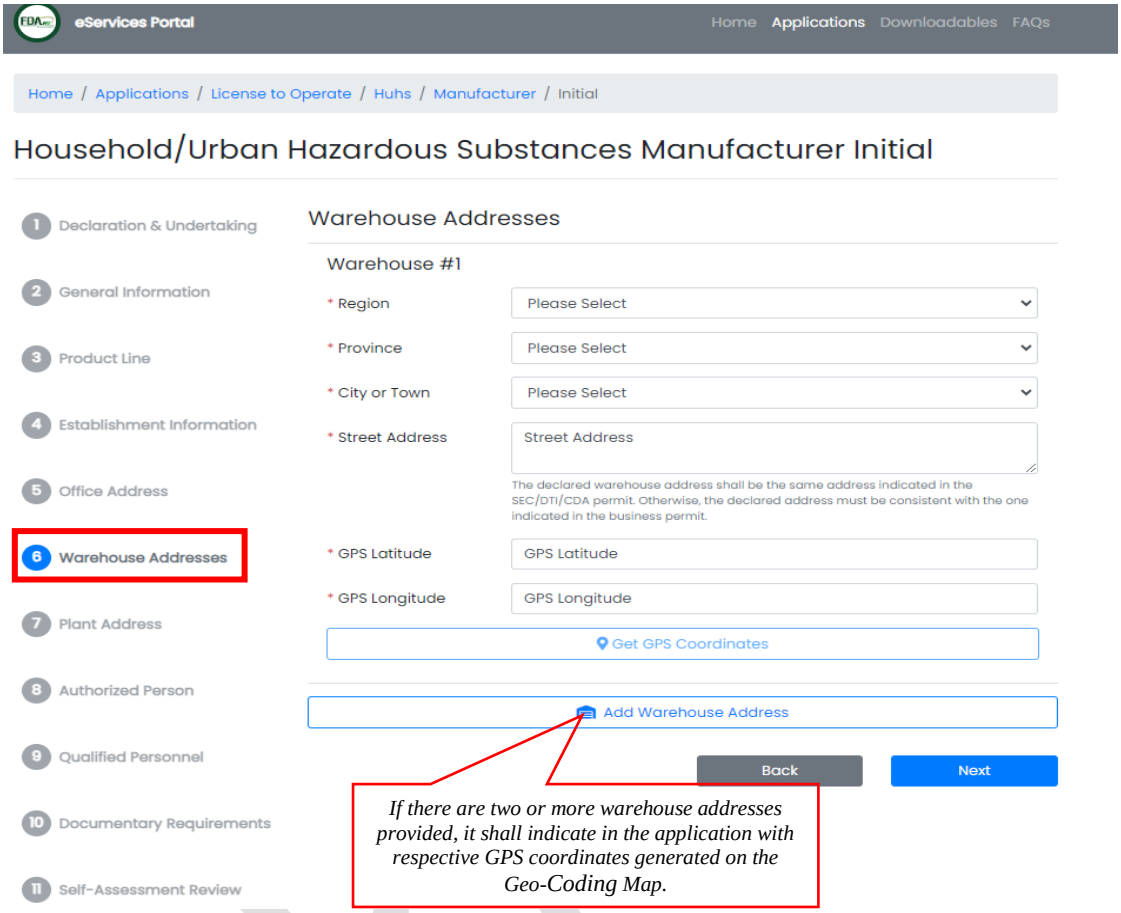
e. **Page 5: Office Address**

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.



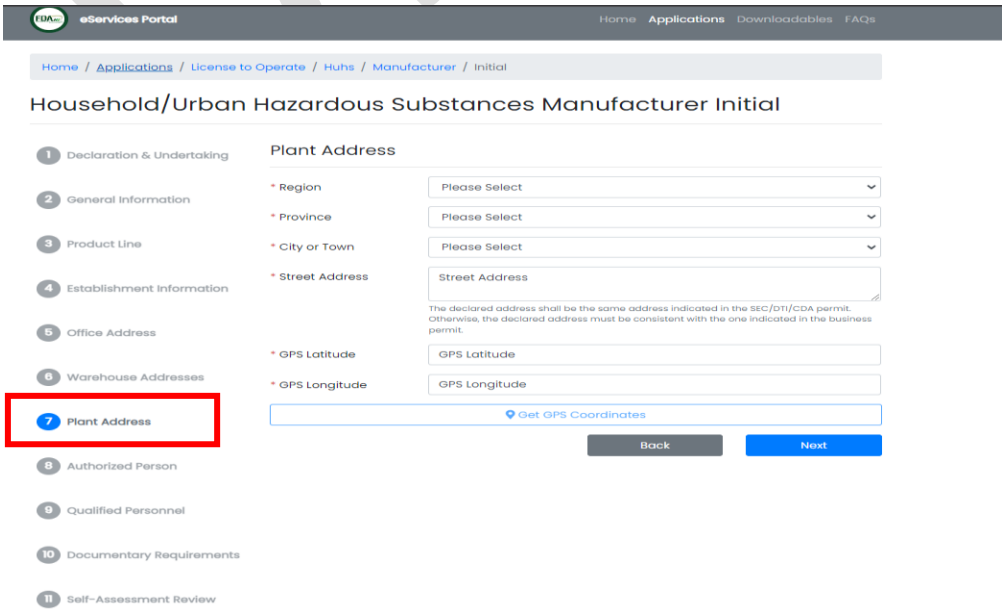
f. **Page 6: Warehouse Address**

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.



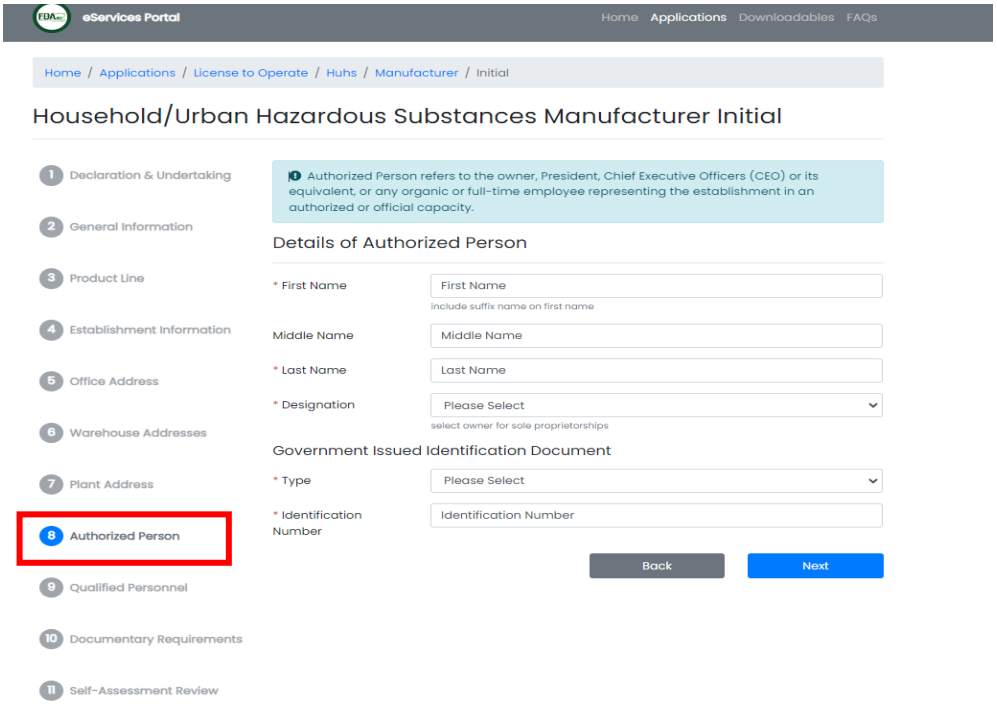
g. **Page 7: Plant Address (For Manufacturer Only)**

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.



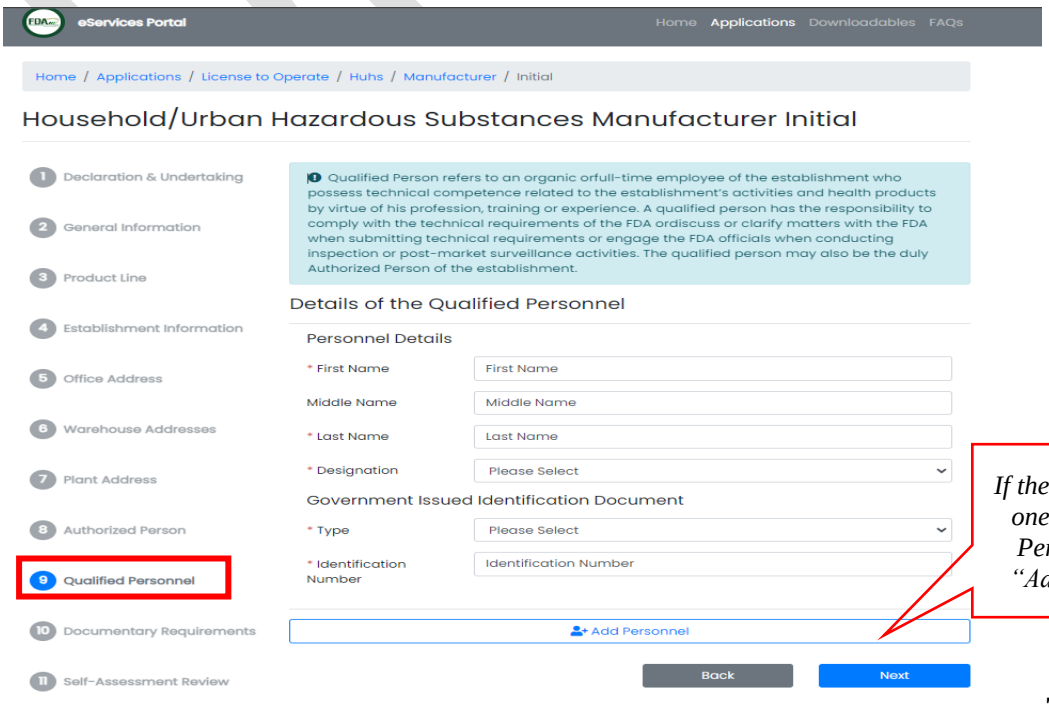
h. **Page 8: Details of Authorized Person**

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.



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

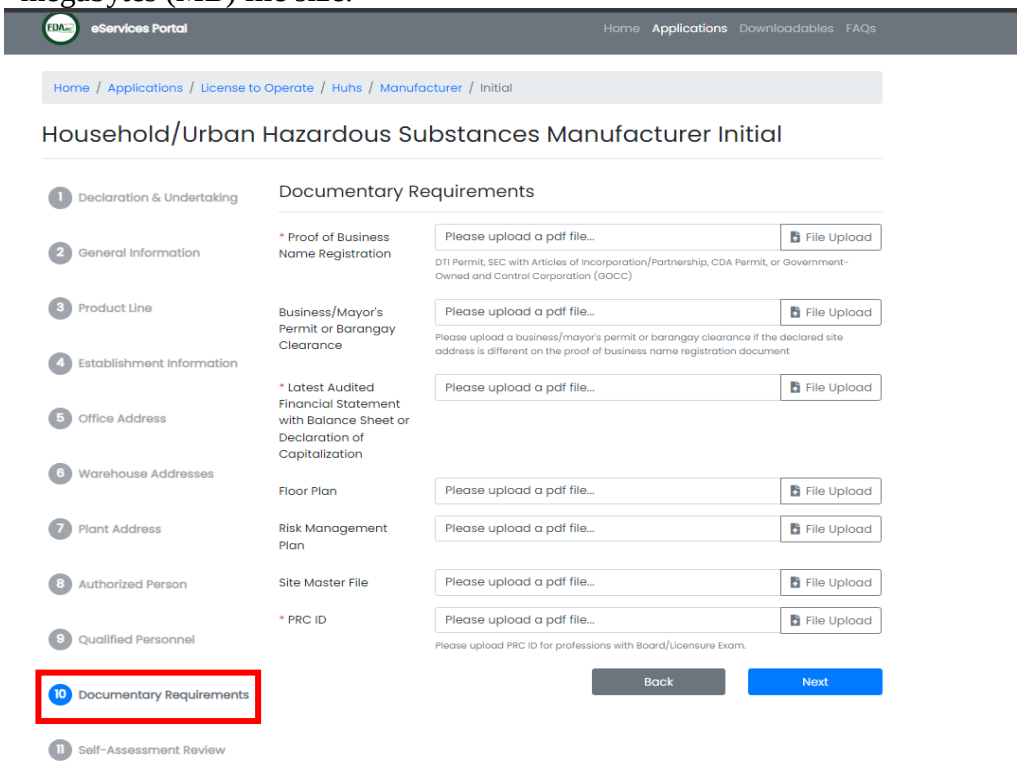
Qualified Person refers to an organic or full-time employee of the establishment who possess technical competence related to the establishment's activities and health products by virtue of his profession, training or experience. A qualified person has the responsibility to comply with the technical requirements 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.



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.



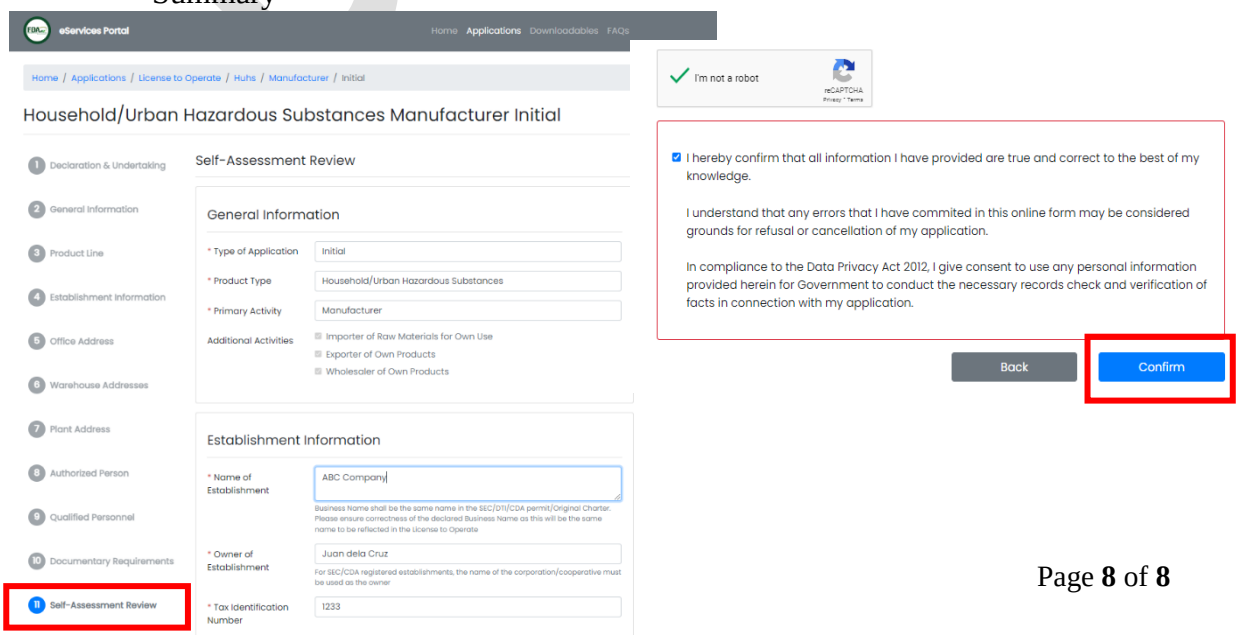
k. **Page 11: Self-Assessment Review**

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



ANNEX C
Procedure in the Submission of Renewal LTO Application

A. Procedure outline

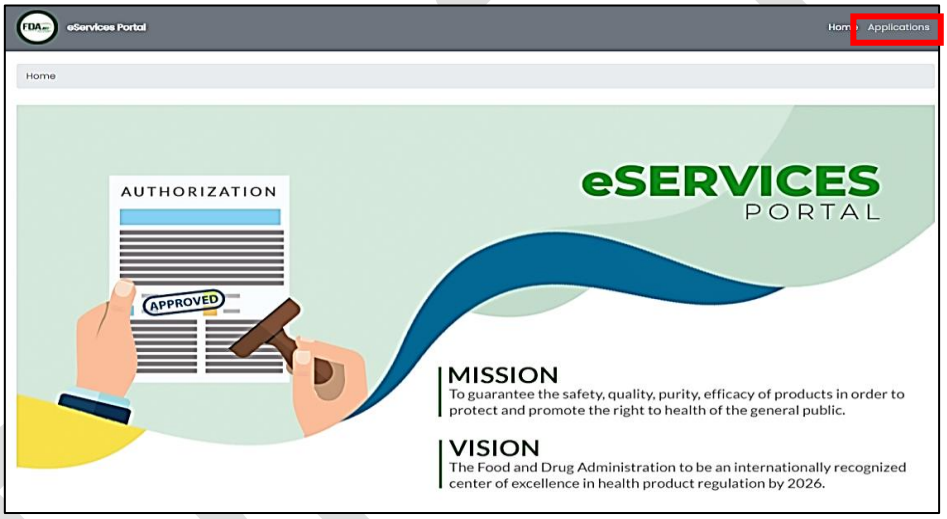
1. Accessing and navigating the FDA eServices Portal System
2. Filing an application
   a. Page 1: Declaration & Undertaking
   b. Page 2: License to Operate
   c. Page 3: Contact Information
   d. Page 4: Self-Assessment Review

B. Step-by-step procedure

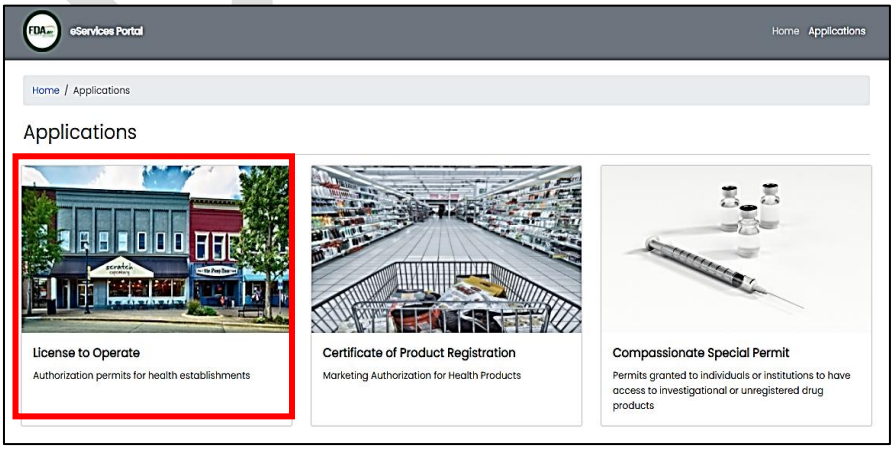
Follow the steps outlined below in order to submit a renewal HUHS LTO application.

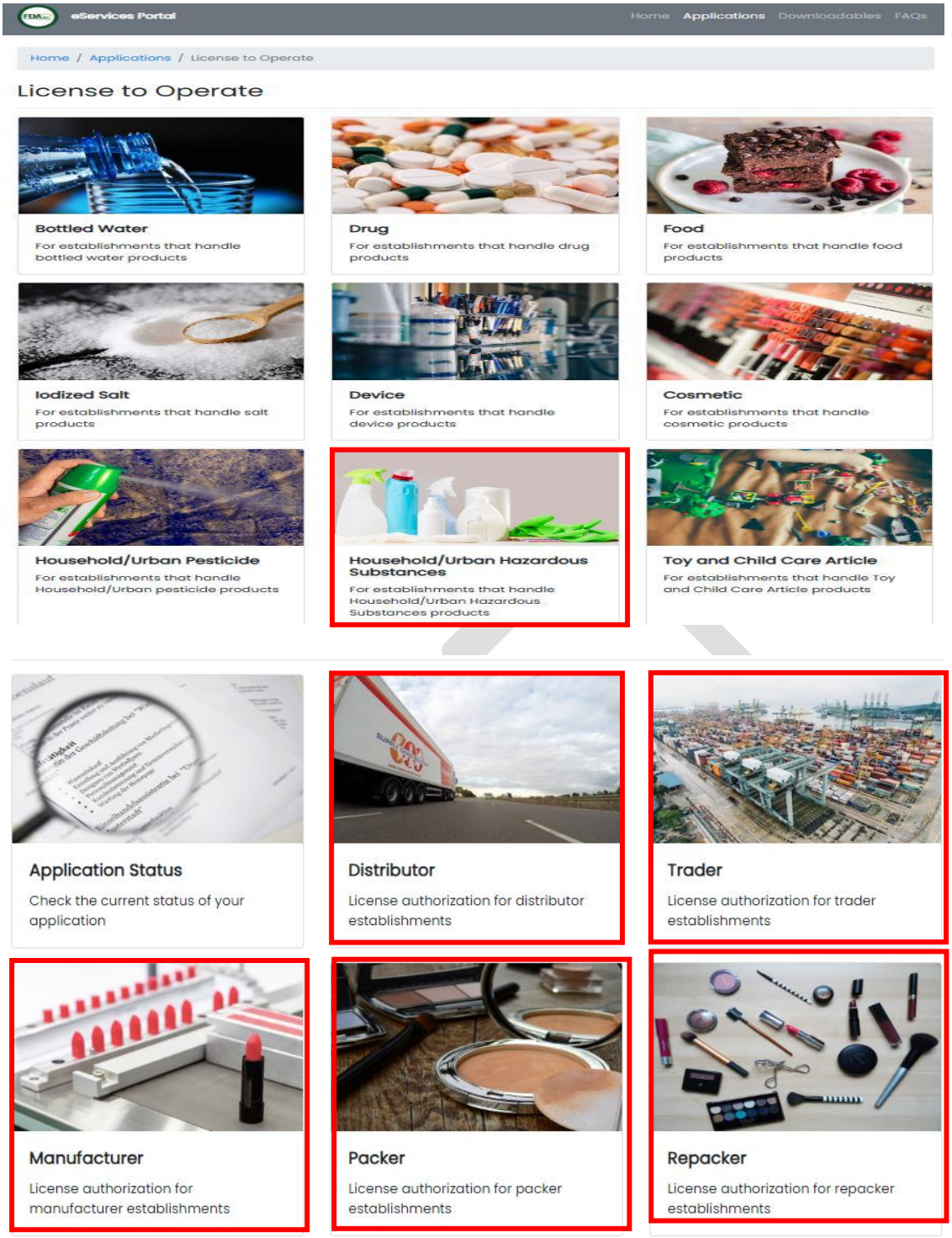
1. Accessing and navigating the FDA eServices Portal System

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)



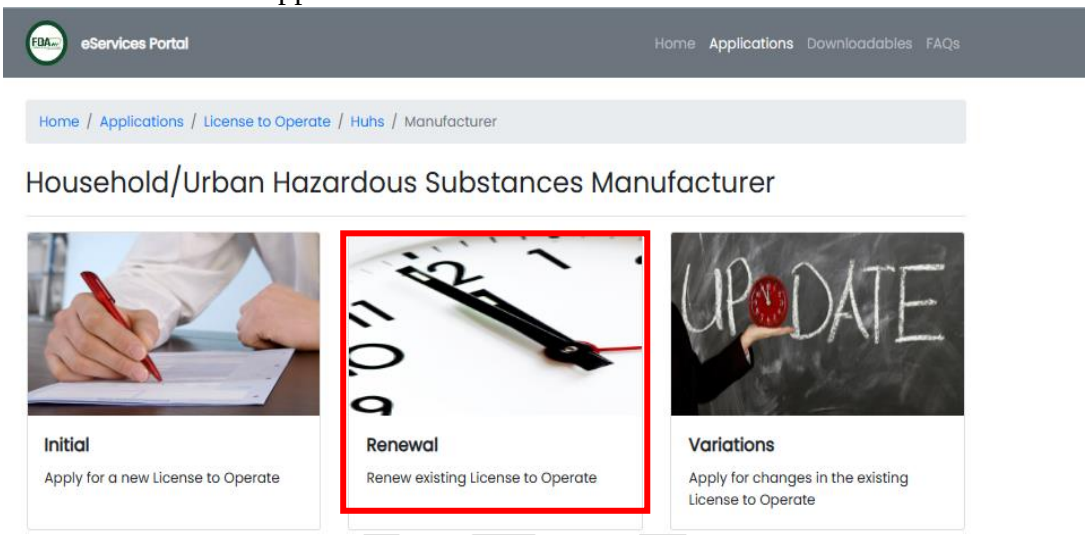


i. Select the primary activity the applicant intends to engage in which may be one of the following:

- **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. If the distributor sell to the general public, it shall be considered a retailer.

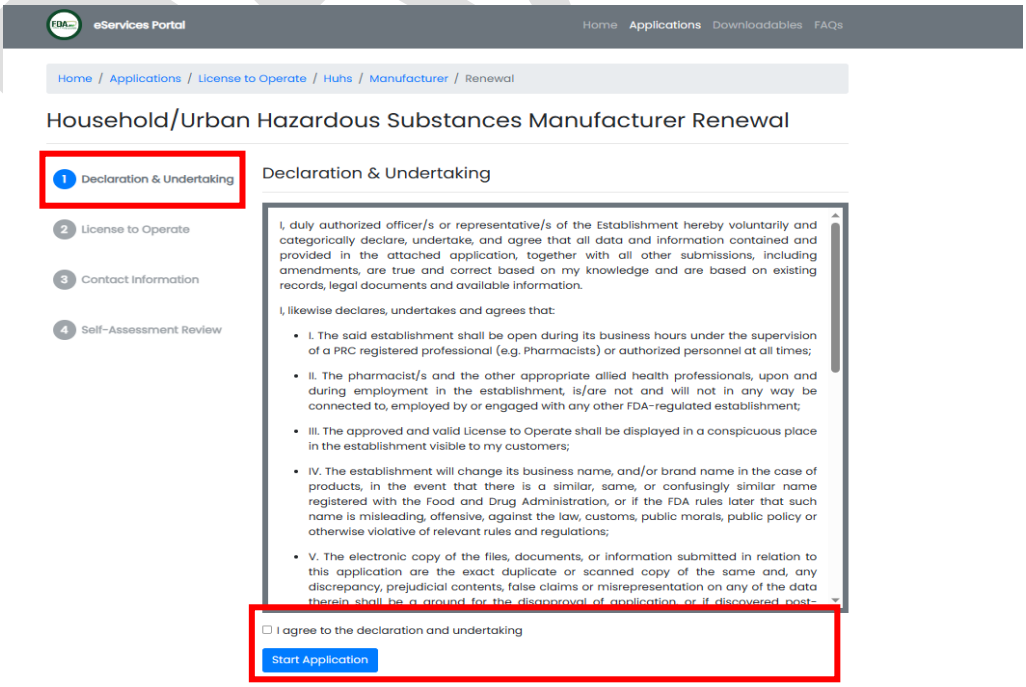
c. Click the Renewal Application.



2. Filing an application

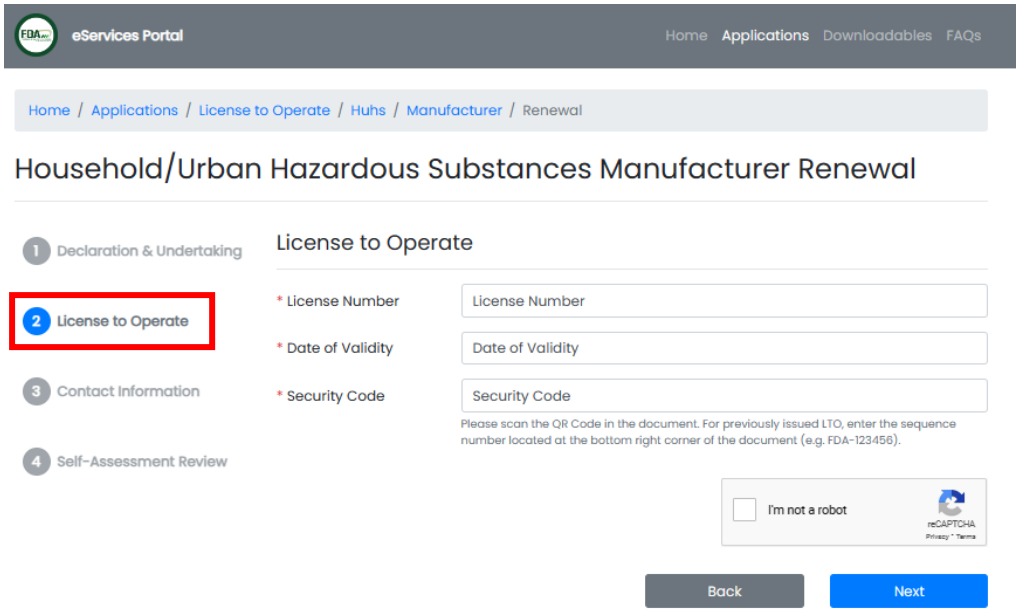
a. **Page 1: Declaration & Undertaking**

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"**.



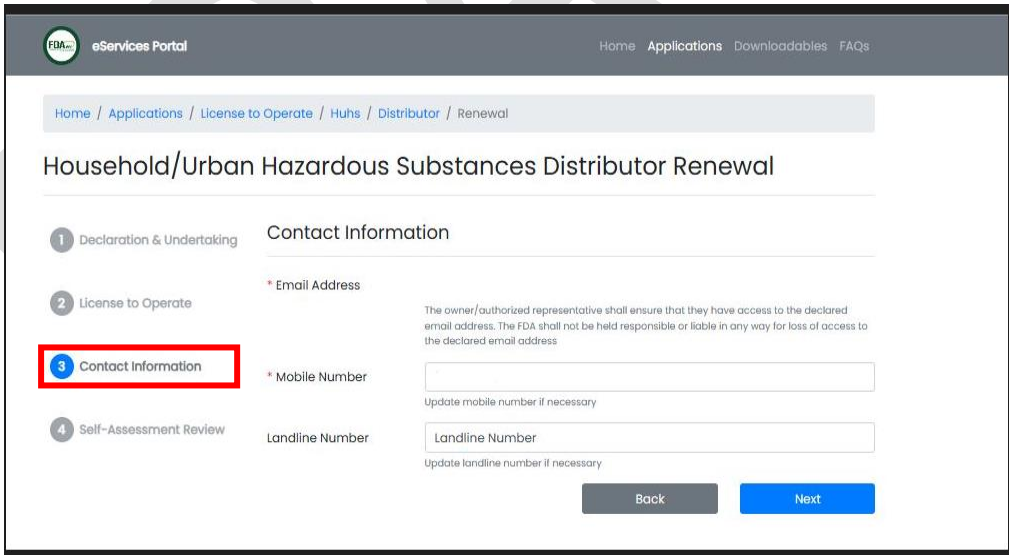
b. **Page 2: License to Operate**

Provide the existing LTO Number, Validity Date, 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.



c. **Page 3: Contact Information**

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

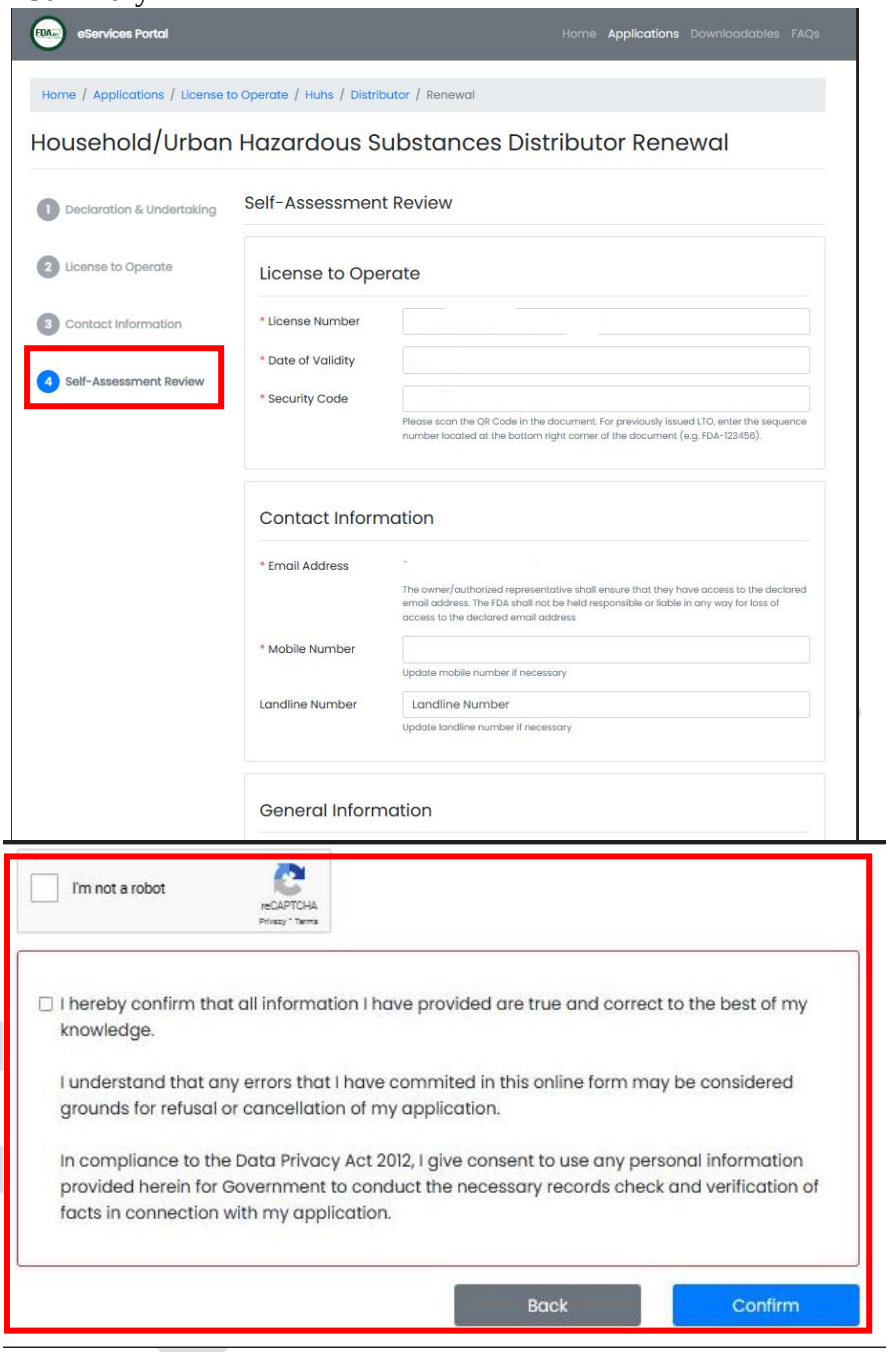


d. **Page 4: Self-Assessment Review**

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 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



ANNEX D
Procedure in the Submission of Variation LTO Application

A. Procedure outline

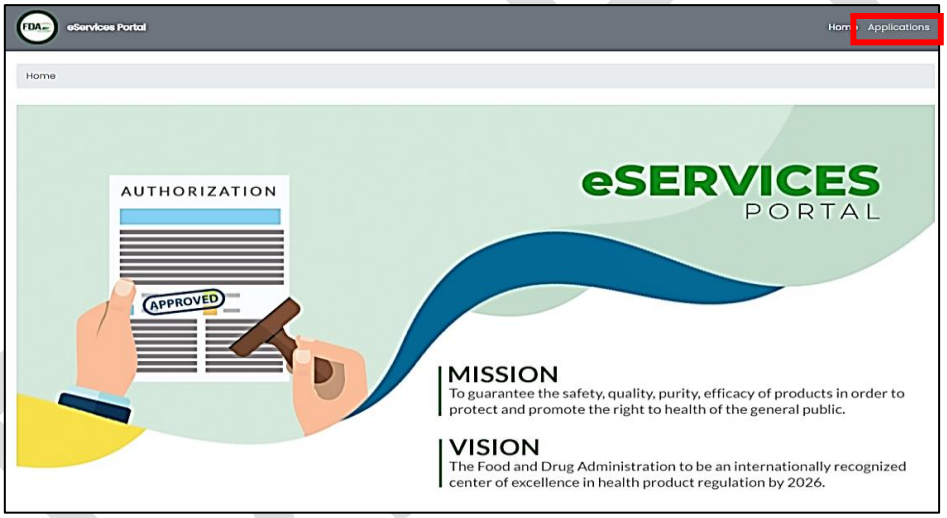
1. Accessing and navigating the FDA eServices Portal System
2. Filing an application
   a. Page 1: Declaration & Undertaking
   b. Page 2: License to Operate
   c. Page 3: Contact Information
   d. Page 4: Type of Variation
   e. Page 5: Self-Assessment Review

B. Step-by-step procedure

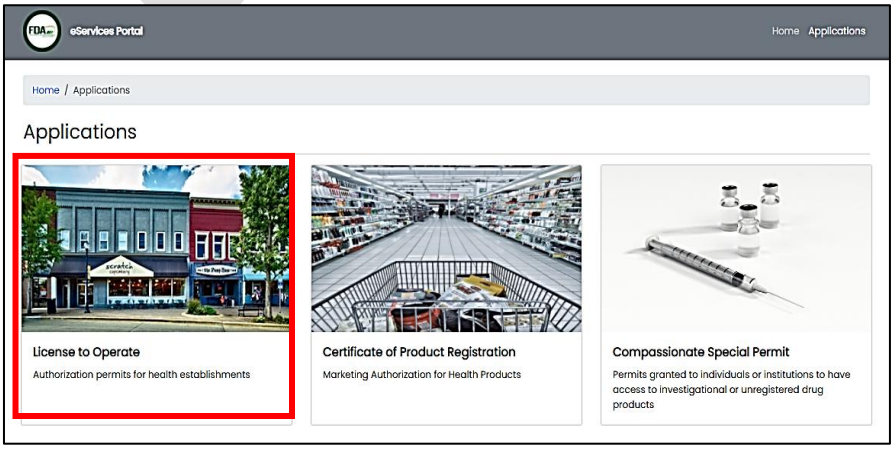
Follow the steps outlined below in order to submit a renewal HUHS LTO application.

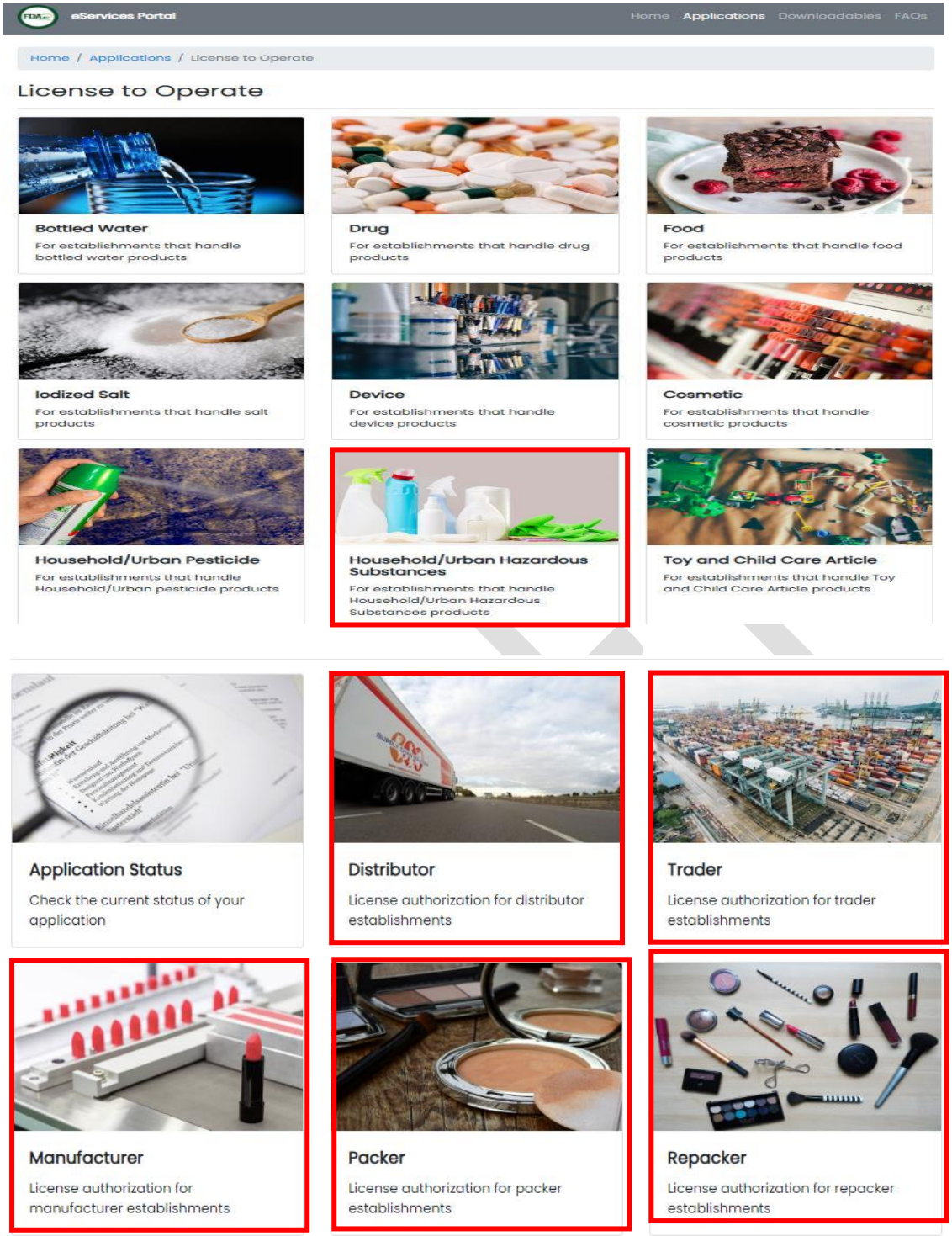
1. Accessing and navigating the FDA eServices Portal System

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)



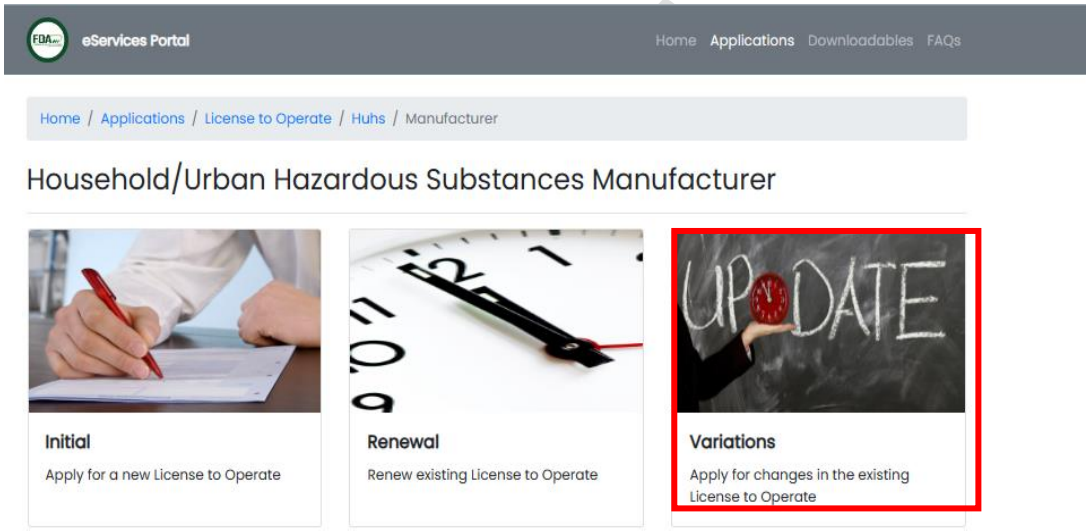


i. Select the primary activity the applicant intends to engage in which may be one of the following:

- **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.

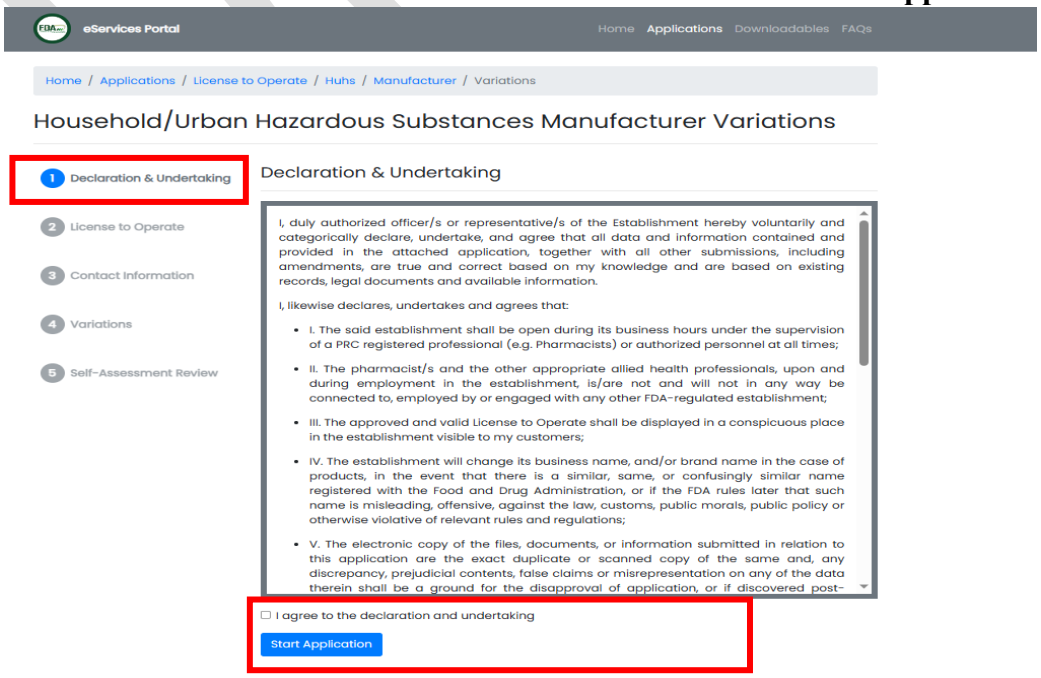
- **Trader**- An establishment which is a registered owner of a HUHS product and procures the raw materials and packing components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such product to a licensed manufacturer.
- **Distributor**- 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. If the distributor sell to the general public, it shall be considered a retailer.



2. Filing an application

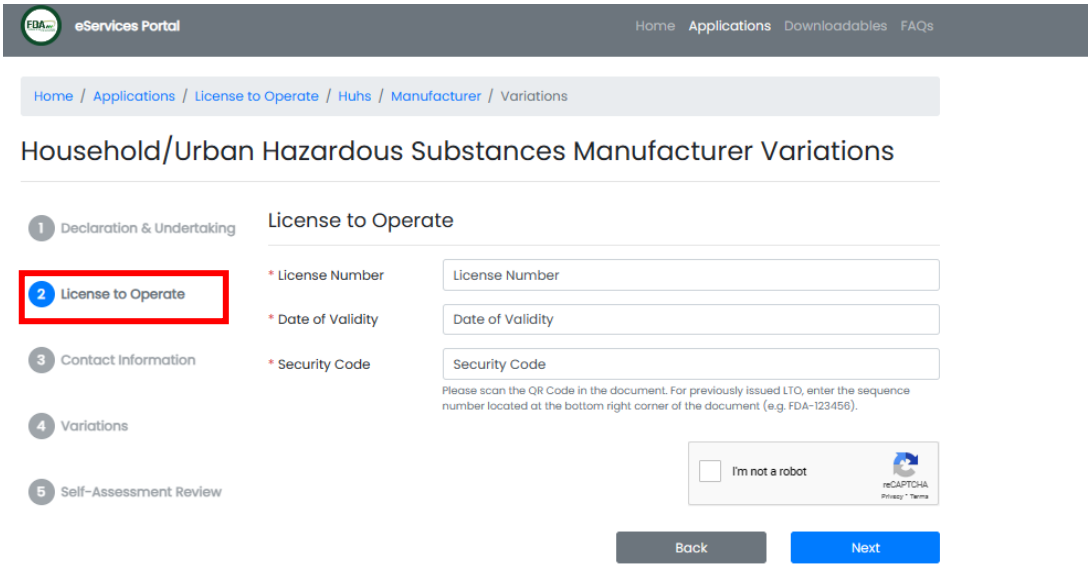
a. **Page 1: Declaration & Undertaking**

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"**.



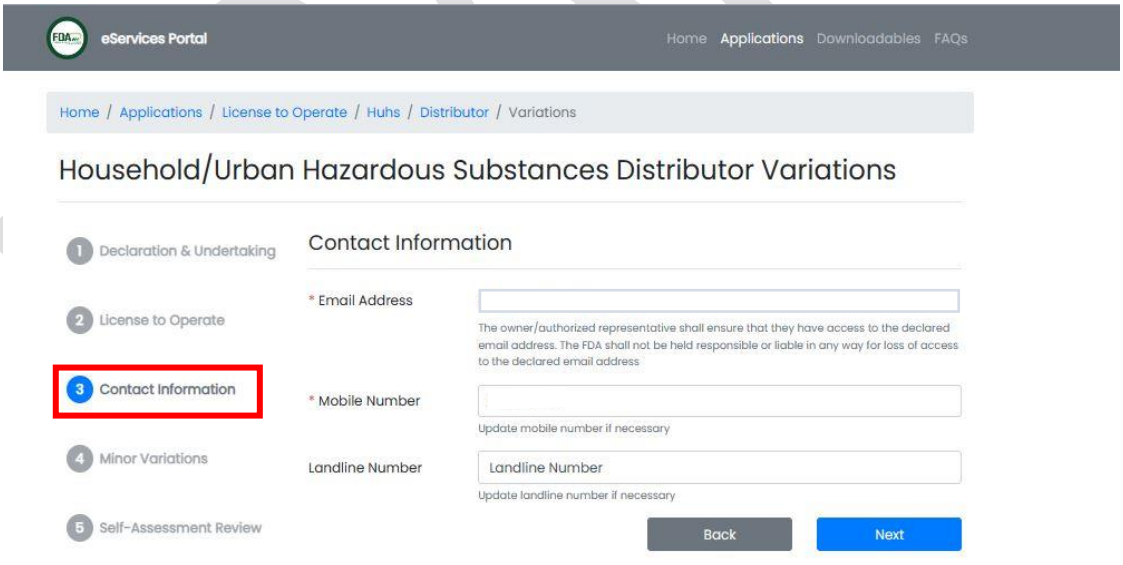
b. **Page 2: License to Operate**

Provide the existing LTO Number, Validity Date, 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.



c. **Page 3: Contact Information**

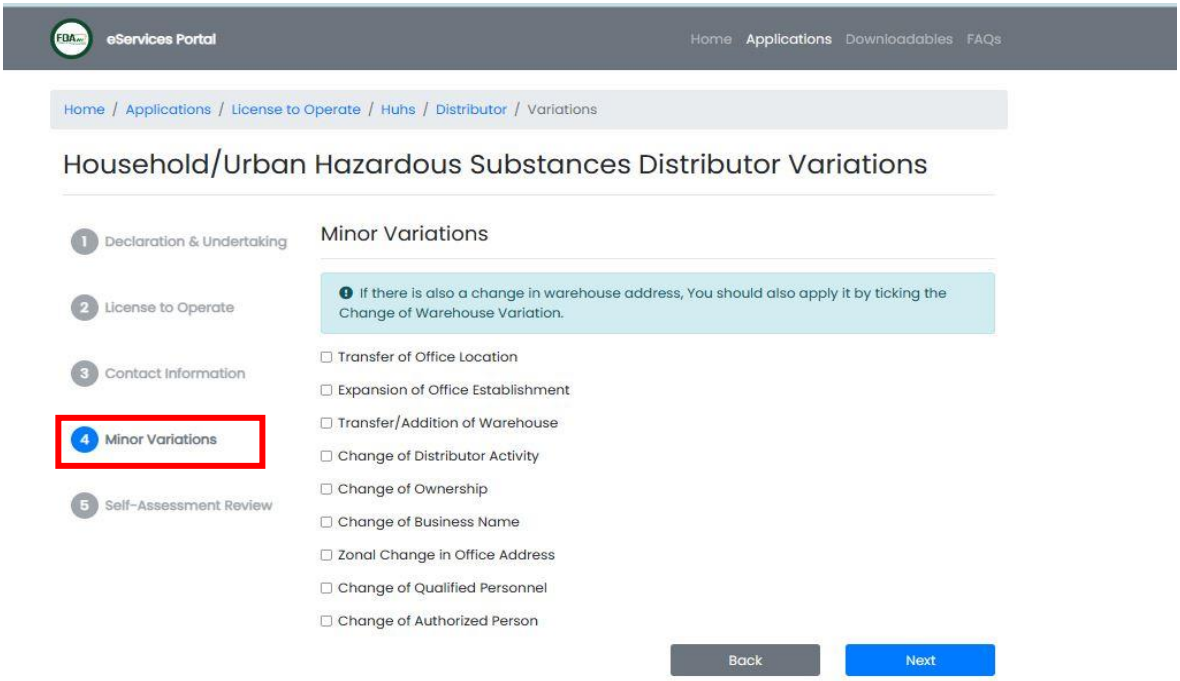
Provide an updated contact information if applicable. Click **"Next"** to proceed.



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.

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



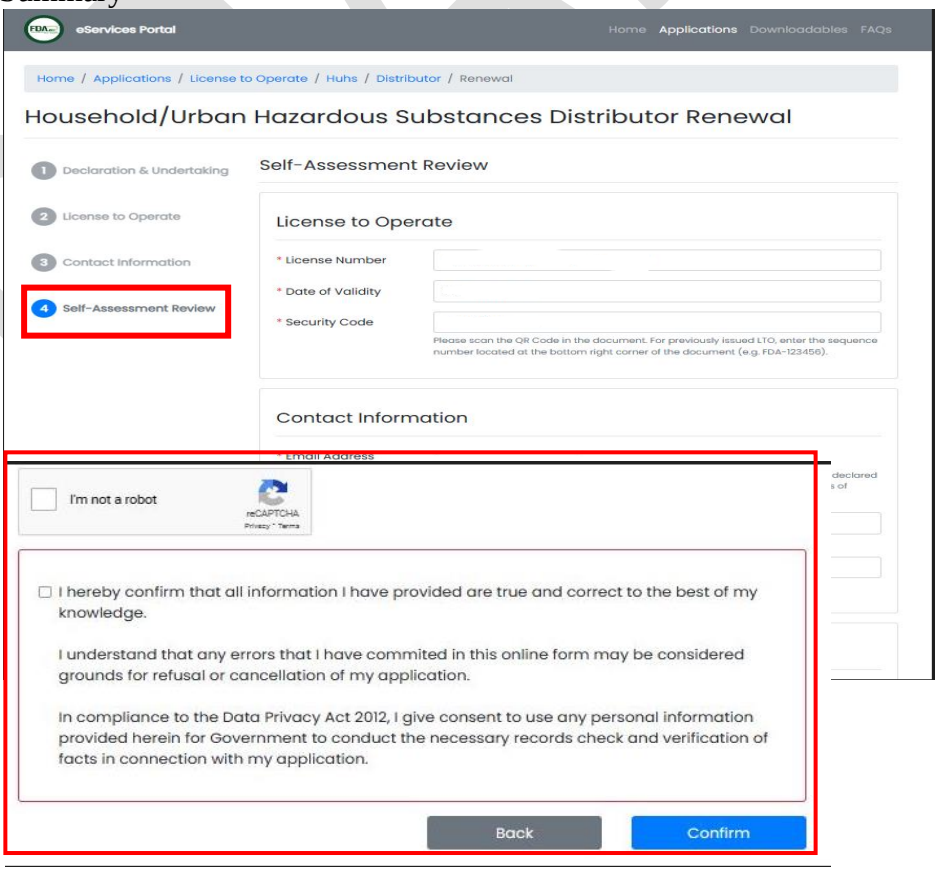
e. **Page 5: Self-Assessment Review**

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

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

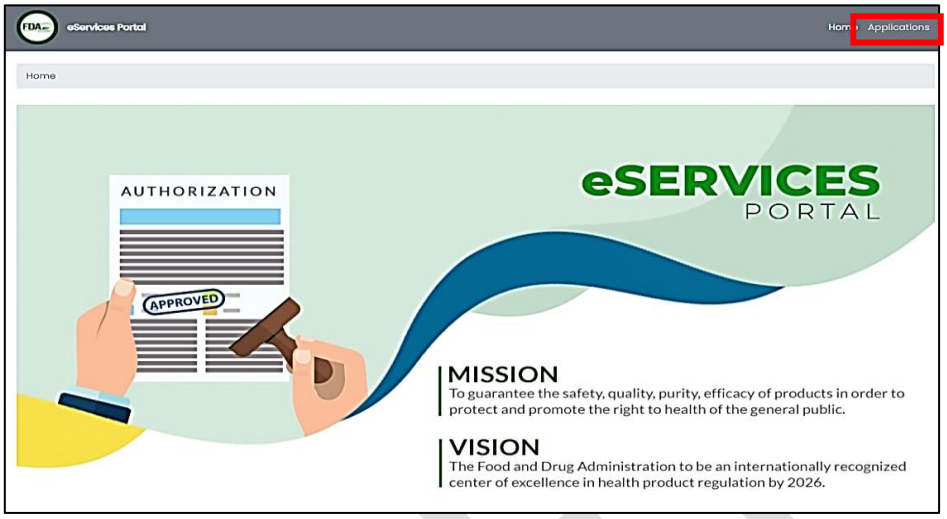
iii. After the self-assessment review, the applicant shall confirm the correctness of the data and uploaded documents. Tick **"I'm not a robot"**, **Data Privacy Act declaration** and click the **"Confirm"** submit the application.

iv. Auto-generated electronic email will be sent containing the Application Summary

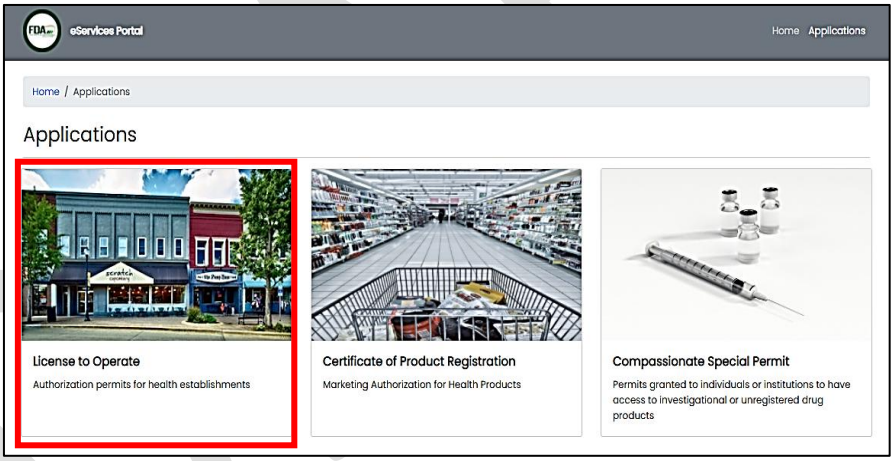


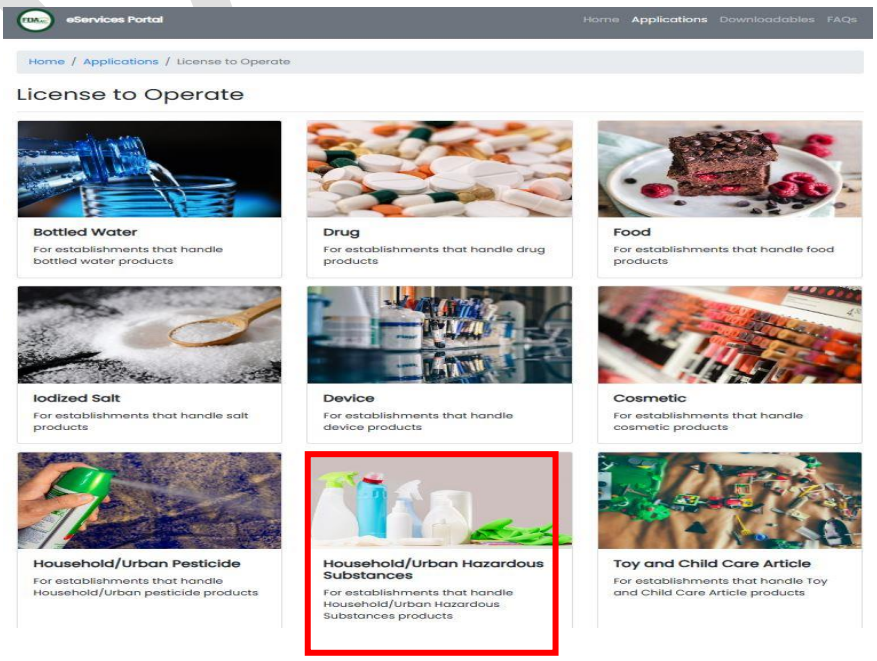
ANNEX E
Procedure for Checking the Status of an Application

1. Access the online portal through (https://eservices.fda.gov.ph/) and click **"Applications"** found on the upper right corner of the eServices landing page.

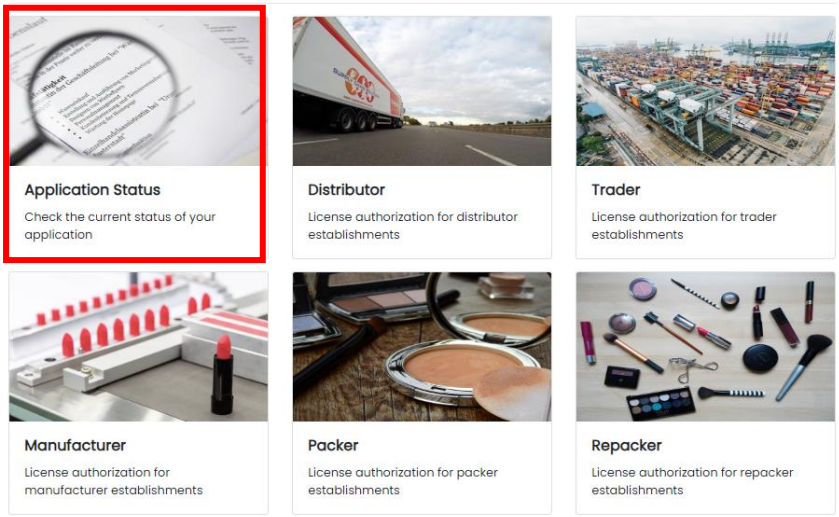


2. Click the License to Operate for Household/Urban Hazardous Substances

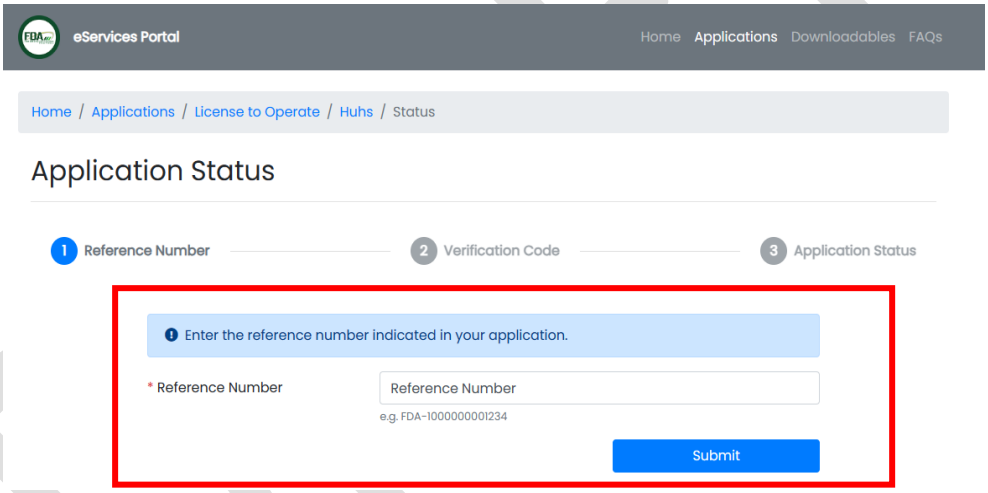




3. To check the status of the application, click **"Application Status".**



4. Enter the Reference Number and click on **"Submit"**

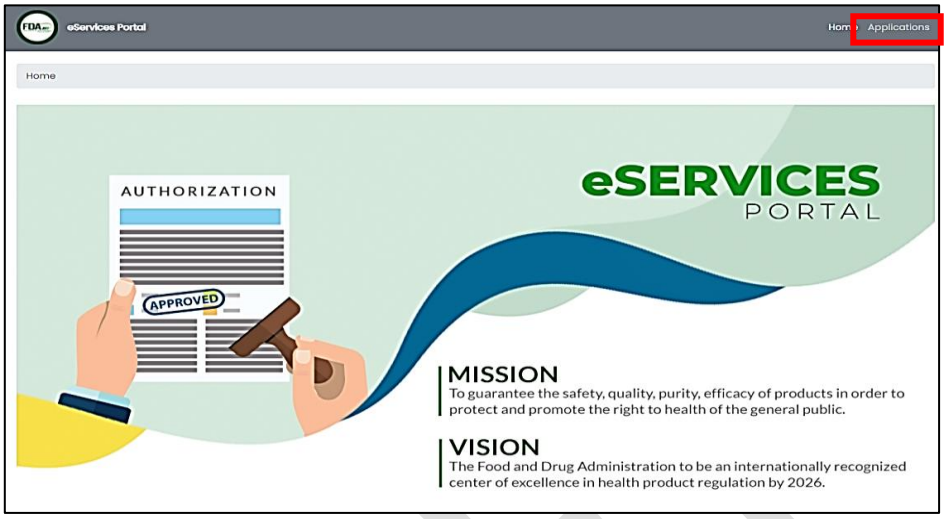


5. A verification code will be sent to applicant's registered e-mail address.

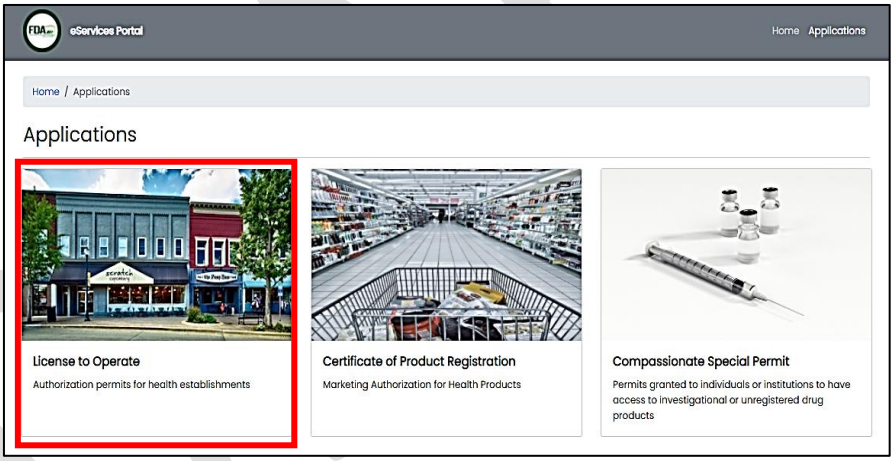
6. Enter the verification code to view the progress.

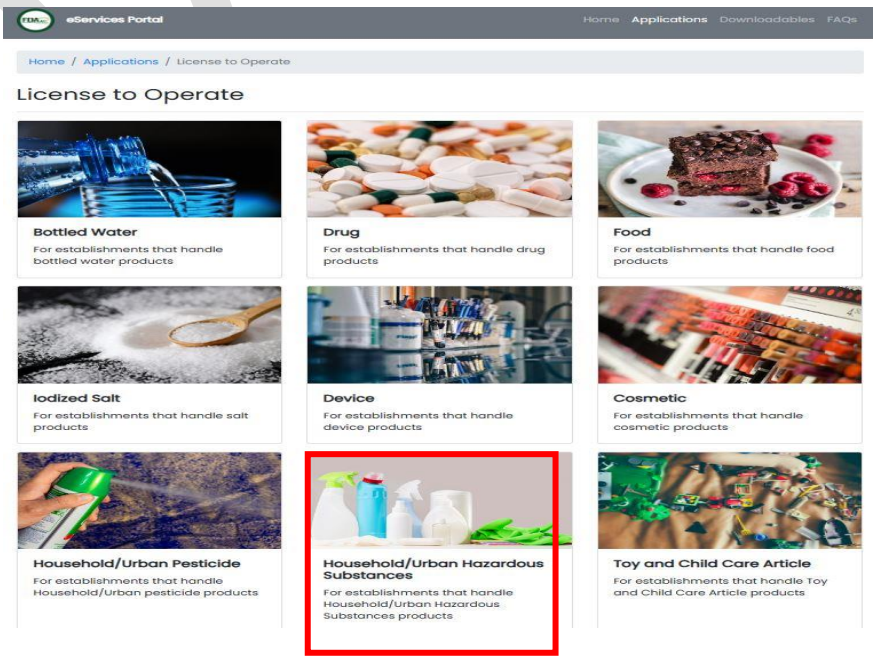
ANNEX F
Procedure for Voluntary Cancellation of an Application

1. Access the online portal through (https://eservices.fda.gov.ph/) and click **"Applications"** found on the upper right corner of the eServices landing page.

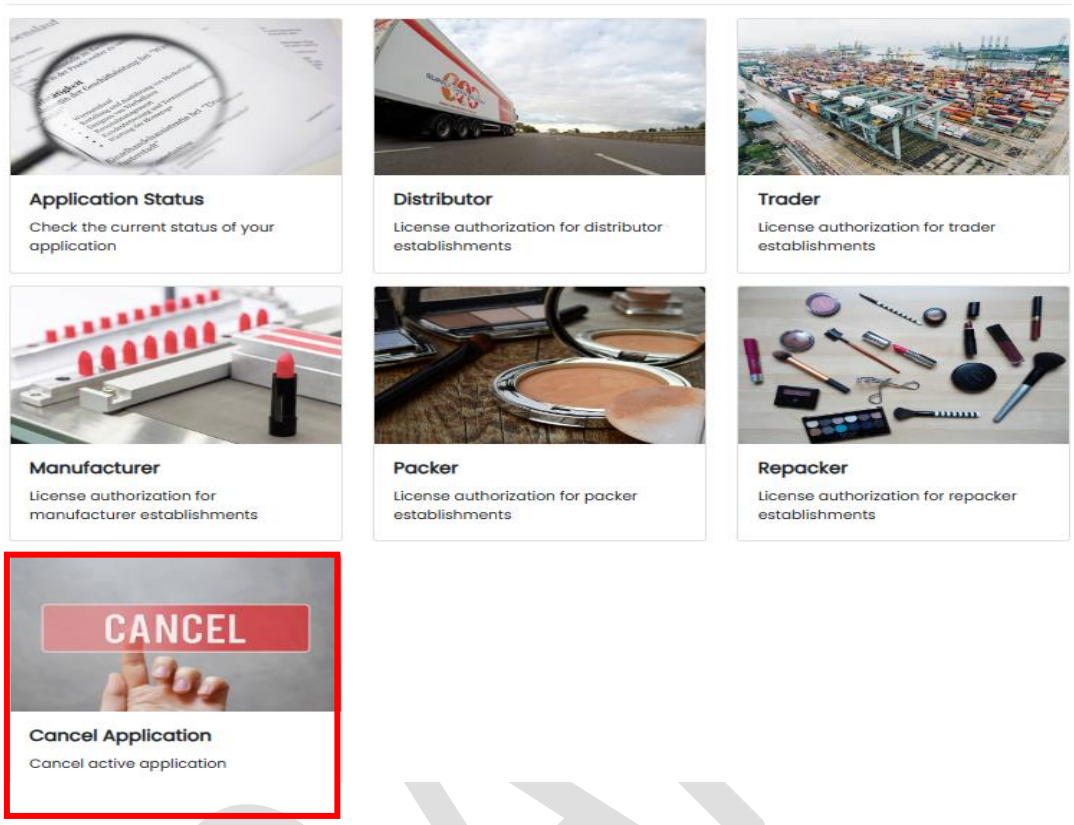


2. Click the License to Operate for Household/Urban Hazardous Substances

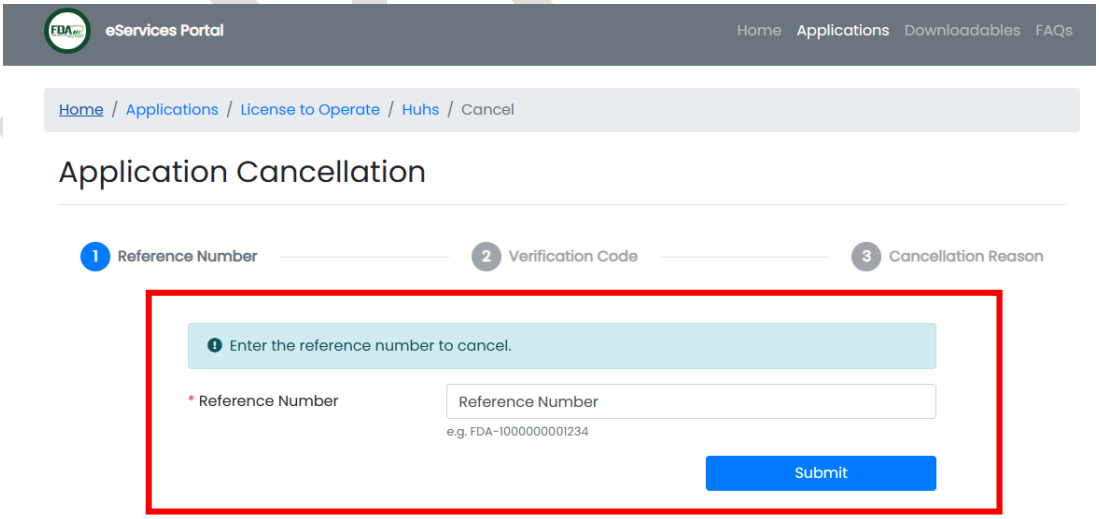




3. To cancel the application, click **"Cancel Application".**



4. Enter the Reference Number and click on **"Submit"**



5. A verification code will be sent to applicant's registered e-mail address.

6. Enter the verification code to state the reason for cancellation.