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1
2 **FDA CIRCULAR**

3 No. _____
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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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8 **I. RATIONALE**
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10 In pursuit of the principles under Republic Act No. 8792, otherwise known as the
11 “Electronic Commerce Act of 2000”, and Republic Act No. 11032, otherwise known as
12 the “Ease of Doing Business and Efficient Government Service Delivery Act of 2018”,
13 national government agencies transitioned into operating electronic systems to promote
14 efficient delivery of government services. In the Food and Drug Administration (FDA),
15 digitalization efforts were initiated beginning in 2013 through the establishment of an
16 electronic application system for cosmetic product notification, followed later on by the
17 online systems for the notification/registration of household/urban hazardous
18 substances (HUHS), toys and childcare articles, food products, and medical devices,
19 and the licensing of health product establishments.
20

21 During the course of the digitalization of FDA licensing and registration services,
22 several systems were gradually built. More recently, regulatory services of the FDA are
23 moving towards a single platform, namely, the FDA eServices Portal System. This
24 platform is envisioned to be a user-friendly and simpler platform to file and submit
25 applications, intended to reduce inefficiency and redundancy presented by multiple
26 application systems. This is also in line with the initiatives which aimed to harmonize
27 and streamline procedures as in Department of Health (DOH) Administrative Order
28 (AO) No. 2020-0017 of the Department of Health entitled, “Revised Guidelines on the
29 Unified Licensing Requirements and Procedures of the Food and Drug Administration
30 Repealing Administrative Order No. 2016-0003”. Through this Circular, the FDA
31 eServices Portal is hereby updated to include License to Operate (LTO) applications of
32 HUHS establishments.
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35 **II. OBJECTIVE**
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37 This Circular aims to provide the procedural guidelines for the filing and submission of
38 LTO applications of HUHS establishments through the FDA eServices Portal System
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41 **III. SCOPE**
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43 This Circular shall cover the following LTO applications:
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3 A. Types of Establishments
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- 5 1. HUHS Manufacturer
6 a. HUHS Manufacturer / Toll Manufacturer
7 b. HUHS Manufacturer-Packer / Toll Packer
8 c. HUHS Manufacturer-Repacker / Toll Repacker
9
10 2. HUHS Distributor
11 a. HUHS Distributor-Importer
12 b. HUHS Distributor-Exporter
13 c. HUHS Distributor-Wholesaler
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15 3. HUHS Trader
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17 B. Types of LTO Applications
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- 19 1. Initial
20 2. Renewal
21 3. Variation
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24 **IV. DEFINITION OF TERMS**
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26 The terms used in this Circular shall have the same definition as prescribed in Republic
27 Act No. 9711 and its Implementing Rules and Regulations (IRR), DOH Administrative
28 Order (AO) No. 2020-0017, DOH AO No. 2019-0019, FDA Circular No. 2020-025,
29 and other applicable laws and regulations
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32 **V. GUIDELINES**
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- 34 A. The procedural guidelines on the filing and submission of an FDA eServices LTO
35 application for establishments enumerated under Section III of this FDA Circular
36 shall be expounded herein. Whereas, the technical requirements and guidelines
37 relative to the licensing and inspection of HUHS establishments are provided in
38 DOH AO No. 2020-0017 and FDA Circular No. 2020-025.
39
40 B. By applying for an FDA LTO, the establishment understands and abides by the rules
41 and regulations set forth by the Agency. The establishment shall have the ultimate
42 responsibility in ensuring compliance with applicable national and/or international
43 standards of safety, quality, purity, and efficacy developed and/or adopted by the
44 FDA for of HUHS products which are manufactured, imported, exported,
45 distributed, sold, offered for sale, promoted, and/or advertised under the
46 authorization granted through their LTO and other marketing authorizations issued
47 by the FDA.
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49 C. **Application Process.** The applicant shall follow the updated procedure, as provided
50 in this Circular, in the submission and filing of applications, amending the procedure

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

3
4 **1. Application Requirements and Procedure.** The application requirements and
5 procedure are specified in the following Annexes of this Circular:

- 6
7 a. Annex A – LTO Requirements for HUHS Establishments
8 b. Annex B – Procedure in the Submission of an Initial LTO Application
9 c. Annex C – Procedure in the Submission of a Renewal LTO Application
10 d. Annex D – Procedure in the Submission of a Variation Application
11 e. Annex E – Procedure for Checking the Status of an Application
12 f. Annex F – Procedure for Voluntary Cancellation of an Application
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14 **2. Filing of an Application**

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16 a. **Accessibility of the FDA eServices Portal System.** Applications shall be
17 filed online through the FDA eServices Portal System website
18 (<https://eservices.fda.gov.ph>). A valid company e-mail address is required
19 to file and submit an application.
20

21 b. **Declaration and Undertaking Upon Submission of the Application.**
22 Agreement to the “Declaration and Undertaking” is required in order to
23 proceed with the application. Such conveys a binding agreement of the
24 applicant company with the FDA to provide true and accurate information
25 in support of the application, to affirm the primary responsibility of the LTO
26 holder over the HUHS products, and to undertake compliance with all
27 applicable FDA standards, rules and regulations contingent with their
28 authorization, including full cooperation with FDA licensing, inspection,
29 and post-marketing surveillance activities.
30

31 Any misrepresentation of the information in this application shall be
32 subjected to administrative and criminal liabilities, provided by Republic
33 Act No. 9711, which includes, but are not limited to disapproval of
34 application, suspension, cancellation, or revocation of the LTO.
35

36 c. **Security of the Declared E-mail Address.** All transactions with the FDA
37 shall be communicated to the applicant company through the declared e-mail
38 address during the application.
39

40 The applicant company shall bear the responsibility of ensuring the
41 accessibility, security and integrity of such e-mail address to their respective
42 Authorized Person/s, Qualified Personnel, and/or owner of the
43 establishment. The FDA shall not be held liable or responsible in any way
44 for the loss and/or any compromise of access to the declared e-mail address.
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46 In the event that the applicant company wishes to change the declared e-mail
47 address during the initial application, the applicant may send a request
48 addressed to the FDA – Food and Drug Action Center at
49 fdac.pacd@fda.gov.ph.
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51 d. **Quality of Declared Information and Uploaded Documents**

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- 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.

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e. Timing and submission of applications

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- 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.

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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.

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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

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

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4 Applications cancelled during the evaluation stage or after the payment has
5 been made shall mean the outright forfeiture of the payment.
6 Resubmission of applications thereafter shall be subject to new fees.
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8 **3. Pre-assessment.** All HUHS licensing applications shall undergo the pre-
9 assessment step, following Republic Act No. 11032, which covers the
10 determination of the completeness of information and documents submitted. The
11 pre-assessment of applications shall be guided by the following.

- 12
13 a. The pre-assessment of applications shall be done within the prescribed
14 working days and office hours of the FDA.
15
16 b. Applications with incomplete data entries and document submissions shall
17 not be accepted for further evaluation and the application will not proceed
18 to the next step of the process.
19
20 c. The FDA shall inform the applicant through the registered email address of
21 the result of the pre-assessment. If the application passed the pre-assessment
22 step, the applicant shall receive the Order of Payment with Reference
23 Number through email indicating the fees to be paid. However, if the
24 application did not pass the pre-assessment step, the FDA shall notify the
25 reason/s for non-acceptance e.g., deficiency/ies found and prompt the
26 applicant to file a new application.
27
28 d. A successfully pre-assessed application is not equivalent to an approved
29 application. The evaluation of the correctness and sufficiency of the
30 submitted documentary requirements with reference to existing
31 administrative and technical standards, rules, and regulations shall be
32 conducted only during the evaluation and inspection steps as determined by
33 the FDA.
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35 **4. Payment of Fees.** The procedure for the payment of fees and charges shall be
36 as follows. Any updates, changes and/or additions to the existing FDA payment
37 channels shall be announced through separate issuances.

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

- 42
43 i. Over-the Counter at the Landbank of the Philippines (LBP) using the
44 LBP Oncoll Payment Slip based on FDA Memorandum Circular No.
45 2013-046 through this link, <https://bit.ly/36ChH4X>
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47 The Oncoll Payment Slip shall reflect the following information:

- 48 1. Account Number (per category of the product/center)
49 2. Reference No. 1 – Account Code (reflected in the Order of
50 Payment)
51 3. Reference No. 2 – Company Name

1 4. Merchant Name – Food and Drug Administration
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4 ii. Online through:
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- 6 1. LBP Online Payment Link.Biz Portal based on FDA Advisory
7 No. 2021-0246 (<https://bit.ly/3DmdPRv>)
8 2. BANCNET online (<https://bit.ly/3uB8PEL>)
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10 Online payments should indicate the reference number reflected in
11 the Order of Payment.
12

- 13 b. Once payment has been made, LBP or Bancnet will process the payment and
14 send a transaction report to FDA which usually takes a minimum of two (2)
15 days. Upon receipt of the report, the Cashier Section of the FDA shall check
16 the details, confirm if the payment has been made in full, and posts the
17 payment in the FDA eServices Portal System. Posting of payment may take
18 a maximum of two (2) days, depending on the volume of paid applications
19 received.
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21 c. Applicants will receive a system-generated message through the registered
22 e-mail address on the status of the payment made once posted or if there is
23 a need to further settle the remaining balance. An Acknowledgment Receipt
24 will be issued if a full payment has been made. Otherwise, a notification on
25 payment deficiency will be issued in cases of incomplete payments.
26
27 d. Applications with complete documentary requirements and payment shall
28 receive an Acknowledgement Receipt from FDA, containing the number or
29 code of the FDA employee who received the application, the reference
30 number, agency logo, the date and time of application, payment, and the
31 statement of completeness of the documents submitted. An application is
32 considered filed once the applicant receives the Acknowledgement Receipt.
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- 34 **5. Evaluation of the Application.** A filed application will undergo evaluation of
35 the correctness and sufficiency of the submitted documentary requirements with
36 reference to existing administrative and technical standards, rules, and
37 regulations. Inspection will be conducted as determined by the FDA, in
38 accordance with the guidelines under DOH AO No. 2020-0017, FDA Circular
39 No. 2020-025, and their future amendments.
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41 An approval of the application shall be based on the satisfactory compliance to
42 the administrative and technical requirements reviewed during evaluation and,
43 if applicable, inspection.
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- 45 **6. Grounds for Disapproval.** The grounds for disapproval of LTO application
46 may be any of the following, as provided in DOH AO No. 2020-0017:
47

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

- 1 c. The applicant made misrepresentations, false entries, withhold relevant data
2 contrary to the provisions of the law or appropriate standards;
3 d. The owner has violated any of the terms and conditions of its license; and,
4 e. Such other analogous grounds or causes as determined by the FDA.
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6 The disapproval of an application is without prejudice to re-application provided
7 the deficiencies listed in the Letter of Disapproval (LOD) have been addressed
8 before submitting the new application. As the disapproval of the application
9 means the outright forfeiture of the payment made, re-submitted applications
10 shall be subject to new fees.
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12 **7. Releasing of the Results of the Application**

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14 a. If the application is approved, the FDA shall send the LTO for initial and
15 renewal applications or the updated LTO for variation applications to the
16 registered e-mail address of the applicant. The LTO may also be accessed
17 through the FDA eServices Portal System.
18

19 Issued LTOs processed filed through this FDA Circular under the FDA
20 eServices Portal System shall be provided an updated LTO number in the
21 following format:

22 Old: **300000XXXXXX**

23 New: **CCHUHSRR- (Region)- HUHS- (Activity)- (Sequence Number)**
24

25 Upon receipt of the LTO, the establishment shall print the LTO on a standard
26 A4 size (21 cm x 29.7 cm) paper, on full-colored page and in portrait
27 orientation. It shall be positioned in the most conspicuous place within the
28 business establishments.
29

- 30 b. If the application is disapproved, the FDA shall inform the applicant through
31 its registered e-mail address of the reason for such action on the application.
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34 **VI. SEPARABILITY CLAUSE**

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

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43 All applications shall be filed online through the eServices Portal System upon the
44 effectivity of this Circular. Applications filed through the FDA ePortal System prior the
45 effectivity of this Circular shall be processed in accordance with DOH AO No. 2020-
46 0017, FDA Circular No. 2023-006, and other applicable guidelines. Establishments
47 with a valid LTO issued via FDA ePortal System shall be honored for the duration of
48 its validity.
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2 **VIII. REPEALING CLAUSE**
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4 This Circular hereby repeals Section IV Items A (on licensing), E.1, E.2, Annex B and
5 Annex C of FDA Circular No. 2023-006 entitled, “Updated Guidelines on the Filing
6 and Submission of Applications for the Licensing and Registration of Household/Urban
7 Hazardous Substances (HUHS) Establishment and Products, Respectively, through the
8 FDA E-Portal V.2 System”. Other related issuances inconsistent or contrary to the
9 provisions of this Circular are hereby amended or modified accordingly.
10

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12 **IX. EFFECTIVITY**
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14 This FDA Circular shall take effect fifteen (15) days following its publication in a
15 newspaper of general circulation and upon filing with the University of the Philippines
16 – Office of the National Administrative Register (UP-ONAR). The provisions
17 stipulated in this FDA Circular shall remain in effect unless otherwise revoked or
18 repealed.
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23 **DR. SAMUEL A. ZACATE**
24 Director General
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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:

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a. Major Variation

Type of Variation	Document Requirement
Transfer of Location of Manufacturing Plant <ul style="list-style-type: none">Physical transfer of the establishment and may entail changes in the previously approved address	<ol style="list-style-type: none">Business Permit reflecting the new addressUpdated Site Master File to be presented upon inspection
Expansion of Manufacturer and/or Additional Product Line; or Change of Manufacturing Activity <ul style="list-style-type: none">Expansion shall refer to expansion made which is adjacent to be existing location of the establishmentAdditional product line shall refer to additional type or class of products produced within the same manufacturing siteChange 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

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b. Minor Variation

Type of Variation	Document Requirement
Transfer of Location of Offices <ul style="list-style-type: none">Physical transfer of the office of the establishment	Proof of business address reflecting the new office location: <ol style="list-style-type: none">For Single Proprietorship: Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location;For Securities and Exchange Commission (SEC)-registered establishments:<ol style="list-style-type: none">Amended Articles of Incorporation (if transferred from one city/municipality/province; or,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 office location

<p>Change of Distributor Activity</p> <ul style="list-style-type: none"> • Shall refer to an additional/deletion of/change in activity that the distributor engage in 	Contract Agreements showing change in activity
<p>Transfer/addition of Warehouse</p> <ul style="list-style-type: none"> • Physical transfer and addition of warehouse of the establishment 	Mayor's Permit or Barangay Business Permit/Clearance reflecting new warehouse location
<p>Expansion of Office Establishments</p> <ul style="list-style-type: none"> • Shall refer to expansion made which is adjacent to the existing location of the establishment 	Expansion floor plan
<p>Change of Ownership</p> <ul style="list-style-type: none"> • Change in ownership of the licensed establishment 	<ol style="list-style-type: none"> 1. Business name registration reflecting new ownership 2. Any proof on the transfer of ownership such as any of the following: <ol style="list-style-type: none"> 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
<p>Change of Business Name</p> <ul style="list-style-type: none"> • Change only in the business name of the establishment 	Business name registration reflecting new business name
<p>Zonal Change in Address</p> <ul style="list-style-type: none"> • Change of the name/number of the street/building without physical transfer of the establishment 	<ol style="list-style-type: none"> 1. Certificate of Zonal Change 2. Certification from Local Government Unit (LGU) (City/Municipality) stating no physical transfer of the establishment
<p>Change of Qualified Person¹</p> <ul style="list-style-type: none"> • Change in the identified qualified person initially registered with the FDA 	<ol style="list-style-type: none"> 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
<p>Change of Authorized Person</p> <ul style="list-style-type: none"> • Change of authorized person initially registered with the FDA 	<ol style="list-style-type: none"> 1. Name of new Authorized Person 2. Valid Government ID 3. Updated contact details

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¹The 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	<ol style="list-style-type: none"> 1. PRC ID for professions with Board/Licensure Exam or Diploma for profession without Board/Licensure Exam; and,

	<p>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</p>
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ANNEX B

Procedure in the Submission of an Initial LTO Application

A. Procedure outline

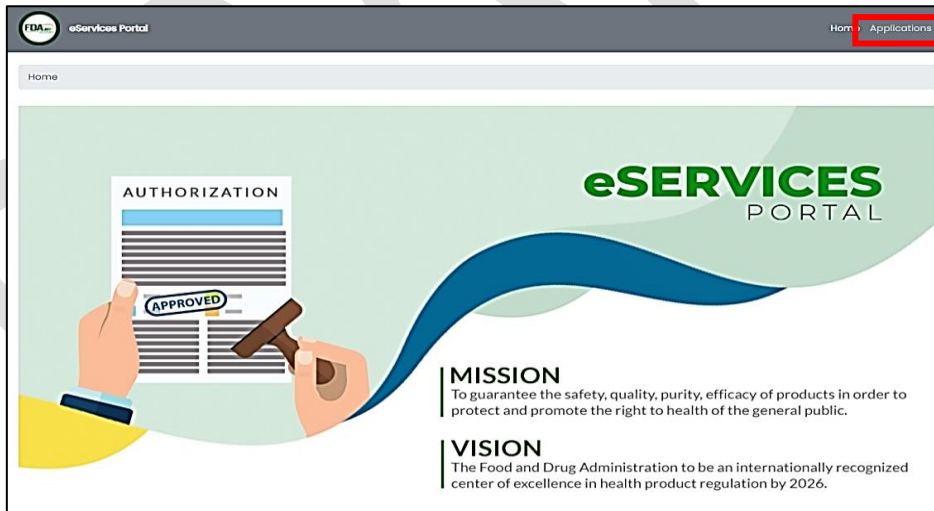
1. Accessing and navigating the FDA eServices Portal System
2. Filing an application
 - a. Page 1: Declaration and Undertaking
 - b. Page 2: General Information
 - c. Page 3: Product Line (*For Manufacturer Only*)
 - d. Page 4: Establishment Information
 - e. Page 5: Office Address
 - f. Page 6: Warehouse 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

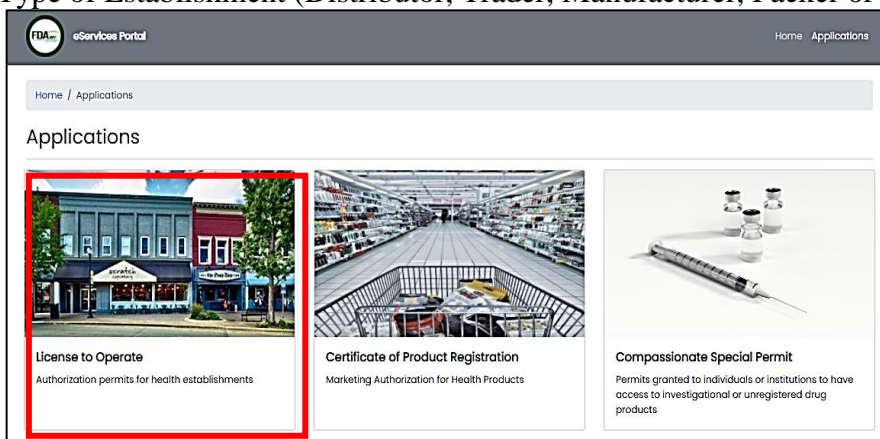
Follow the steps outlined below in order to submit an initial HUHS LTO application.

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)















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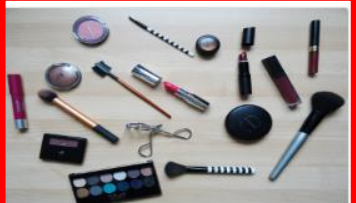
eServices Portal Home Applications Downloadables FAQs

Home / Applications / License to Operate

License to Operate

 <p>Bottled Water For establishments that handle bottled water products</p>	 <p>Drug For establishments that handle drug products</p>	 <p>Food For establishments that handle food products</p>
 <p>Iodized Salt For establishments that handle salt products</p>	 <p>Device For establishments that handle device products</p>	 <p>Cosmetic For establishments that handle cosmetic products</p>
 <p>Household/Urban Pesticide For establishments that handle Household/Urban pesticide products</p>	 <p>Household/Urban Hazardous Substances For establishments that handle Household/Urban Hazardous Substances products</p>	 <p>Toy and Child Care Article For establishments that handle Toy and Child Care Article products</p>

 <p>Application Status Check the current status of your application</p>	 <p>Distributor License authorization for distributor establishments</p>	 <p>Trader License authorization for trader establishments</p>
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 <p>Manufacturer License authorization for manufacturer establishments</p>	 <p>Packer License authorization for packer establishments</p>	 <p>Repacker License authorization for repacker establishments</p>
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24 i. Select the primary activity the applicant intends to engage in which may be one of
25 the following:

- 26
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- 28 • **Manufacturer**- An establishment that is engaged in any and all operations
29 involved in the production of HUHS products including preparation, processing,
30 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.

The screenshot shows the 'eServices Portal' interface. The breadcrumb trail is 'Home / Applications / License to Operate / Huhs / Manufacturer'. The main heading is 'Household/Urban Hazardous Substances Manufacturer'. There are three main options: 'Initial' (Apply for a new License to Operate), 'Renewal' (Renew existing License to Operate), and 'Variations' (Apply for changes in the existing License to Operate). The 'Initial' option is highlighted with a red box.

2. Filing an application

a. Page 1: Declaration & Undertaking

To start the application, read carefully and agree to the Declaration & Undertaking form. Make sure to check the box found below and click on **“Start Application”**.

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

I, duly authorized officer/s or representative/s of the Establishment hereby voluntarily and categorically declare, undertake, and agree that all data and information contained and provided in the attached application, together with all other submissions, including amendments, are true and correct based on my knowledge and are based on existing records, legal documents and available information.

I, likewise declares, undertakes and agrees that:

I. The said establishment shall be open during its business hours under the supervision of a PRC registered pharmacist/s or authorized personnel at all times;

II. The registered pharmacist/s and the other appropriate allied health professionals, upon and during employment in the establishment, is/are not and will not in any way be connected to, employed by or engaged with any other FDA-regulated establishment;

III. The approved and valid license to Operate shall be displayed in a conspicuous place in the establishment visible to my customers;

IV. The establishment will change its business name, and/or brand name in the case of products, in the event that there is a similar, same, or confusingly similar name registered with the Food and Drug Administration, or if the FDA rules later that such name is misleading, offensive, against the law, customs, public morals, public policy or otherwise violative of relevant rules and regulations;

At the bottom, there is a checkbox labeled 'I agree to the declaration and undertaking' which is checked, and a blue 'Start Application' button. Both the checkbox and the button are highlighted with a red box.

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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

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

Household/Urban Hazardous Substances Manufacturer Initial

1 Declaration & Undertaking

2 **General Information**

3 Product Line

4 Establishment Information

5 Office Address

6 Warehouse Addresses

7 Plant Address

8 Authorized Person

9 Qualified Personnel

10 Documentary Requirements

11 Self-Assessment Review

General Information

* Type of Application: Initial

* Product Type: Household/Urban Hazardous Substances

* Primary Activity: Manufacturer

Additional Activities: Importer of Raw Materials for Own Use, Exporter of Own Products, Wholesaler of Own Products

* Primary Activity: Trader

Additional Activities: Importer of Raw Materials for Own Use, Exporter of Own Products, Wholesaler of Own Products

Primary Activity: Distributor

Distributor Activities: Importer, Exporter, Wholesaler

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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”.

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

Household/Urban Hazardous Substances Manufacturer Initial

1 Declaration & Undertaking

2 General Information

3 **Product Line**

4 Establishment Information

5 Office Address

6 Warehouse Addresses

7 Plant Address

8 Authorized Person

9 Qualified Personnel

Product Line Details

* Type: Please Select

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

+ Add Product Line

Back Next

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2 **d. Page 4: Establishment Information**

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

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

Household/Urban Hazardous Substances Manufacturer Initial

1 Declaration & Undertaking | Establishment Information

2 General Information

3 Product Line

4 Establishment Information

5 Office Address

6 Warehouse Addresses

7 Plant Address

8 Authorized Person

9 Qualified Personnel

10 Documentary Requirements

11 Self-Assessment Review

* Name of Establishment: Name of Establishment

* Owner of Establishment: Owner of Establishment

* Tax Identification Number: Tax Identification Number

* Declared Capital: Please Select

Contact Information

* Email Address: Email Address

* Mobile Number: Mobile Number

Landline Number: Landline Number

Back Next

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

24 **e. Page 5: Office Address**

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

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

Household/Urban Hazardous Substances Manufacturer Initial

1 Declaration & Undertaking | Office Address

2 General Information

3 Product Line

4 Establishment Information

5 Office Address

6 Warehouse Addresses

7 Plant Address

8 Authorized Person

9 Qualified Personnel

10 Documentary Requirements

11 Self-Assessment Review

* Region: Please Select

* Province: Please Select

* City or Town: Please Select

* Street Address: Street Address

* GPS Latitude: GPS Latitude


* GPS Longitude: GPS Longitude

Get GPS Coordinates

Back Next

1 **f. Page 6: Warehouse Address**

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

5  eServices Portal Home Applications Downloadables FAQs

6

7 [Home](#) / [Applications](#) / [License to Operate](#) / [Huhs](#) / [Manufacturer](#) / Initial

8 **Household/Urban Hazardous Substances Manufacturer Initial**

9

10 **Warehouse Addresses**

11 **1** Declaration & Undertaking

12 **2** General Information

13 **3** Product Line

14 **4** Establishment Information

15 **5** Office Address

16 **6** Warehouse Addresses

17 **7** Plant Address

18 **8** Authorized Person

19 **9** Qualified Personnel

20 **10** Documentary Requirements

21 **11** Self-Assessment Review

Warehouse #1

* Region

* Province

* City or Town

* Street Address

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

* GPS Latitude


* GPS Longitude

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

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

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

35  eServices Portal Home Applications Downloadables FAQs

36

37 [Home](#) / [Applications](#) / [License to Operate](#) / [Huhs](#) / [Manufacturer](#) / Initial

38 **Household/Urban Hazardous Substances Manufacturer Initial**

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40 **Plant Address**

41 **1** Declaration & Undertaking

42 **2** General Information

43 **3** Product Line

44 **4** Establishment Information

45 **5** Office Address

46 **6** Warehouse Addresses

47 **7** Plant Address

48 **8** Authorized Person

49 **9** Qualified Personnel

50 **10** Documentary Requirements

51 **11** Self-Assessment Review

* Region

* Province

* City or Town

* Street Address

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

* GPS Latitude

* GPS Longitude

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

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

5

6 [Home](#) / [Applications](#) / [License to Operate](#) / [Huhs](#) / [Manufacturer](#) / [Initial](#)

7 Household/Urban Hazardous Substances Manufacturer Initial

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10 **1** Declaration & Undertaking 1 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.

11 **2** General Information

12 **3** Product Line

13 **4** Establishment Information

14 **5** Office Address

15 **6** Warehouse Addresses

16 **7** Plant Address

17 **8** Authorized Person

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21 **9** Qualified Personnel

22 **10** Documentary Requirements

23 **11** Self-Assessment Review

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Details of Authorized Person

* First Name
include suffix name on first name

Middle Name

* Last Name

* Designation
select owner for sole proprietorships

Government Issued Identification Document

* Type

* Identification Number

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

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

34

35 [Home](#) / [Applications](#) / [License to Operate](#) / [Huhs](#) / [Manufacturer](#) / [Initial](#)

36 Household/Urban Hazardous Substances Manufacturer Initial

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39 **1** Declaration & Undertaking 1 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.

40 **2** General Information

41 **3** Product Line

42 **4** Establishment Information

43 **5** Office Address

44 **6** Warehouse Addresses

45 **7** Plant Address

46 **8** Authorized Person

47 **9** Qualified Personnel

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51 **10** Documentary Requirements

11 Self-Assessment Review

Details of the Qualified Personnel

Personnel Details

* First Name

Middle Name

* Last Name

* Designation
select owner for sole proprietorships

Government Issued Identification Document

* Type

* Identification Number

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

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j. Page 10: Documentary Requirements

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

The screenshot shows the 'eServices Portal' interface for 'Household/Urban Hazardous Substances Manufacturer Initial'. The navigation bar includes 'Home', 'Applications', 'License to Operate', 'Huhs', 'Manufacturer', and 'Initial'. The main heading is 'Household/Urban Hazardous Substances Manufacturer Initial'. A sidebar on the left lists steps 1 through 11, with step 10 'Documentary Requirements' highlighted in a red box. The main content area shows various document upload fields, each with a 'File Upload' button. The fields include: 'Proof of Business Name Registration' (DTI Permit, SEC with Articles of Incorporation/Partnership, CDA Permit, or Government-Owned and Control Corporation (GOCC)), 'Business/Mayor's Permit or Barangay Clearance', 'Latest Audited Financial Statement with Balance Sheet or Declaration of Capitalization', 'Floor Plan', 'Risk Management Plan', 'Site Master File', and 'PRC ID' (Please upload PRC ID for professions with Board/Licensure Exam). At the bottom, there are 'Back' and 'Next' buttons.

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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

The screenshot shows the 'eServices Portal' interface for 'Household/Urban Hazardous Substances Manufacturer Initial'. The navigation bar includes 'Home', 'Applications', 'License to Operate', 'Huhs', 'Manufacturer', and 'Initial'. The main heading is 'Household/Urban Hazardous Substances Manufacturer Initial'. A sidebar on the left lists steps 1 through 11, with step 11 'Self-Assessment Review' highlighted in a red box. The main content area shows the 'Self-Assessment Review' form. It includes a 'General Information' section with fields for 'Type of Application' (Initial), 'Product Type' (Household/Urban Hazardous Substances), and 'Primary Activity' (Manufacturer). There are also checkboxes for 'Additional Activities'. Below this is the 'Establishment Information' section with fields for 'Name of Establishment' (ABC Company), 'Owner of Establishment' (Juan dela Cruz), and 'Tax Identification Number' (1233). To the right of the form is a 'Captcha' area with a green checkmark and the text 'I'm not a robot'. Below the captcha is a red-bordered box containing a confirmation statement: 'I hereby confirm that all information I have provided are true and correct to the best of my knowledge. I understand that any errors that I have committed in this online form may be considered grounds for refusal or cancellation of my application. In compliance to the Data Privacy Act 2012, I give consent to use any personal information provided herein for Government to conduct the necessary records check and verification of facts in connection with my application.' At the bottom right of this box are 'Back' and 'Confirm' buttons, with the 'Confirm' button highlighted in a red box.

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4 **ANNEX C**
5 **Procedure in the Submission of Renewal LTO Application**

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12 **A. Procedure outline**

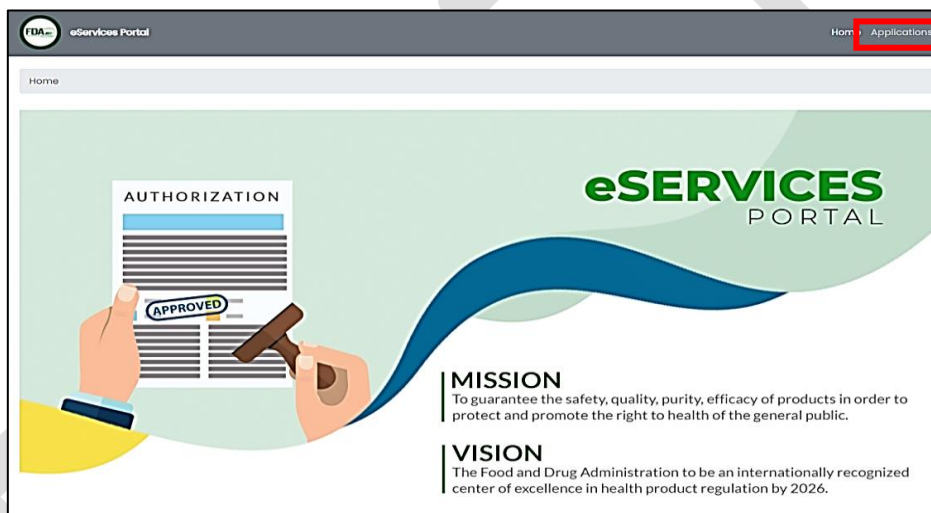
1. Accessing and navigating the FDA eServices Portal System
2. Filing an application
 - a. Page 1: Declaration & Undertaking
 - b. Page 2: License to Operate
 - c. Page 3: Contact Information
 - d. Page 4: Self-Assessment Review

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15 **B. Step-by-step procedure**

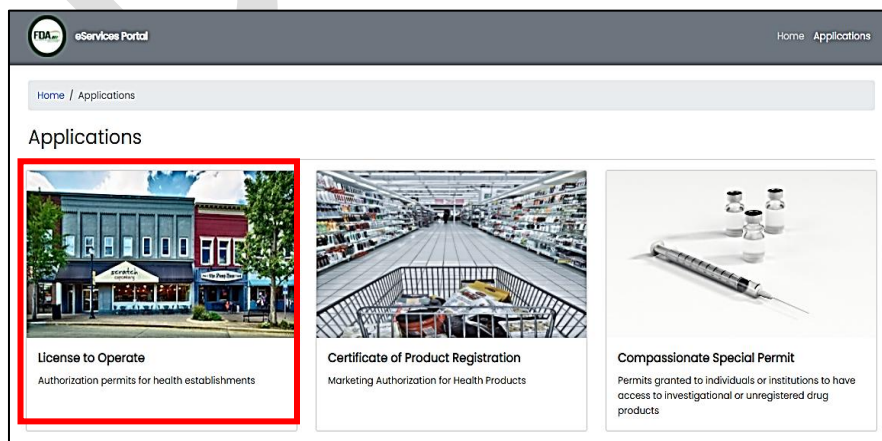
Follow the steps outlined below in order to submit a renewal HUHS LTO application.

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19 **1. Accessing and navigating the FDA eServices Portal System**

- a. Access the online portal through (<https://eservices.fda.gov.ph/>) and click “Applications” found on the upper right corner of the eServices landing page.



- b. Click the License to Operate for Household/Urban Hazardous Substances and Type of Establishment (Distributor, Trader, Manufacturer, Packer or Repacker)



License to Operate



Bottled Water
For establishments that handle bottled water products



Drug
For establishments that handle drug products



Food
For establishments that handle food products



Iodized Salt
For establishments that handle salt products



Device
For establishments that handle device products



Cosmetic
For establishments that handle cosmetic products



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



Household/Urban Hazardous Substances
For establishments that handle Household/Urban Hazardous Substances products



Toy and Child Care Article
For establishments that handle Toy and Child Care Article products



Application Status
Check the current status of your application



Distributor
License authorization for distributor establishments



Trader
License authorization for trader establishments



Manufacturer
License authorization for manufacturer establishments



Packer
License authorization for packer establishments



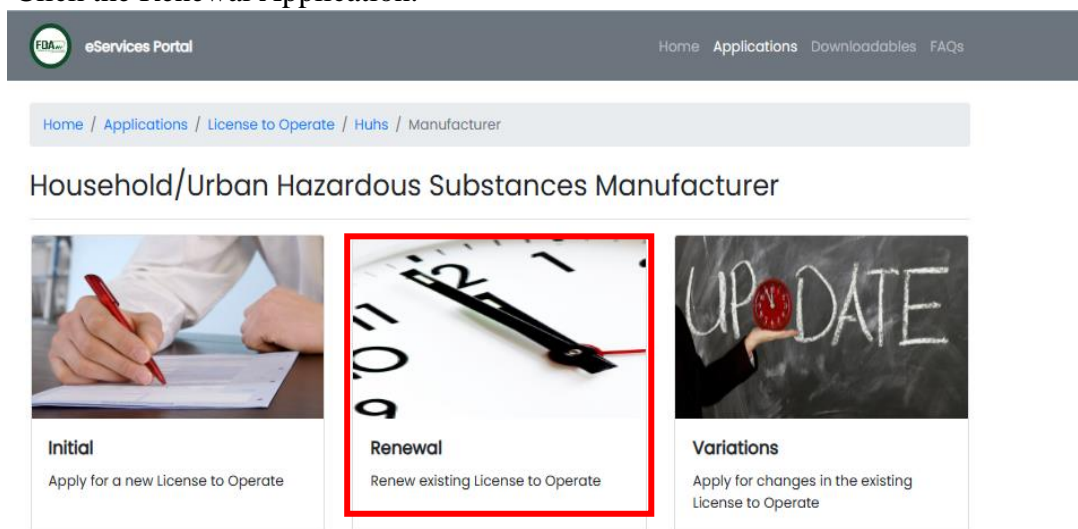
Repacker
License authorization for repacker establishments

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

- **Manufacturer-** An establishment that is engaged in any and all operations involved in the production of HUHS products including preparation, processing, formulating, filling, packaging, repacking, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution.
- **Packer-** An establishment that packages bulk HUHS product into its immediate container with the end view of storage, distribution, or sale of the product.
- **Repacker-** An establishment that repacks a finished product into smaller quantities in a separate container and/or into secondary packaging, including but not limited to relabeling, stickering, and bundling for promo packs with the end view of storage, distribution, or sale of the product.

- **Trader**- An establishment which is a registered owner of a HUHS product and procures the raw materials and packing components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such product to a licensed manufacturer.
- **Distributor**- Any establishment that imports/exports raw materials, active ingredients and/or HUHS products for its own use or for wholesale distribution to other establishments or outlets. If the distributor sell to the general public, it shall be considered a retailer.

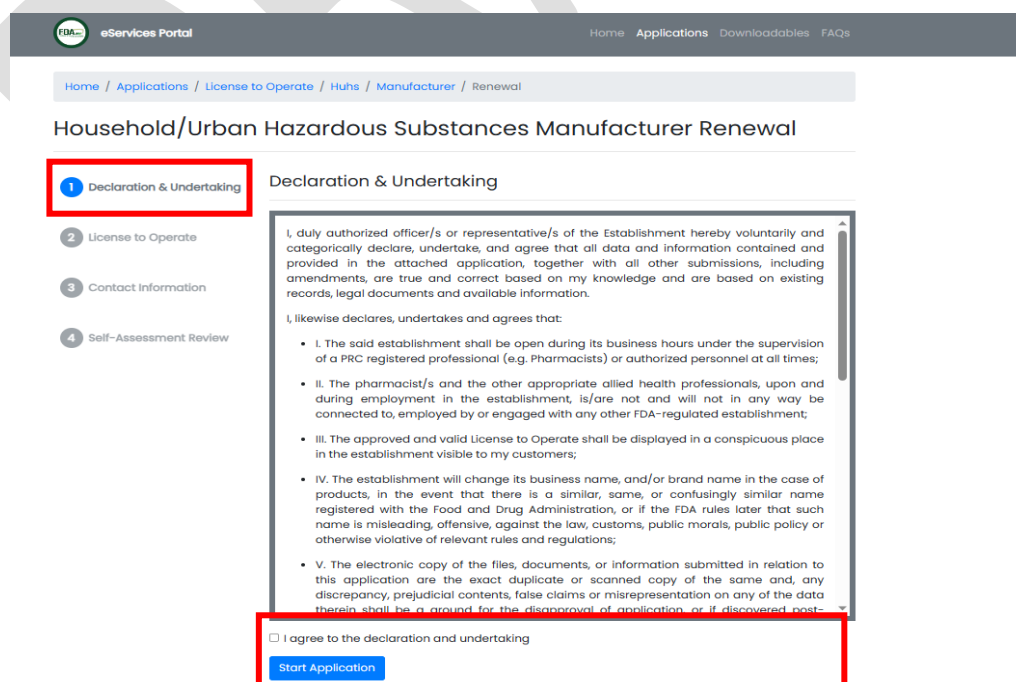
c. Click the Renewal Application.



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”**.



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

2 Provide the existing LTO Number, Validity Date, and Security Code (by scanning
3 the QR Code from the given document). Please ensure the correctness of the data
4 given to proceed with the change in licensing authorization. Tick **“I’m not a robot”**
5 then click **“Next”** to proceed.

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eServices Portal Home Applications Downloadables FAQs

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

Household/Urban Hazardous Substances Manufacturer Renewal

1 Declaration & Undertaking License to Operate

2 License to Operate

3 Contact Information

4 Self-Assessment Review

* License Number License Number

* Date of Validity Date of Validity

* Security Code Security Code

Please scan the QR Code in the document. For previously issued LTO, enter the sequence number located at the bottom right corner of the document (e.g. FDA-123456).

I'm not a robot reCAPTCHA Privacy Terms

Back Next

25 **c. Page 3: Contact Information**

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

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eServices Portal Home Applications Downloadables FAQs

Home / Applications / License to Operate / Huhs / Distributor / Renewal

Household/Urban Hazardous Substances Distributor Renewal

1 Declaration & Undertaking Contact Information

2 License to Operate

3 Contact Information

4 Self-Assessment Review

* Email Address

The owner/authorized representative shall ensure that they have access to the declared email address. The FDA shall not be held responsible or liable in any way for loss of access to the declared email address

* Mobile Number

Update mobile number if necessary

Landline Number

Update landline number if necessary

Back Next

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

- 46 i. A Self-Assessment Review summary will appear that reflects all the declared
47 information.
- 48 ii. After the self-assessment review, the applicant shall confirm the correctness of
49 the data and uploaded documents. Tick **“I’m not a robot”**, **Data Privacy Act**
50 **declaration** and click the **“Confirm”** submit the application.

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

eServices Portal Home Applications Downloadables FAQs

Home / Applications / License to Operate / Huhs / Distributor / Renewal

Household/Urban Hazardous Substances Distributor Renewal

1 Declaration & Undertaking
2 License to Operate
3 Contact Information
4 **Self-Assessment Review**

Self-Assessment Review

License to Operate

* License Number

* Date of Validity

* Security Code

Please scan the QR Code in the document. For previously issued LTO, enter the sequence number located at the bottom right corner of the document (e.g. FDA-123456).

Contact Information

* Email Address

The owner/authorized representative shall ensure that they have access to the declared email address. The FDA shall not be held responsible or liable in any way for loss of access to the declared email address.


* Mobile Number

Update mobile number if necessary

Landline Number

Update landline number if necessary

General Information

I'm not a robot  [Privacy](#) [Terms](#)

I hereby confirm that all information I have provided are true and correct to the best of my knowledge.

I understand that any errors that I have committed in this online form may be considered grounds for refusal or cancellation of my application.

In compliance to the Data Privacy Act 2012, I give consent to use any personal information provided herein for Government to conduct the necessary records check and verification of facts in connection with my application.

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3 **ANNEX D**
4 **Procedure in the Submission of Variation LTO Application**

5 **A. Procedure outline**

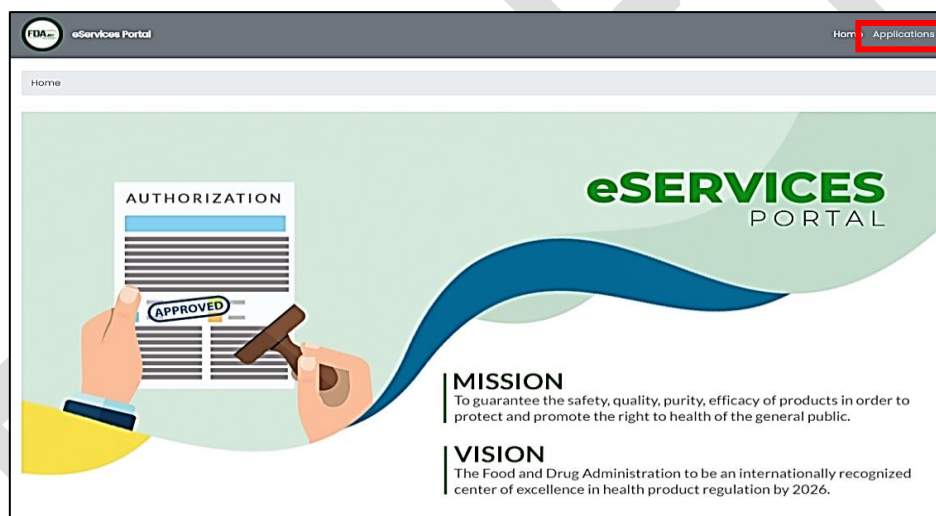
- 6
7 1. Accessing and navigating the FDA eServices Portal System
8 2. Filing an application
9 a. Page 1: Declaration & Undertaking
10 b. Page 2: License to Operate
11 c. Page 3: Contact Information
12 d. Page 4: Type of Variation
13 e. Page 5: Self-Assessment Review
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15 **B. Step-by-step procedure**

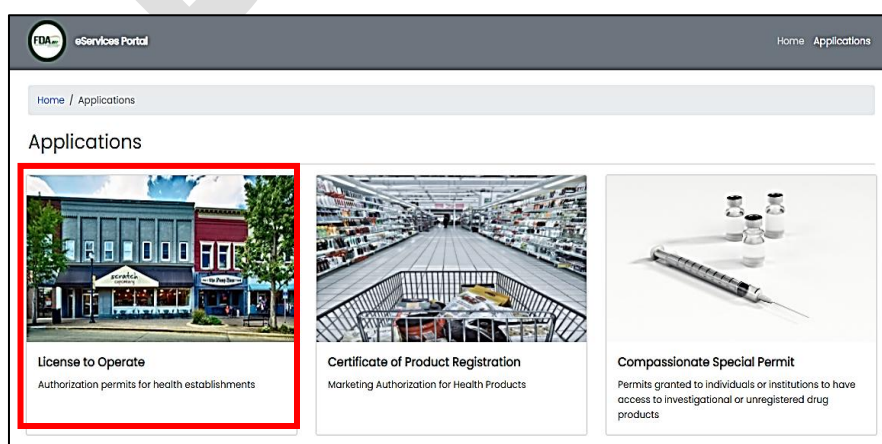
16 Follow the steps outlined below in order to submit a renewal HUHS LTO application.

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18 **1. Accessing and navigating the FDA eServices Portal System**

- 19 a. Access the online portal through (<https://eservices.fda.gov.ph/>) and click
20 “Applications” found on the upper right corner of the eServices landing page.
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- 36 b. Click the License to Operate for Household/Urban Hazardous Substances and
37 Type of Establishment (Distributor, Trader, Manufacturer, Packer or Repacker)
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eServices Portal Home Applications Downloadables FAQs

Home / Applications / License to Operate


License to Operate




Bottled Water
For establishments that handle bottled water products




Drug
For establishments that handle drug products




Food
For establishments that handle food products



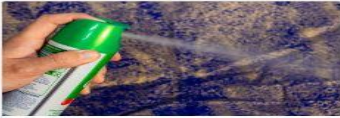
Iodized Salt
For establishments that handle salt products




Device
For establishments that handle device products




Cosmetic
For establishments that handle cosmetic products




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




Household/Urban Hazardous Substances
For establishments that handle Household/Urban Hazardous Substances products




Toy and Child Care Article
For establishments that handle Toy and Child Care Article products




Application Status
Check the current status of your application




Distributor
License authorization for distributor establishments




Trader
License authorization for trader establishments



Manufacturer
License authorization for manufacturer establishments



Packer
License authorization for packer establishments



Repacker
License authorization for repacker establishments

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

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- **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.

The screenshot shows the 'eServices Portal' header with navigation links: Home, Applications, Downloadables, FAQs. Below the header is a breadcrumb trail: Home / Applications / License to Operate / Huhs / Manufacturer. The main heading is 'Household/Urban Hazardous Substances Manufacturer'. There are three cards: 'Initial' with a photo of a person writing, 'Renewal' with a photo of a clock, and 'Variations' with a photo of a hand holding a red pill. The 'Variations' card is highlighted with a red border.

2. Filing an application

a. Page 1: Declaration & Undertaking

To start the application, read carefully and agree to the declaration & undertaking form. Make sure to check the box found below and click on “Start Application”.

The screenshot shows the 'eServices Portal' header with navigation links: Home, Applications, Downloadables, FAQs. Below the header is a breadcrumb trail: Home / Applications / License to Operate / Huhs / Manufacturer / Variations. The main heading is 'Household/Urban Hazardous Substances Manufacturer Variations'. On the left is a vertical list of steps: 1 Declaration & Undertaking (highlighted with a red border), 2 License to Operate, 3 Contact Information, 4 Variations, 5 Self-Assessment Review. The main content area is titled 'Declaration & Undertaking' and contains a text box with the following text: 'I, duly authorized officer/s or representative/s of the Establishment hereby voluntarily and categorically declare, undertake, and agree that all data and information contained and provided in the attached application, together with all other submissions, including amendments, are true and correct based on my knowledge and are based on existing records, legal documents and available information. I, likewise declares, undertakes and agrees that:'. Below this are five bullet points: 'I. The said establishment shall be open during its business hours under the supervision of a PRC registered professional (e.g. Pharmacists) or authorized personnel at all times;', 'II. The pharmacist/s and the other appropriate allied health professionals, upon and during employment in the establishment, is/are not and will not in any way be connected to, employed by or engaged with any other FDA-regulated establishment;', 'III. The approved and valid License to Operate shall be displayed in a conspicuous place in the establishment visible to my customers;', 'IV. The establishment will change its business name, and/or brand name in the case of products, in the event that there is a similar, same, or confusingly similar name registered with the Food and Drug Administration, or if the FDA rules later that such name is misleading, offensive, against the law, customs, public morals, public policy or otherwise violative of relevant rules and regulations;', 'V. The electronic copy of the files, documents, or information submitted in relation to this application are the exact duplicate or scanned copy of the same and, any discrepancy, prejudicial contents, false claims or misrepresentation on any of the data therein shall be a ground for the disapproval of application, or if discovered post-'. At the bottom of the form is a checkbox labeled 'I agree to the declaration and undertaking' (highlighted with a red border) and a blue 'Start Application' button (highlighted with a red border).

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

2 Provide the existing LTO Number, Validity Date, and Security Code (by scanning
3 the QR Code from the given document). Please ensure the correctness of the data
4 given to proceed with the change in licensing authorization. Tick **“I’m not a robot”**
5 then click **“Next”** to proceed.

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eServices Portal Home Applications Downloadables FAQs

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

Household/Urban Hazardous Substances Manufacturer Variations

1 Declaration & Undertaking License to Operate

2 License to Operate

* License Number License Number

* Date of Validity Date of Validity

* Security Code Security Code

Please scan the QR Code in the document. For previously issued LTO, enter the sequence number located at the bottom right corner of the document (e.g. FDA-123456).

I'm not a robot reCAPTCHA Privacy Terms

Back Next

24 **c. Page 3: Contact Information**

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

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eServices Portal Home Applications Downloadables FAQs

Home / Applications / License to Operate / Huhs / Distributor / Variations

Household/Urban Hazardous Substances Distributor Variations

1 Declaration & Undertaking Contact Information

2 License to Operate

3 Contact Information

* Email Address

The owner/authorized representative shall ensure that they have access to the declared email address. The FDA shall not be held responsible or liable in any way for loss of access to the declared email address.

* Mobile Number

Update mobile number if necessary

Landline Number

Update landline number if necessary

Back Next

43 **d. Page 4: Variations**

- 44 i. Choose and tick the box of the type of variation/s applicable for your LTO.
45 More than one type of HUHS LTO variation can be applied simultaneously in
46 a single application.
- 47 ii. Upload the required document/s for the variation/s in accordance to FDA
48 Circular No. 2020-025 and DOH AO 2020-0017, in pdf format by clicking
49 **“Upload Files”**, then click **“Next”**
- 50
51

Household/Urban Hazardous Substances Distributor Variations

1 Declaration & Undertaking

Minor Variations

2 License to Operate

1 If there is also a change in warehouse address, You should also apply it by ticking the Change of Warehouse Variation.

3 Contact Information

- Transfer of Office Location
- Expansion of Office Establishment
- Transfer/Addition of Warehouse
- Change of Distributor Activity
- Change of Ownership
- Change of Business Name
- Zonal Change in Office Address
- Change of Qualified Personnel
- Change of Authorized Person

4 Minor Variations

5 Self-Assessment Review

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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

Home / Applications / License to Operate / Huhs / Distributor / Renewal

Household/Urban Hazardous Substances Distributor Renewal

1 Declaration & Undertaking

2 License to Operate

3 Contact Information

4 Self-Assessment Review

Self-Assessment Review

License to Operate

* License Number

* Date of Validity

* Security Code

Please scan the QR Code in the document. For previously issued LTO, enter the sequence number located at the bottom right corner of the document (e.g. FDA-123456).

Contact Information

Email Address

I'm not a robot

I hereby confirm that all information I have provided are true and correct to the best of my knowledge.

I understand that any errors that I have committed in this online form may be considered grounds for refusal or cancellation of my application.

In compliance to the Data Privacy Act 2012, I give consent to use any personal information provided herein for Government to conduct the necessary records check and verification of facts in connection with my application.

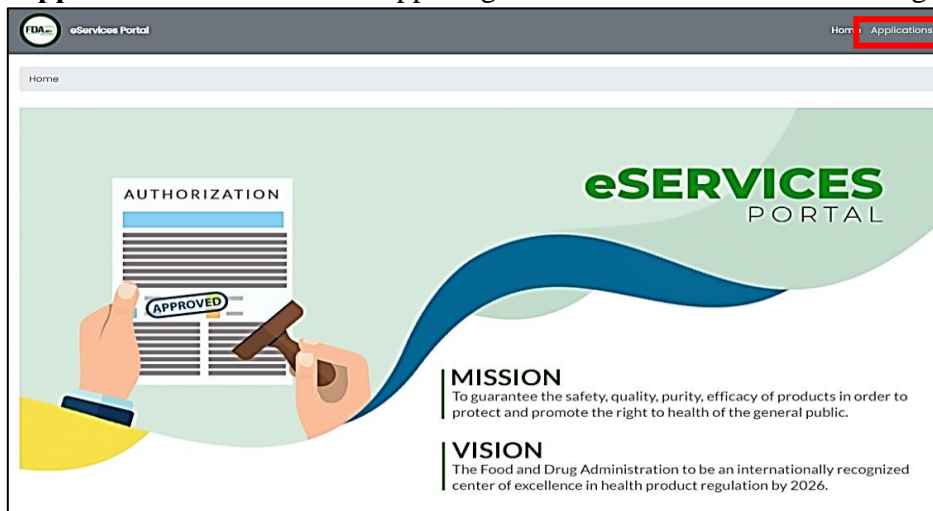
Back Confirm

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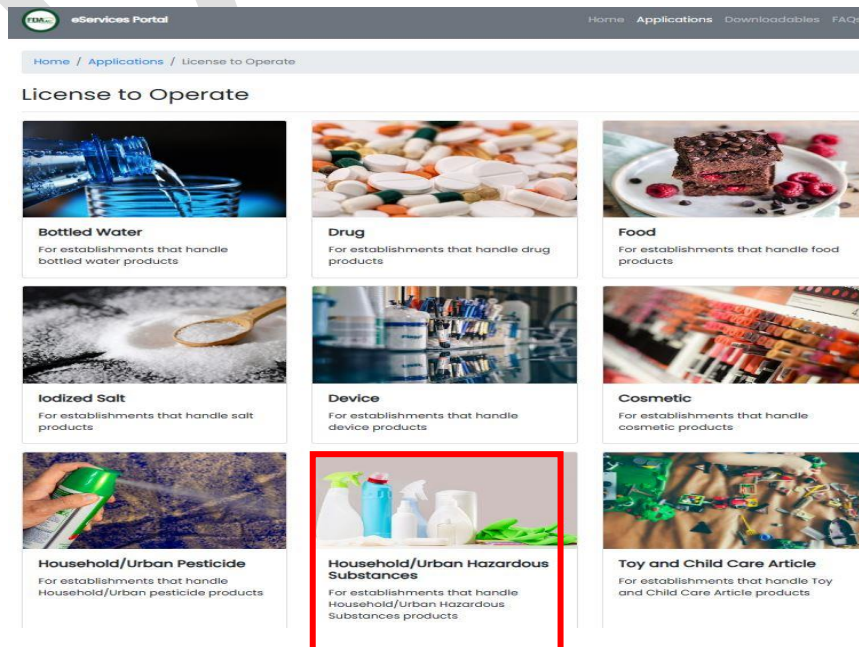
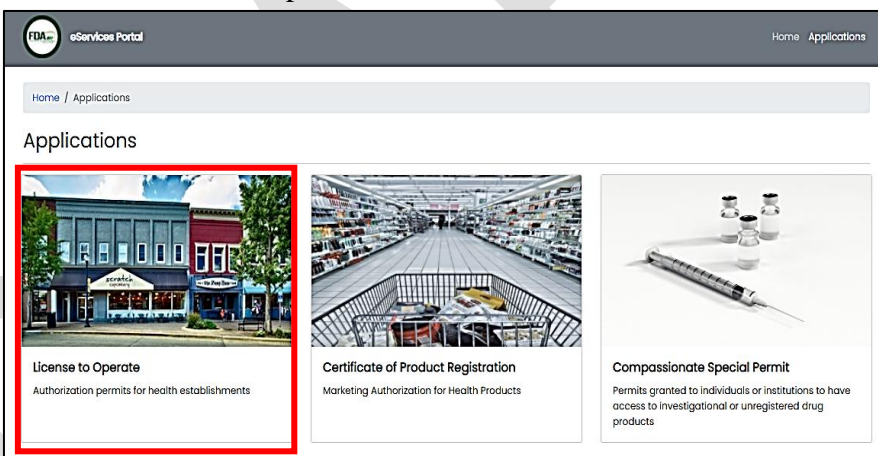
ANNEX E

Procedure for Checking the Status of an Application

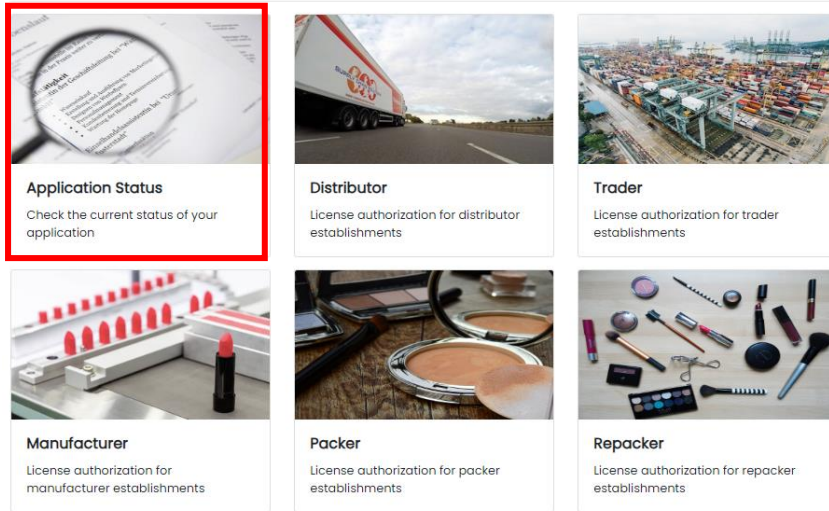
- 22
- 23 Access the online portal through (<https://eservices.fda.gov.ph/>) and click
24 “Applications” found on the upper right corner of the eServices landing page.



- 37
- 38 Click the License to Operate for Household/Urban Hazardous Substances



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2 **3. To check the status of the application, click “Application Status”.**
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19 **4. Enter the Reference Number and click on “Submit”**

The screenshot shows the 'Application Status' page on the FDA eServices Portal. The page has a navigation bar with 'Home Applications Downloadables FAQs' and a breadcrumb trail: 'Home / Applications / License to Operate / Huhs / Status'. The main heading is 'Application Status'. Below the heading, there are three steps: 1. Reference Number, 2. Verification Code, and 3. Application Status. Step 1 is active. A red box highlights the input area for the Reference Number, which includes a blue instruction box: 'Enter the reference number indicated in your application.' Below this is a text input field labeled 'Reference Number' with a placeholder 'e.g. FDA-100000001234' and a blue 'Submit' button.

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36 **5. A verification code will be sent to applicant’s registered e-mail address.**
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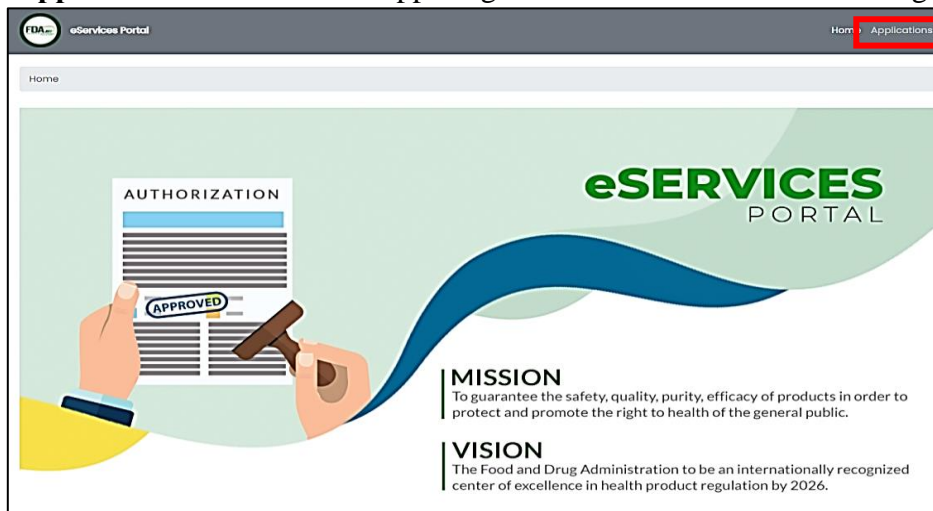
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39 **6. Enter the verification code to view the progress.**

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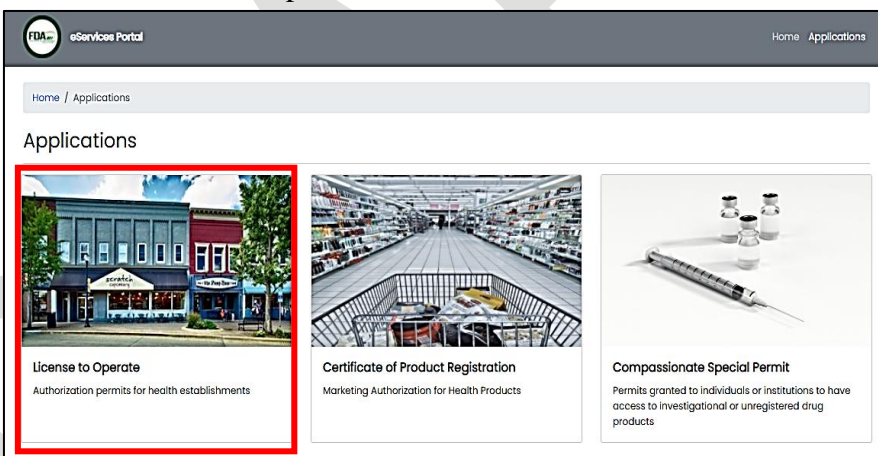
ANNEX F

Procedure for Voluntary Cancellation of an Application

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- 23 Access the online portal through (<https://eservices.fda.gov.ph/>) and click
24 “Applications” found on the upper right corner of the eServices landing page.

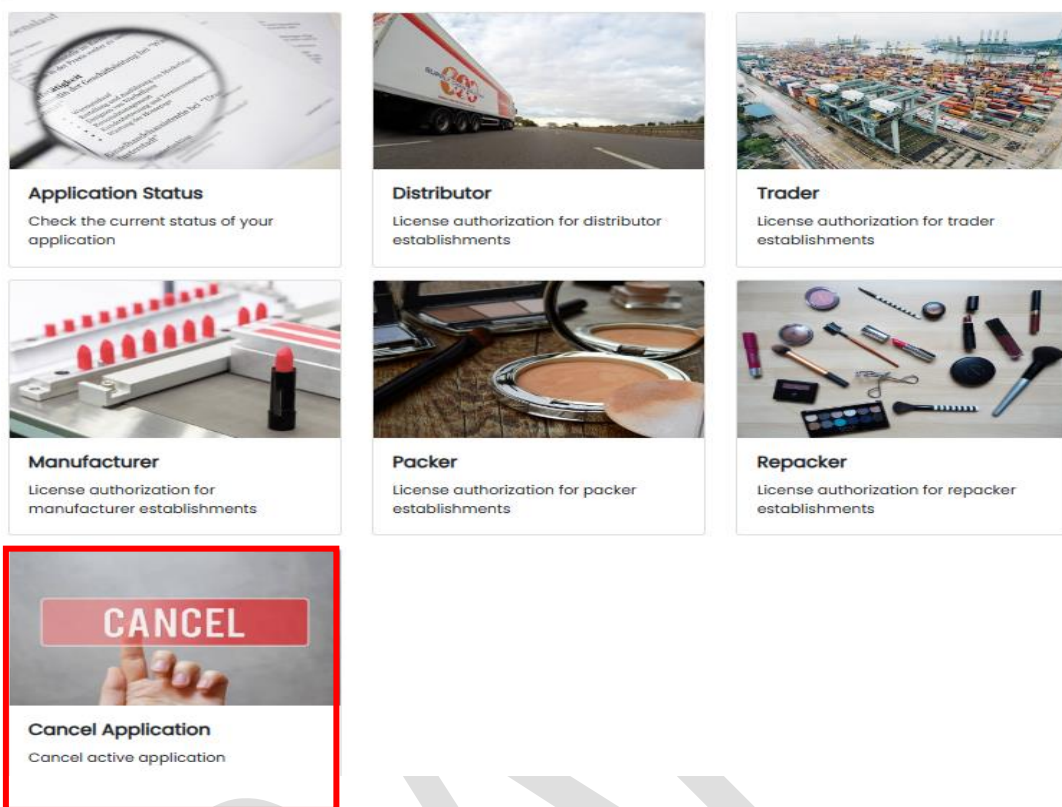


- 37
- 38 Click the License to Operate for Household/Urban Hazardous Substances



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2 **3. To cancel the application, click “Cancel Application”.**
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Application Status
Check the current status of your application

Distributor
License authorization for distributor establishments

Trader
License authorization for trader establishments

Manufacturer
License authorization for manufacturer establishments

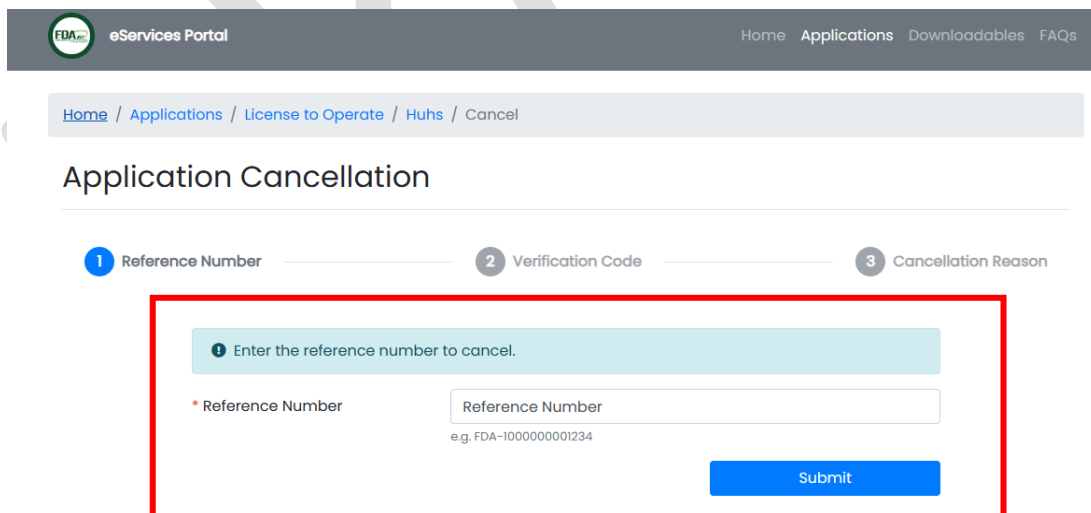
Packer
License authorization for packer establishments

Repacker
License authorization for repacker establishments

CANCEL
Cancel Application
Cancel active application

28 **4. Enter the Reference Number and click on “Submit”**

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Home Applications Downloadables FAQs

Home / Applications / License to Operate / Huhs / Cancel

Application Cancellation

1 Reference Number 2 Verification Code 3 Cancellation Reason

Enter the reference number to cancel.

* Reference Number Reference Number
e.g. FDA-1000000001234

Submit

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

46
47
48 **6. Enter the verification code to state the reason for cancellation.**

DRAFT