



FDA CIRCULAR
No. 2021-014

24 JUN 2021

SUBJECT : Guidelines for the Use of the Food and Drug Administration (FDA) eServices Portal System for License to Operate (LTO) Application of Traders and Distributors including Wholesalers, Importers, and Exporters of Medical Devices, Equipment or Devices Used for Treating Sharps, Pathological and Infectious Waste and Water Treatment Devices/Systems

I. BACKGROUND

Streamlining of License to Operate (LTO) application procedures is one of the key infrastructures that the Food and Drug Administration (FDA) is undertaking. This is in line with the initiatives embodied in the Administrative Order (A.O.) No. 2020-0017 of the Department of Health (DOH) entitled, “*Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003*”. The objective of AO 2020-0017 is to re-engineer and streamline FDA’s processes, specifically, on the issuance of LTO through a web-based application platform.

Further, Republic Act (RA) No. 11032, otherwise known as the “*Ease of Doing Business and Efficient Government Service Delivery Act of 2018*”, mandates all government agencies to simplify and expedite documentary requirements and procedures for business and non-business-related transactions. Such efforts are also compliant with the provisions of RA 8792 or the “*Electronic Commerce Act of 2000*” that promotes the universal use of electronic transaction in the government services.

In this light, the FDA eServices Portal System has been developed to provide a streamlined online platform for FDA Authorization applications. Through this Circular, the FDA eServices Portal has also been updated to include LTO applications of Traders and Distributors including Wholesalers, Importers, and Exporters of medical devices, equipment or devices used for treating sharps, pathological and infectious waste, and water treatment devices/systems.

II. OBJECTIVE

The objective of this Circular is to provide the guidelines on the FDA eServices Portal System in applying for LTO applications of Traders and Distributors including Wholesalers, Importers, and Exporters of medical devices, equipment or devices used for treating sharps, pathological and infectious waste, and water treatment devices/systems.



III. SCOPE

This FDA Circular shall cover the following LTO applications:

A. Types of Establishments:

1. Traders; and
2. Distributors (Wholesalers/Importers/Exporters)

B. Types of Health Product:

1. Medical Devices; and
2. Health-related devices;
 - i. Equipment or Devices used for Treating Sharps, Pathological and Infectious Waste; and
 - ii. Water Treatment Devices/Systems

C. Types of LTO application:

1. Initial;
2. Renewal; and
3. Variation

IV. DEFINITION OF TERMS

The terms used in this Circular shall have the same definition as prescribed in RA 9711 and its Implementing Rules and Regulations (IRR), AO No. 2020-0017, and other applicable laws and regulations.

V. GUIDELINES

- A. The General and Specific Guidelines** on the application for LTO as indicated in AO No. 2020-0017 shall be adopted and expounded in this FDA Circular.

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 as to their compliance to national and/or international standards of safety, quality, purity, and efficacy of health products they provide to the consumers and the general public.

B. Application Requirements

Based on AO No. 2020-0017, the requirements that follow must be submitted:

1. Initial Application
 - a. Accomplished eApplication form with Declaration and Undertaking
 - i. Location Plan;

- ii. Global Positioning System (GPS) Coordinates; and
 - iii. Name of Qualified Person, depending on the type of health product establishment
- b. Proof of Business Name Registration
- i. For Single Proprietorship, Certificate of Business Registration issued by the Department of Trade and Industry (DTI).
 - ii. For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Security and Exchange Commission (SEC) and Articles of Incorporation.
 - iii. 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.
 - iv. For Cooperatives, proof of Business Name Registration issued by the Cooperative Development Authority.
- c. Proof of Income (in pdf, 2MB maximum file size) such as the latest audited Financial Statement with Balance Sheet (in pdf) shall be submitted. This is to verify the capitalization of the establishment to their corresponding application fees. For newly established companies that have no financial statement yet, Statement/Certification of Initial Capitalization must be submitted.
- d. Payment of Fees based on the latest FDA issuance
- e. 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.

2. Renewal Application

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

3. Variation Application

- a. Accomplished e-Application Form with Declaration of Undertaking;
- b. Documentary requirements depending on the variation of circumstances of the establishment or the product; and

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"> 1. For Single Proprietorship:

	<p>Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new office location;</p> <p>2. For Securities and Exchange Commission (SEC)-registered establishments:</p> <p>a. Amended Articles of Incorporation (if transferred from one city/municipality/province; or</p> <p>b. Updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality/province)</p> <p>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</p>
<p>Change of Distributor Activity</p> <ul style="list-style-type: none"> Additional/deletion or change in activity that the distributor is currently engaged 	Contract Agreement 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>Change of Ownership</p> <ul style="list-style-type: none"> Change in ownership of the licensed establishment 	<p>1. Business name registration reflecting new ownership</p> <p>2. Any proof on the transfer of ownership such as any of the following:</p> <p>a. Deed of sale or assignment or transfer of rights/ownership;</p> <p>b. Memorandum of Agreement; or</p> <p>c. Notarized Affidavit of the owner, proprietor, Chairman or Chief Executive Officer (CEO) of the establishment validating the transfer</p>
<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 	<p>1. Certificate of Zonal Change</p> <p>2. Certification from Local Government Unit (LGU) (City/Municipality) stating no physical transfer of the establishment</p>
<p>Change of Qualified Person</p> <ul style="list-style-type: none"> Change in the identified qualified person initially registered with the FDA 	<p>1. Name of new Qualified Person</p> <p>2. Valid Professional Regulation Commission (PRC) ID</p>

	3. Signed Letter of Resignation duly noted by the former employer, if previously connected with another pharmacy/establishment
Change of Authorized Person <ul style="list-style-type: none"> Change of authorized person initially registered with the FDA 	1. Name of new Authorized Person 2. Valid Government ID 3. Updated contact details

c. Payment of Fees based on the latest FDA issuance.

C. Qualification and Credential Requirements of the Qualified Person

Qualification	Training Requirements
<p>For Medical Devices</p> <ul style="list-style-type: none"> Registered professional or graduates in the field of allied health profession: Pharmacy, Nursing, Medical Technology, Dentistry, Radiologic Technology, Medicine, Physical Therapy, and other allied science courses relevant the device to be distributed Engineering profession (includes the following course but not limited to EE, ECE, ME, CoE, CHE, SE), Computer Science, and Chemistry <p>For Health-Related Devices Graduate of engineering courses preferably chemical, sanitary, civil or mechanical or other science courses relevant to the device to be distributed</p>	<p>a. PRC ID for professions with Board/Licensure Exam or Diploma for profession without Board/Licensure Exam</p> <p>b. Certificate of Attendance to seminars, training, learning and development activities on medical device safety and quality given by the academe, industry, organization, professional organization, National Regulatory Authorities, international organization like the WHO and ISO</p>

D. Application Process

1. The application shall be filed online through the eServices Portal website (eservices.fda.gov.ph). The creation of account and password is no longer a requirement to obtain access to the eServices Portal.
2. The applicant is expected to read and agree with the “**Declaration and Undertaking**” in order to continue with the application. Such conveys a binding agreement of the applicant company with the FDA to provide accurate information, affirm primary responsibility over the products, and comply with all the rules and regulations set forth during and after the application process. Any false misrepresentation of the information in this application shall be subjected to administrative and criminal liabilities, provided by R.A. 9711, which includes, but not limited to suspension, cancellation, or revocation of the LTO.

3. In filling-up the fields in the eApplication form, the applicant will be assisted with written warnings/pop-ups/reminders before proceeding to the next step to ensure accuracy of the information being provided. The establishment applying for LTO shall ensure that the declared information in the eApplication form is consistent with the uploaded supporting documents, i.e., establishment name and owner, establishment's address, and others.
4. The declared e-mail address under the Contact Information is **unalterable**. Hence, the applicant shall be responsible in making sure that the e-mail address is within the scope and access of the Authorized Person/s, Qualified Personnel, and/or owner of the establishment. The FDA shall not be held liable in any way for loss of access to the declared e-mail address.

The Company Authorized Officer or Qualified Personnel shall have the responsibility to comply with the regulatory and technical requirements of the FDA wherein:

- a. The **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; and
 - b. The **Qualified Person** refers to an organic or full-time employee of the establishment who possesses 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 FDA or discuss/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.
5. All Traders and Distributors including Wholesalers, Importers, and Exporters shall submit a notification of sources immediately after the approval of the LTO.
 6. Variation and renewal applications must be applied separately. If a Medical Device Establishment is due for renewal, but is expected to apply for changes in information that need to be reflected in the system or registry, then a renewal application must first be submitted.

The clients should be informed that the LTO to be issued upon renewal will reflect the previous information and the updating should be done through filing of a separate variation. In addition, the clients cannot apply for a renewal of application if not within ninety (90) days before the expiration date of the LTO.

7. For any variation, the establishment is required to file for a new notification.
8. For applications filed through the FDA eServices Portal System, there shall be a change in the format of LTO number as such;

Old: **300000XXXXXX**

New: **CDRRHR-(Region)-(Activity)- (Sequence Number)**

9. Documents required to be uploaded in the eApplication form shall be in portable document file (PDF), with no more than 2 megabytes (MB) file size.
10. Once the eApplication 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 to the correctness of information provided and data privacy terms.
11. The Application Summary shall be automatically sent to the applicant's registered email address to indicate the successful submission of the application in the eServices Portal.
12. Applications filed after the prescribed working/office hours or during weekends and holidays shall be considered filed on the next working day.
13. The status of the application can be monitored at eServices website by validating thru the e-mail address used for the application.
14. Establishments with existing LTO applications via ePortal may opt to apply to the eServices Portal for a new fee. The previous payment will be forfeited as the filed applications are already in-process.

(The step-by-step procedure in the eServices Portal is attached as Annex in this issuance)

E. Pre-assessment

1. An FDA evaluator/assessor shall conduct a pre-assessment on the submitted application and documentary requirements with regards to their completeness. Applications with incomplete document submissions shall not be accepted and the application will not proceed to the next step of the process.
2. The Pre-assessment of applications shall be done within the prescribed working days and office hours of the FDA.
3. 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 apply again through the eServices Portal.

F. Payment of Fees

1. The payment of the total application fee as indicated in the Order of Payment (OP) maybe done through Over-the-counter (OTC) payment at FDAC, On-coll payment at Land Bank of the Philippines (LBP) branches, or online payment thru Bancnet (including LBP bills payment), based on the existing FDA issuances. The clients should always indicate the reference number reflected in the OP when paying through FDA available online payment channels. Otherwise, when transacting through over-the-counter payment method, the print-out OP should be endorsed to Cashier Officer for the processing of payment. Clients will be informed of other available channels of payment through an FDA issuance.
2. Once the payment is made, the payment channel -LBP or Bancnet (except for OTC at FDAC) will send a transaction report to FDA which usually takes a minimum of two (2) days. Upon receipt of the report, the Cashier Section checks the details and posts the payment in the eServices Portal if payment is made in full. Posting of payment may take a maximum of two (2) days, depending on the volume of paid applications received.
3. Incomplete payment (amount paid is less than that of OP amount) will not be posted until the full amount as indicated in OP is settled. As such, applications with incomplete or unsettled payments will not proceed to the next step of the process.
4. Applicants will receive a system-generated message through the registered email address on the status of the payment made once posted or need further settlement. If full payment is made, the e-mail will contain Acknowledgment Receipt, otherwise, a notification on payment deficiency.

G. Approval of Application

1. The veracity of the application and compliance with all relevant FDA requirements and standards shall be checked.
2. The applications with complete documentary requirements and payment, shall receive an Acknowledgement Receipt from FDA, containing the employees' number/code who received the application, 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.
3. If the application is approved, the FDA shall send the LTO to the registered e-mail address of the applicant. 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.

H. Disapproval of Application

- 1. For emphasis, the grounds for disapproval of LTO application may be any of the following, as stated in A.O 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. However, disapproval shall mean outright forfeiture of payment.

I. Release of LTO

1. The applicant shall receive the LTO in their registered e-mail address and may also be accessed through the FDA eServices Portal.
2. Upon receipt of the LTO, the establishments 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 on the most conspicuous place within the business establishments.
3. A QR Code verifier shall be included in the LTO as basis of legitimacy of the document.
4. For Variation, the applied variation shall automatically be reflected on the LTO. An updated LTO shall be provided to the registered e-mail address of the applicant.

VI. SEPARABILITY CLAUSE

If any part or term of provision of this Circular shall be declared invalid or unenforceable, the validity or enforceability of the remaining portion or provision should not be affected, and this Circular shall be construed as it did not contain the invalid or unenforceable part, term or provision.

VII. REPEALING CLAUSE

Issuances, rules and regulations on the LTO applications for Traders, and Distributors including Wholesalers, Importers, and Exporters of medical devices, equipment/devices used for treating sharps, pathological and infectious waste, and water treatment devices/systems found inconsistent with the provisions of this Circular are hereby amended or repealed accordingly.

VIII. EFFECTIVITY

This Circular shall be effective immediately.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN: 20200928104025

ANNEX A

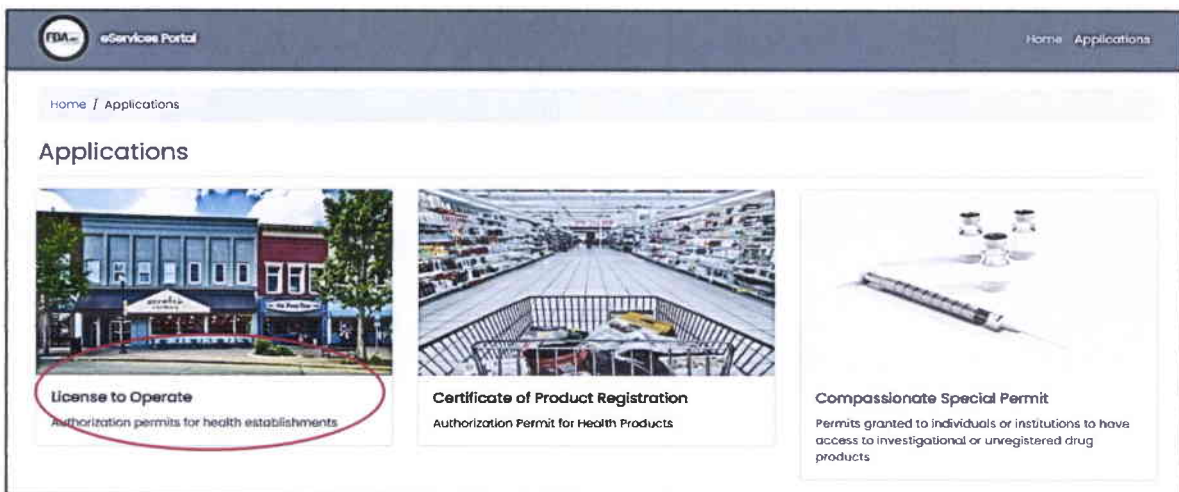
Procedure for the Use of the FDA eServices Portal for License to Operate (LTO) Application of Traders and Distributors including Wholesalers, Importers, and Exporters of Medical Devices

A. APPLICATION FOR INITIAL LTO OF MEDICAL DEVICE DISTRIBUTOR

1. Access the online portal through 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 Device and the type of health product (Medical Device) and Business Establishment (Distributor).



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



Device

For establishments that handle device products

Device



Medical Device

For establishments that handle Medical Device



Health Related Device

For establishments that handle Health-Related Device products

Medical Device



Application Status

Check the current status of your application



Distributor

License authorization for establishment that imports and exports medical device or procure products from local establishments and distribute to other establishment on a wholesale basis.



Trailer

License authorization for establishments that import or export raw materials, active ingredients and/or finished products for own use and wholesale distribution to other establishments or outlets but subcontracts the manufacture of such product to a licensed manufacturer

3. Click the Initial Application.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Medical / Distributor

Medical Device Distributor

Initial
Apply for a new License to Operate

Renewal
Renew existing License to Operate

Variations
Apply for changes in the existing License to Operate

4. Read carefully the “Declaration and Undertaking” before proceeding with the application process. Make sure to check the box found below and click on “Start Application”.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Medical device / Distributor / Initial

Medical Device Distributor Initial

1 Declaration & Undertaking

2 General Information

3 Product Line

4 Establishment Information

5 Office Address

6 Warehouse Addresses

7 Authorized Officer

8 Qualified Personnel

9 Documentary Requirements

10 Self-Assessment Review

Declaration & Undertaking

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 Qualified Person (PRC registered professional or graduates in the field of allied health profession) or authorized personnel at all times;
- II. The Qualified Person, upon and during employment in the establishment, is 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-approval shall be a ground for the appropriate sanctions including the revocation of this license or, and/or the filing of the appropriate legal action against me, the owner, its officers or the establishment whenever possible.

I agree to the declaration and undertaking
In order to proceed with your application, you need to agree with the declaration and undertaking

Start Application

5. Fill out the necessary information accurately based on establishment's activity/ies (Importer, Exporter, or Wholesaler). Make sure to properly tick the corresponding activity/ies before proceeding on the next step.

The screenshot shows the 'Medical Device Distributor Initial' form at the 'General Information' step. The left sidebar contains a list of steps from 1 to 10, with '2 General Information' circled in red. The main form area has the following fields: 'Type of Application' (dropdown menu with 'Initial' selected), 'Product Type' (dropdown menu with 'Medical Device' selected), 'Primary Activity' (dropdown menu with 'Distributor' selected), and 'Distributor Activities' (checkboxes for 'Importer', 'Exporter', and 'Wholesaler', all of which are circled in red). At the bottom right, there are 'Back' and 'Next' buttons.

6. Indicate the Medical Device Product Line and its description. If there are two or more product lines, click on the "Add Product Line".

The screenshot shows the 'Medical Device Distributor Initial' form at the 'Product Line/s' step. The left sidebar contains a list of steps from 1 to 10, with '3 Product Line/s' circled in red. The main form area has the following fields: 'Product Line #1' (text input), 'Product Type' (dropdown menu with 'Please Select' selected), and 'Product Description' (text input with a red 'X' icon). Below these fields is a red-bordered box containing an 'Add Product Line' button with a plus icon, which is circled in red. At the bottom right, there are 'Back' and 'Next' buttons.

7. The e-mail address shall be official and the applicant shall make sure that it is within the scope and access of the Authorized Representative/s.

Please take note that all the fields marked with asterisks (*) are required to be filled out.

The screenshot shows the 'Medical Device Distributor Initial' form at the 'Establishment Information' step. The left sidebar lists steps 1 through 10, with step 4 'Establishment Information' circled in red. The main form area contains the following fields:

- Establishment Information**
 - * Name of Establishment: Text input field with placeholder 'Name of Establishment'. Below it, a note states: 'Business Name shall be the same name in the SEC/DTI/CDA permit/Original Charter. Please ensure correctness of the declared Business Name as this will be the same name to be reflected in the License to Operate.'
 - * Owner of Establishment: Text input field with placeholder 'Owner of Establishment'. Below it, a note states: 'For SEC/CDA registered establishments, the name of the corporation/cooperative must be used as the owner.'
 - * Tax Identification Number: Text input field with placeholder 'Tax Identification Number'.
- Contact Information**
 - Email Address: Text input field with placeholder 'Email Address'. Below it, a note states: '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: Text input field with placeholder 'Mobile Number'. Below it, a note states: 'Please indicate an 11 digit mobile number.'
 - Landline Number: Text input field with placeholder 'Landline Number'. Below it, a note states: 'Please indicate the area code followed by the landline number.'

At the bottom right of the form are 'Back' and 'Next' buttons.

8. Click the "Get GPS Coordinates" to determine the exact location of the Office Address. Pin accurately the location on the map.

The screenshot shows the 'Medical Device Distributor Initial' form at the 'Office Address' step. The left sidebar lists steps 1 through 10, with step 5 'Office Address' circled in red. The main form area contains the following fields:

- Office Address**
 - * Region: Dropdown menu with placeholder 'Please Select'.
 - * Province: Dropdown menu with placeholder 'Please Select'.
 - * City or Town: Dropdown menu with placeholder 'Please Select'.
 - * Street Address: Text input field with placeholder 'Street Address'. Below it, a note states: '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.'
 - * OPS Latitude: Text input field with placeholder 'GPS Latitude'.
 - * OPS Longitude: Text input field with placeholder 'GPS Longitude'.

At the bottom of the form is a button labeled 'Get GPS Coordinates' circled in red, along with 'Back' and 'Next' buttons.

9. 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.

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

Home / Applications / License to Operate / Device / Medical / Distributor / Initial

Medical Device Distributor Initial

- 1 Declaration & Undertaking
- 2 General Information
- 3 Product Line/s
- 4 Establishment Information
- 5 Office Address
- 6 Warehouse Addresses**
- 7 Authorized Officer
- 8 Qualified Personnel
- 9 Documentary Requirements
- 10 Self-Assessment Review

Warehouse Addresses

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:

10. The declared name of the Authorized Officer is understood to be the one transacting with FDA and shall only have the authority to transact on behalf of the establishment (i.e., follow ups, received result, etc.).

Home / Applications / License to Operate / Medical device / Distributor / Initial

Medical Device Distributor Initial

- 1 Declaration & Undertaking
- 2 General Information
- 3 Product Line
- 4 Establishment Information
- 5 Office Address
- 6 Warehouse Addresses
- 7 Authorized Officer**
- 8 Qualified Personnel
- 9 Documentary Requirements
- 10 Self-Assessment Review

The declared name of the authorized officer is understood to be the one transacting with FDA and shall only have the authority to transact on behalf of the establishment (i.e. follow-ups, receives result).

Details of Authorized Officer

* 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:

11. Fill out the details of the Qualified Personnel.

1 Declaration & Undertaking

2 General Information

3 Product Line

4 Establishment Information

5 Office Address

6 Warehouse Addresses

8 Authorized Officer

9 Qualified Personnel

Details of the Qualified Personnel

Personnel Details

* First Name

Middle Name

* Last Name

* Designation

* Profession

Government Issued Identification Document

* Type

* Identification Number

12. Upload the necessary documents.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Medical device / Distributor / Initial

Medical Device Distributor Initial

1 Declaration & Undertaking

2 General Information

3 Product Line

4 Establishment Information

5 Office Address

6 Warehouse Addresses

7 Authorized Officer

9 Documentory Requirements

10 Self-Assessment Review

Documentory Requirements

* 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
Please upload a business/mayor's permit or barangay clearance if the declared site address is different on the proof of business name registration document.

13. The applicant may review all the details of the applications in the “Self-Assessment Review”.

1 Declaration & Undertaking
2 General Information
3 Product Line
4 Establishment Information
5 Office Address
6 Warehouse Addresses
7 Authorized Officer
8 Qualified Personnel
9 Documentary Requirements
10 Self-Assessment Review

Self-Assessment Review

General Information

* Type of Application: Initial
* Product Type: Medical Device
* Primary Activity: Distributor
* Distributor Activities: Importer, Exporter, Wholesaler

Medical Device Product Line

Product Line 1: Medical Device
* Product Type: Medical Device
* Product Description: [Text Area]
Add Product Line

14. After the self-assessment review, the applicant shall confirm the correctness of the data and uploaded documents and click on “Confirm” to submit the application.

I'm not a robot reCAPTCHA 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.
I consent to the use of any personal information provided herein for Government to conduct the necessary records check and verification of facts in connection with my application.

Back Confirm

B. APPLICATION FOR INITIAL LTO OF MEDICAL DEVICE TRADER

Proceed as in Step No. 1 to Step No. 14 of Item A (Application for Initial LTO for Medical Device Distributor). Make sure to click the appropriate type of establishment under Step No. 2. However, please indicate the Toll Manufacturer details under Step 5 of the eServices Portal System.

Fill out the Toll Manufacturer details including the address and contract validity.

Toll Manufacturer Details

1 Declaration & Undertaking

2 General Information

3 Product Line

4 Establishment Information

5 Toll Manufacturer

6 Office Address

7 Warehouse Addresses

* Name of Toll Manufacturer:

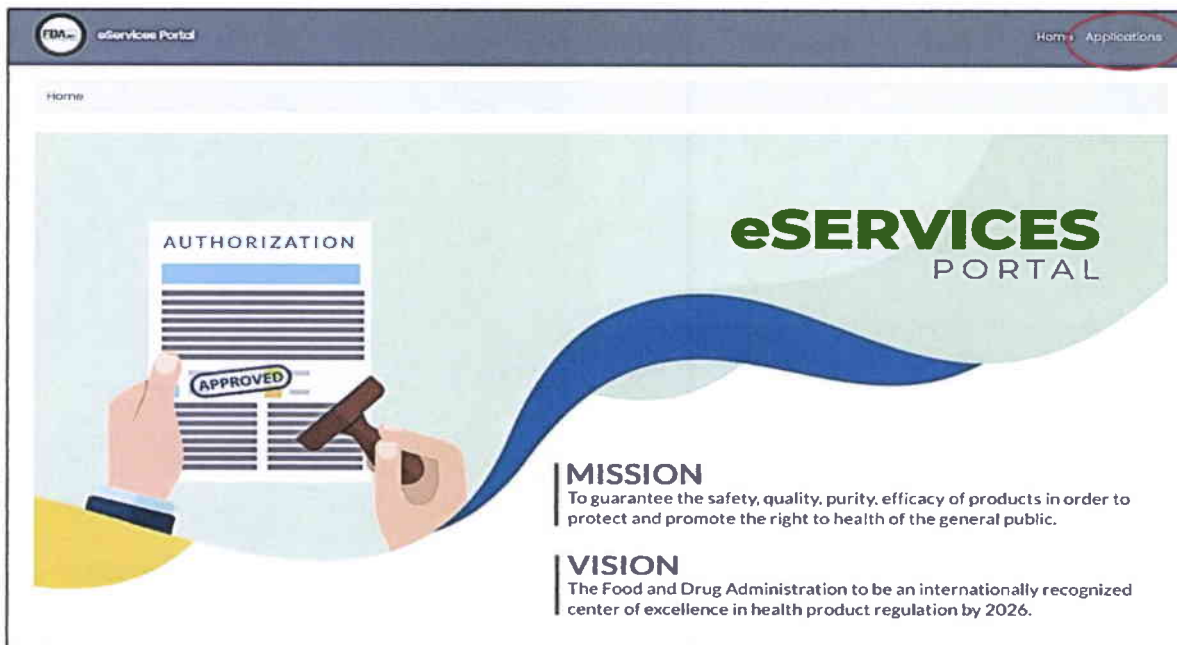
* Address:

* Contract Validity:

Back Next

C. APPLICATION FOR RENEWAL LTO OF MEDICAL DEVICE DISTRIBUTOR

1. Access the online portal through 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 Device and the type of health product (Medical Device) and Business Establishment (Distributor).



Home / Applications

Applications



License to Operate
Authorization permits for health establishments.



Certificate of Product Registration
Authorization Permit for Health Products



Compassionate Special Permit
Permits granted to individuals or institutions to have access to investigational or unregistered drug products

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



Device
For establishments that handle device products



Home / Applications / License to Operate / Device

Device



Medical Device
For establishments that handle Medical Device products




Health Related Device
For establishments that handle Health-Related Device products


FDA eServices Portal Home Applications

Home / Applications / License to Operate / Medical device


Medical Device



Application Status
Check the current status of your application



Distributor
License authorization for establishment that imports and exports medical device or procure products from local establishments and distribute to other establishment on a wholesale basis.




Trader
License authorization for establishments that import or export raw materials, active ingredients and/or finished products for own use and wholesale distribution to other establishments or outlets but subcontracts the manufacture of such product to a licensed manufacturer

3. Click the Renewal Application.


FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Medical / Distributor


Medical Device Distributor



Initial
Apply for a new license to Operate



Renewal
Renew existing License to Operate



Variations
Apply for changes in the existing License to Operate

4. Read carefully the **“Declaration and Undertaking”** before proceeding with the application process. Make sure to check the box found below and click on **“Start Application”**.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Medical / Distributor / Renewal

Medical Device Distributor Renewal

1 Declaration & Undertaking

2 License to Operate

3 Contact Information

4 Self-Assessment Review

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 Qualified Person (PRC registered professional or graduates in the field of allied health profession) or authorized personnel at all times;
- II. The Qualified Person, upon and during employment in the establishment, is 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-approval shall be a ground for the appropriate sanctions including the revocation of the license or, and/or the filing of the appropriate legal action against me, the owner, its officers, directors, representatives, or authorized personnel.

I agree to the declaration and undertaking

Start Application

5. Fill out the necessary details such as the valid License Number, its date of validity, and security code.

The security code is generated by scanning the QR Code found in the document. If everything is in order, tick the Captcha box and click “Next” to proceed to Contact Information.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Medical / Distributor / Renewal

Medical Device Distributor Renewal

1 Declaration & Undertaking

2 License to Operate

3 Contact Information

4 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).

I'm not a robot 

Back **Next**

6. Update the contact number if necessary. Click “Next” to proceed to “Self-Assessment Review”.
7. The applicant may review all the details of the applications in the “Self-Assessment Review”.

D. APPLICATION FOR RENEWAL LTO OF MEDICAL DEVICE TRADER

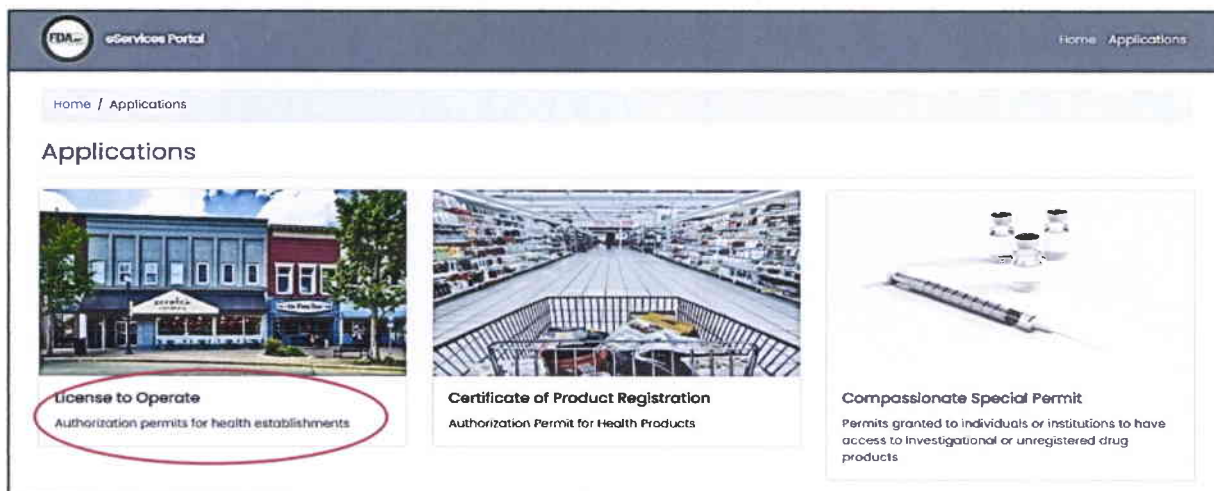
Proceed as in Step No. 1 to Step No. 7 of Item C (**Application for Renewal of LTO of Medical Device Distributor**). Make sure to click the appropriate type of establishment under Step No. 2.

E. APPLICATION FOR VARIATION IN LTO OF MEDICAL DEVICE DISTRIBUTOR

1. Access the online portal through 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 Device and the type of health product (Medical Device) and Business Establishment (Distributor).



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



Device

For establishments that handle device products

Device



Medical Device

For establishments that handle Medical Device products



Health Related Device

For establishments that handle Health-Related Device products

Medical Device



Application Status

Check the current status of your application



Distributor

License authorization for establishment that imports and exports medical device or procure products from local establishments and distribute to other establishment on a wholesale basis.



Trader

License authorization for establishments that import or export raw materials, active ingredients and/or finished products for own use and wholesale distribution to other establishments or outlets but subcontracts the manufacture of such product to a licensed manufacturer

3. Click the Variation application.

The screenshot shows the FDA eServices Portal interface. The breadcrumb trail is: Home / Applications / License to Operate / Device / Medical / Distributor. The main heading is "Medical Device Distributor". There are three application options, each with an image and a description:

- Initial**: Apply for a new License to Operate. Image: A person writing on a document.
- Renewal**: Renew existing License to Operate. Image: A clock face with a pen.
- Variations**: Apply for changes in the existing License to Operate. Image: A hand holding a red pill in front of a chalkboard with "UPDATE" written on it. This option is circled in red.

4. Read carefully the “Declaration and Undertaking” before proceeding with the application process. Make sure to check the box found below and click on “Start Application”.

The screenshot shows the "Medical Device Distributor Variations" application page. The breadcrumb trail is: Home / Applications / License to Operate / Device / Medical / Distributor / Variations. The main heading is "Medical Device Distributor Variations". On the left, there is a navigation menu with six steps:

- 1 Declaration & Undertaking (circled in red)
- 2 License to Operate
- 3 Contact Information
- 4 Minor Variations
- 5 Self-Assessment Review
- 6 Self-Assessment Review

The main content area is titled "Declaration & Undertaking" and 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 Qualified Person (PRC registered professional or graduates in the field of allied health profession) or authorized personnel at all times;
- II. The Qualified Person, upon and during employment in the establishment, is 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-approval shall be a ground for the appropriate actions including the revocation of the license or, and/or the filing of the appropriate legal action against me.

At the bottom, there is a checkbox labeled "I agree to the declaration and undertaking" with the text "In order to proceed with your application, you need to agree with the declaration and undertaking" below it. This checkbox is circled in red. Below the checkbox is a blue button labeled "Start Application".

5. 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.

The screenshot shows the FDA eServices Portal interface for 'Medical Device Distributor Variations'. The page has a breadcrumb trail: Home / Applications / License to Operate / Device / Medical / Distributor / Variations. The main heading is 'Medical Device Distributor Variations'. On the left, a vertical navigation menu lists six steps: 1. Declaration & Undertaking, 2. License to Operate (highlighted with a red circle), 3. Contact Information, 4. Minor Variations, and 5. Self-Assessment Review. The 'License to Operate' section contains three input fields: 'License Number', 'Date of Validity', and 'Security Code'. Below these fields is a note: 'Please scan the QR Code in the document. For previously issued LTO, enter the sequence number located at the bottom right corner of the document (e.g. FDA-23156)'. At the bottom right, there is a reCAPTCHA 'I'm not a robot' checkbox and 'Back' and 'Next' buttons.

6. Provide an updated contact information if applicable.
7. Key in the required fields. To upload documents, click the File Upload. Fill out the necessary variations (ex. Transfer of Location of Offices, Change of Distributor Activity, additional warehouse, and expansion of office establishments, change of business name, qualified person, or authorized person).
8. User may review if all details are correct in the “Self-Assessment Review”.
9. Once reviewed, the User shall confirm the correctness of data given and click on “**Confirm**” to submit the application.

F. APPLICATION FOR VARIATION IN LTO OF MEDICAL DEVICE TRADER

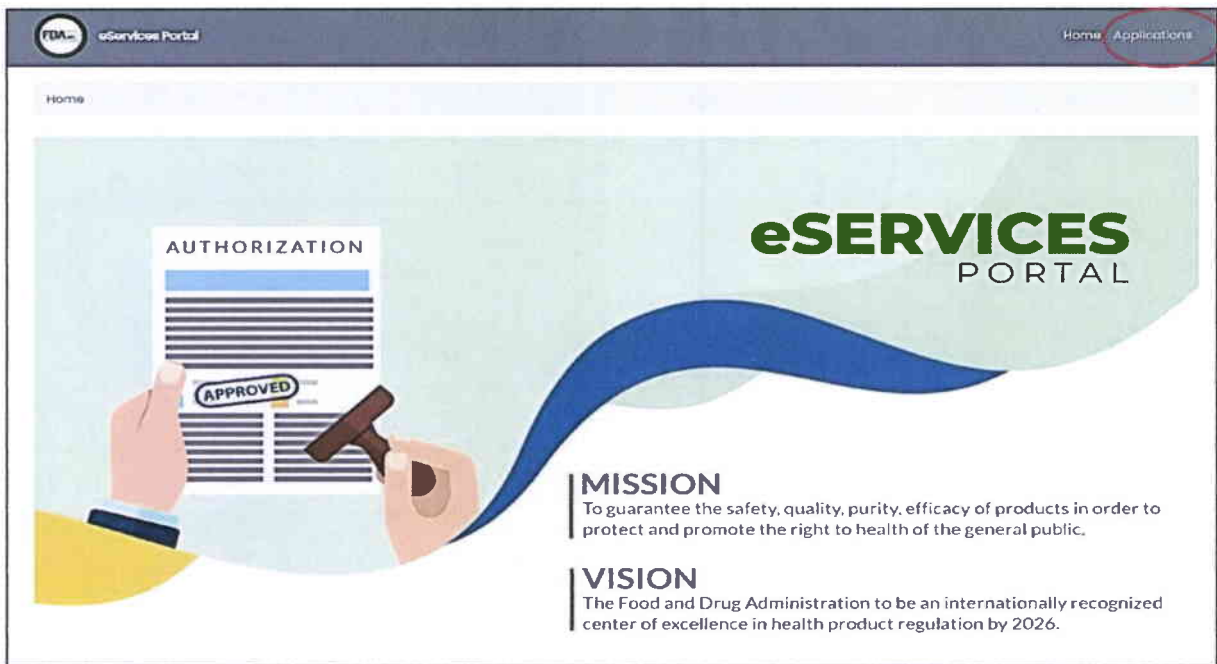
Proceed as in Step No. 1 to Step No. 9 of Item E (**Application for Variation in LTO of Medical Device Distributor**). Make sure to click the appropriate type of establishment under Step No. 2.

ANNEX B

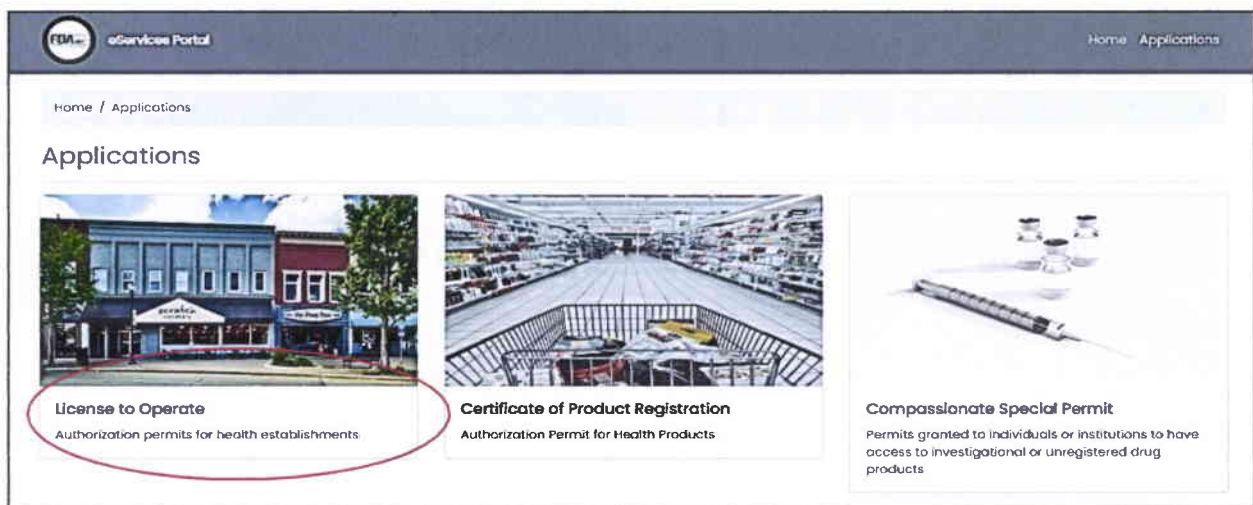
Procedure for the Use of the FDA eServices Portal for License to Operate (LTO) Application of Traders and Distributors including Wholesalers, Importers, and Exporters of Health-Related Devices such as Equipment or Devices Used for Treating Sharps, Pathological, and Infectious Waste and Water Treatment Devices/Systems

A. APPLICATION FOR INITIAL LTO FOR WATER TREATMENT DEVICE/SYSTEM DISTRIBUTOR

1. Access the online portal through 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 Device and the type of health product (Health-Related Device – Water Treatment Device/System) and Business Establishment (Distributor).



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



Device

For establishments that handle device products

Device



Medical Device

For establishments that handle Medical Device products



Health Related Device

For establishments that handle Health-Related Device products

Health Related Device



Water Treatment Device/System

For establishments that handle water treatment device/system



Devices used for Sharps, Pathological and Infectious Waste

For establishments that handle devices used for treating sharps, pathological, and infectious waste

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Health / Water

Water Treatment Device/System Distributor



Application Status
Check the current status of your application.



Distributor
License authorization for distributor establishments




Trader
License authorization for trader establishments

3. Click the Initial application.


FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Health / Water / Distributor


Water Treatment Device/System Distributor Initial



Initial
Apply for a new License to Operate



Renewal
Renew existing License to Operate



Variations
Apply for changes in the existing License to Operate

4. Read carefully the “**Declaration and Undertaking**” before proceeding with the application process. Make sure to check the box found below and click on “**Start Application**”.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Health / Water / Distributor / Initial

Water Treatment Device/System Distributor Initial

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10

Declaration & Undertaking

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 Qualified Person (PRC registered professional or graduates in the field of allied health profession) or authorized personnel at all times;
- II. The Qualified Person, upon and during employment in the establishment, is 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-approval shall be a ground for the appropriate sanctions including the revocation of the license or, post/or the filing of the appropriate legal action against me, the owner, its

I agree to the declaration and undertaking

[Start Application](#)

- Fill out the necessary information accurately based on establishment's activity/ies (Importer, Exporter, or Wholesaler). Make sure to properly tick the corresponding activity/ies before proceeding on the next step.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Health / Water / Distributor / Initial

Water Treatment Device/System Distributor Initial

- Declaration & Undertaking
- General Information**
- Product Line/s
- Establishment Information
- Office Address
- Warehouse Addresses
- Authorized Officer
- Qualified Personnel
- Documentary Requirements
- Self-Assessment Review

General Information

* Type of Application: Initial

* Product Type: Health-Related Device

* Primary Activity: Distributor

* Distributor Activities:

- Importer
- Exporter
- Wholesaler

Back Next

- Indicate the Health-Related Device Product Line (Water Treatment Device/System) and its description. If there are two or more product lines, click on the "Add Product Line".

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Water / Distributor / Initial

Water Treatment Device/System Distributor Initial

- Declaration & Undertaking
- General Information
- Product Line/s**
- Establishment Information
- Office Address
- Warehouse Addresses
- Authorized Officer
- Qualified Personnel
- Documentary Requirements
- Self-Assessment Review

Product Line/s

Product Line #1

* Product Type: Please Select

* Product Description:

Product Line #2 required field

Add Product Line

Back Next

- The e-mail address shall be official and the applicant shall make sure that it is within the scope and access of the Authorized Representative/s.

Please take note that all the fields marked with asterisks (*) are required to be filled out.

Water Treatment Device/System Distributor Initial

1 Declaration & Undertaking
 2 General Information
 3 Product Line
 4 **Establishment Information**
 5 Office Address
 6 Warehouse Addresses
 7 Authorized Officer
 8 Qualified Personnel
 9 Documentary Requirements
 10 Self-Assessment Review

Establishment Information

* Name of Establishment: Name of Establishment
Business Name shall be the same name in the SEC/DTI/CDA permit/Original Charter. Please ensure correctness of the declared Business Name as this will be the same name to be reflected in the License to Operate

* Owner of Establishment: Owner of Establishment
For SEC/CDA registered establishments, the name of the corporation/cooperative must be used as the owner

* Tax Identification Number: Tax Identification Number

Contact Information

* Email Address: 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: Mobile Number
Please indicate an 11 digit mobile number

Landline Number: Landline Number
Please indicate the area code followed by the landline number

Back Next

- Click the “Get GPS Coordinates” to determine the exact location of the Office Address. Pin accurately the location on the map.

Water Treatment Device/System Distributor Initial

1 Declaration & Undertaking
 2 General Information
 3 Product Line
 4 Establishment Information
 5 **Office Address**
 6 Warehouse Addresses
 7 Authorized Officer
 8 Qualified Personnel
 9 Documentary Requirements
 10 Self-Assessment Review

Office Address

* Region: Please Select
 * Province: Please Select
 * City or Town: Please Select
 * Street Address: Street Address
The declared address shall be the same address submitted in the SEC/DTI/CDA permit. Likewise, the declared address must be consistent with the one submitted in the business permit

* GPS Latitude: GPS Latitude
 * GPS Longitude: GPS Longitude

Get GPS Coordinates

Back Next

- 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.

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

FDA eService Portal Home Applications

Home / Applications / License to Operate / Device / Water / Distributor / Initial

Water Treatment Device/System Distributor Initial

- 1 Declaration & Undertaking
- 2 General Information
- 3 Product Line/s
- 4 Establishment Information
- 5 Office Address
- 6 Warehouse Addresses**
- 7 Authorized Officer
- 8 Qualified Personnel
- 9 Documentary Requirements
- 10 Self-Assessment Review

Warehouse Addresses

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

- The declared name of the Authorized Officer is understood to be the one transacting with FDA and shall only have the authority to transact on behalf of the establishment (i.e., follow ups, received result, etc.)

FDA eService Portal Home Applications

Home / Applications / License to Operate / Water / Distributor / Initial

Water Treatment Device/System Distributor Initial

- 1 Declaration & Undertaking
- 2 General Information
- 3 Product Line
- 4 Establishment Information
- 5 Office Address
- 6 Warehouse Addresses
- 7 Authorized Officer**
- 8 Qualified Personnel
- 9 Documentary Requirements
- 10 Self-Assessment Review

The declared name of the authorized officer is understood to be the one transacting with FDA and shall only have the authority to transact on behalf of the establishment (i.e. follow-ups, receives result).

Details of Authorized Officer

* 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

11. Fill out the details of the Qualified Personnel.

1 Declaration & Undertaking
2 General Information
3 Product Line
4 Establishment Information
5 Office Address
6 Warehouse Addresses
7 Authorized Officer
8 Qualified Personnel
9 Documentary Requirements
10 Self-Assessment Review

Details of the Qualified Personnel

Personnel Details

- * First Name:
- Middle Name:
- * Last Name:
- * Designation:
- * Profession:

Government Issued Identification Document

- * Type:
- * Identification Number:

12. Upload the necessary documents.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Water / Distributor / Initial

Water Treatment Device/System Distributor Initial

1 Declaration & Undertaking
2 General Information
3 Product Line
4 Establishment Information
5 Office Address
6 Warehouse Addresses
7 Authorized Officer
8 Qualified Personnel
9 Documentary Requirements
10 Self-Assessment Review

Documentary Requirements

- * Proof of Business Name Registration:
D11 Permit, SEC with Articles of Incorporation/Partnership, CDA Permit, or Government-Owned and Control Corporation (GOCC)
- Business/Mayor's Permit or Barangay Clearance:
Please upload a business/mayor's permit or barangay clearance if the declared site address is different on the proof of business name registration document.

13. The applicant may review all the details of the applications in the “Self-Assessment Review”.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Water / Distributor / Initial

Water Treatment Device/System Distributor Initial

Self-Assessment Review

- 1 Declaration & Undertaking
- 2 General Information
- 3 Product Line
- 4 Establishment Information
- 5 Office Address
- 6 Warehouse Addresses
- 7 Authorized Officer
- 8 Qualified Personnel
- 9 Documentary Requirements
- 10 Self-Assessment Review**

General Information

* Type of Application: Initial

* Product Type: Medical Device

* Primary Activity: Distributor

* Distributor Activities:
 Importer
 Exporter
 Wholesaler

Medical Device Product Line

Product Line 1

* Product Type: Medical Device

* Product Description: [Text Area]

+ Add Product Line

14. After the self-assessment review, the applicant shall confirm the correctness of the data and uploaded documents and click on “Confirm” to submit the application.

I'm not a robot

reCAPTCHA 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.

I consent to the use of any personal information provided herein for Government to conduct the necessary records check and verification of facts in connection with my application.

Back Confirm

B. APPLICATION FOR INITIAL LTO FOR WATER TREATMENT DEVICE/SYSTEM TRADER

Proceed as in Step No. 1 to Step No. 14 of Item G (**Application for Initial LTO for Water Treatment Device/System Distributor**). Make sure to click the appropriate type of establishment under Step No. 2. However, please indicate the Toll Manufacturer details under Step 5 of the eServices Portal System.

Fill out the Toll Manufacturer details including the address and contract validity.

Toll Manufacturer Details

1 Declaration & Undertaking

2 General Information

3 Product Line

4 Establishment Information

5 Toll Manufacturer

6 Office Address

7 Warehouse Addresses

* Name of Toll Manufacturer: Company Name

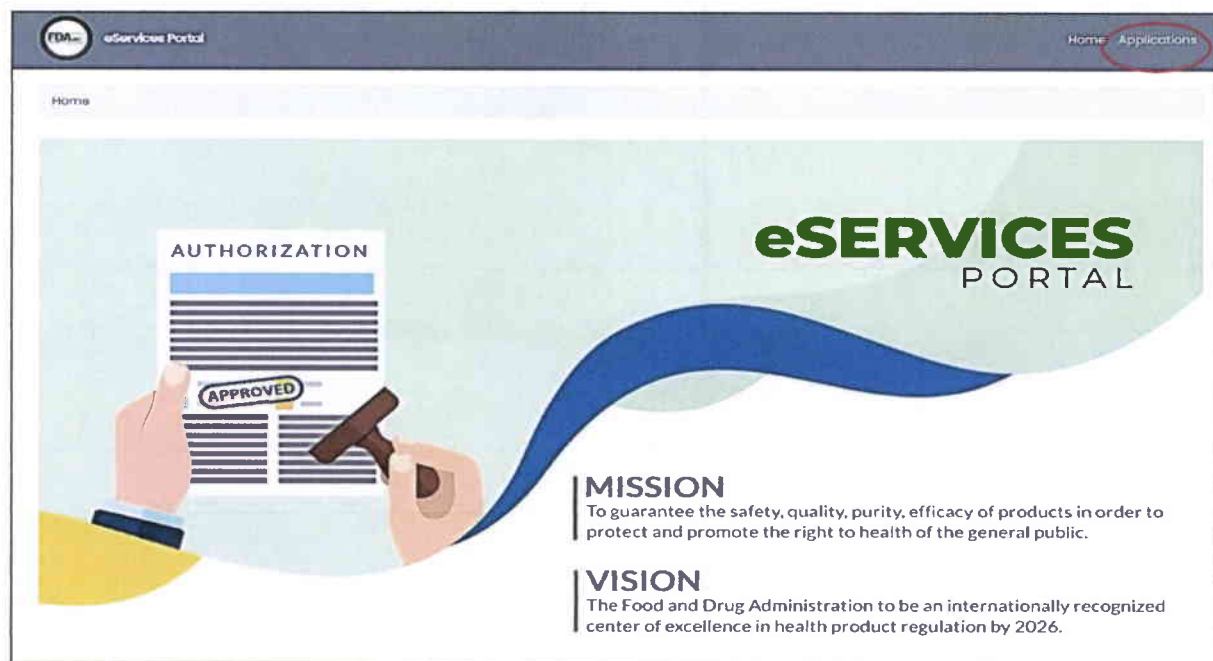
* Address: Address

* Contract Validity: Contract Validity

Back Next

C. APPLICATION FOR RENEWAL LTO FOR WATER TREATMENT DEVICE/SYSTEM DISTRIBUTOR

1. Access the online portal through eservices.fda.gov.ph and click “Applications” found on the upper right corner of the eServices landing page.




- Click the License to Operate for Device and the type of health product (Health-Related Device – Water Treatment Device/System) and Business Establishment (Distributor).


FDA eServices Portal Home Applications

Home / Applications


Applications



License to Operate
Authorization permits for health establishments



Certificate of Product Registration
Authorization Permit for Health Products



Compassionate Special Permit
Permits granted to individuals or institutions to have access to investigational or unregistered drug products

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




Device
For establishments that handle device products


FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device

Device



Medical Device
For establishments that handle Medical Device products




Health Related Device
For establishments that handle Health-Related Device products


FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Health

Health Related Device



Water Treatment Device/System
For establishments that handle water treatment devices/systems



Devices used for Sharps, Pathological and Infectious Waste
For establishments that handle devices used for treating sharps, pathological, and infectious waste

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Health / Water

Health Related Device



Application Status
Check the current status of your application



Distributor
License authorization for distributor establishments




Trader
License authorization for trader establishments

3. Click the Renewal Application.


FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Health / Water / Distributor


Water Treatment Device/System Distributor



Initial
Apply for a new License to Operate



Renewal
Renew existing License to Operate



Variations
Apply for changes in the existing License to Operate

4. Read carefully the “Declaration and Undertaking” before proceeding with the application process. Make sure to check the box found below and click on “Start Application”.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Water Distributor / Renewal

Water Treatment Device/System Distributor Renewal

1 Declaration & Undertaking

2 License to Operate

3 Contact Information

4 Self-Assessment Review

Declaration & Undertaking

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 Qualified Person (PRC registered professional or graduates in the field of allied health profession) or authorized personnel at all times;
- II. The Qualified Person, upon and during employment in the establishment, is 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-approval shall be a ground for the appropriate sanctions including the revocation of the license or, and/or the filing of the appropriate legal action against me, the owner, its officers or the establishment whenever possible.

I agree to the declaration and undertaking

Start Application

5. Fill out the necessary details such as the valid License Number, its date of validity, and security code.

The security code is generated by scanning the QR Code found in the document. If everything is in order, tick the Captcha box and click “Next” to proceed to Contact Information.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Water Distributor / Renewal

Water Treatment Device/System Distributor Renewal

1 Declaration & Undertaking

2 License to Operate

3 Contact Information

4 Self-Assessment Review

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-123156).

I'm not a robot

reCAPTCHA
Privacy - Terms

Back Next

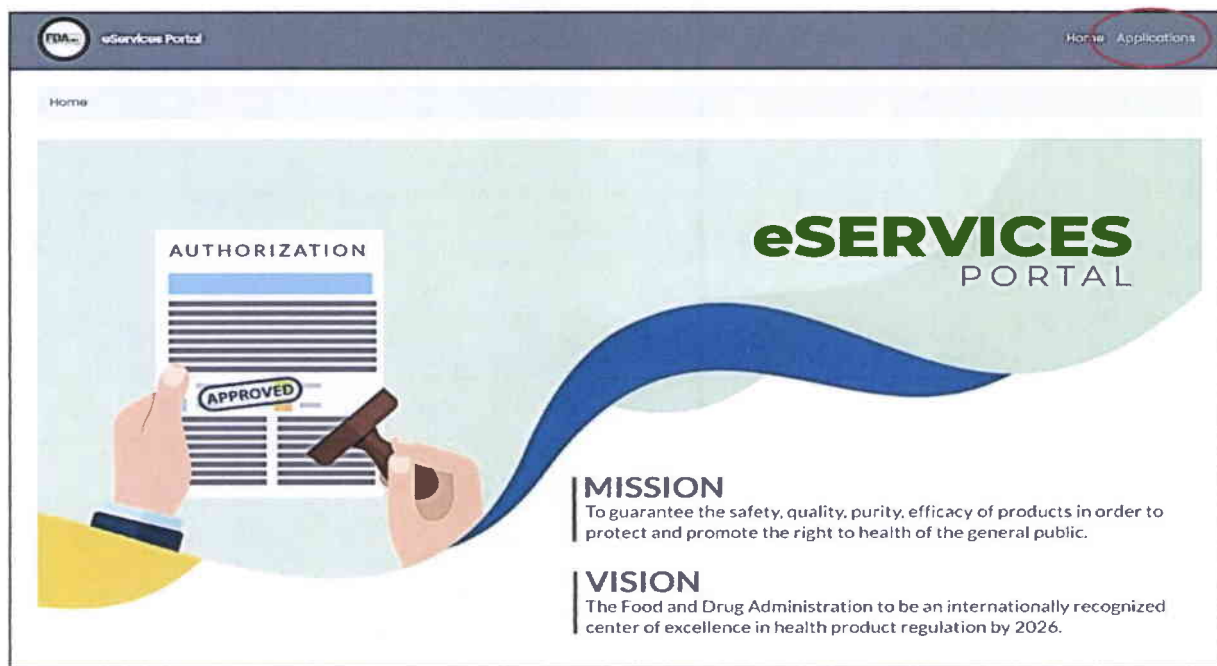
6. Update the contact number if necessary. Click “Next” to proceed to “Self-Assessment Review”.
7. The applicant may review all the details of the applications in the “Self-Assessment Review”.

D. APPLICATION FOR RENEWAL LTO FOR WATER TREATMENT DEVICE/SYSTEM TRADER

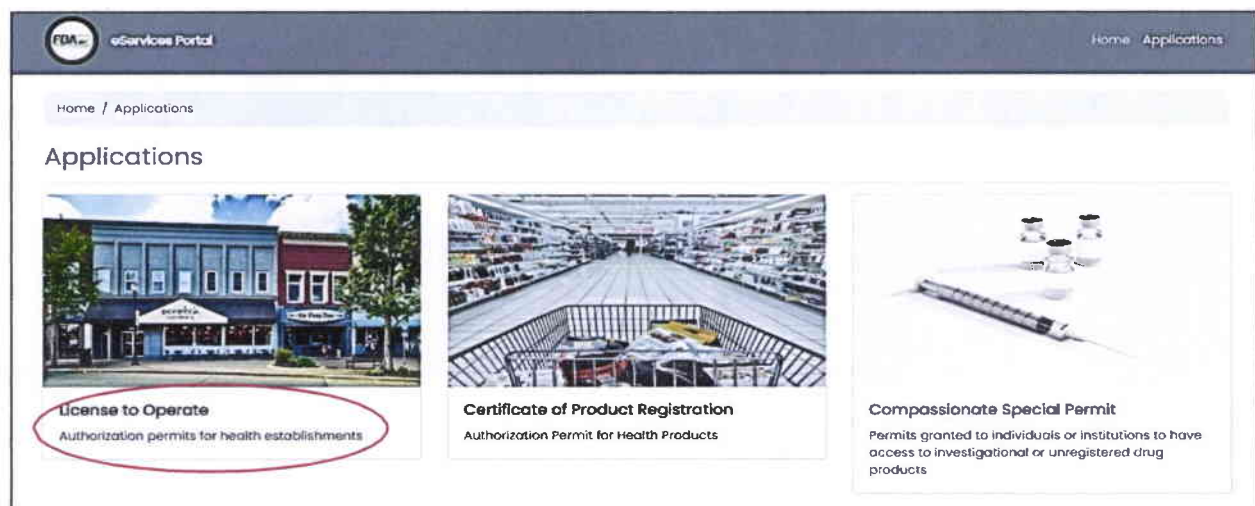
Proceed as in Step No. 1 to Step No. 7 of Item C (**Application for Renewal LTO for Water Treatment Device/System Distributor**). Make sure to click the appropriate type of product and establishment under Step No. 2.

E. APPLICATION FOR VARIATION IN LTO FOR WATER TREATMENT DEVICE/SYSTEM DISTRIBUTOR

1. Access the online portal through 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 Device and the type of health product (Health-Related Device – Water Treatment Device/System) and Business Establishment (Distributor).



Device



Medical Device

For establishments that handle Medical Device products



Health Related Device

For establishments that handle Health-Related Device products

Health Related Device



Water Treatment Device/System

For establishments that handle water treatment devices/systems



Devices used for Sharps, Pathological and Infectious Waste

For establishments that handle devices used for treating sharps, pathological, and infectious waste

Health Related Device



Application Status

Check the current status of your application



Distributor

License authorization for distributor establishments



Trader

License authorization for trader establishments

3. Click the Variation application.

FDA eService Portal Home Applications

Home / Applications / License to Operate / Device / Health / Water / Distributor

Water Treatment Device/System Distributor

Initial
Apply for a new License to Operate

Renewal
Renew existing License to Operate

Variations
Apply for changes in the existing License to Operate

4. Read carefully the “Declaration and Undertaking” before proceeding with the application process. Make sure to check the box found below and click on “Start Application”.

FDA eService Portal Home Applications

Home / Applications / License to Operate / Device Water Distributor / Variations

Water Treatment Device/System Distributor Variation

1 Declaration & Undertaking

2 License to Operate

3 Contact Information

4 Minor Variations

5 Self-Assessment Review

Declaration & Undertaking

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 Qualified Person (PRC registered professional or graduates in the field of allied health profession) or authorized personnel at all times;
- II. The Qualified Person, upon and during employment in the establishment, is 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-approval shall be a ground for the appropriate sanctions including the revocation of the license or, and/or the filing of the appropriate legal action against me.

I agree to the declaration and undertaking
In order to proceed with your application, you need to agree with the declaration and undertaking

Start Application

5. 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.

The screenshot shows the FDA eServices Portal interface for a 'Water Treatment Device/System Distributor Variation'. The navigation path is 'Home / Applications / License to Operate / Device Water Distributor / Variations'. The main heading is 'Water Treatment Device/System Distributor Variation'. On the left, a vertical list of steps is shown: 1 Declaration & Undertaking, 2 License to Operate (highlighted with a red circle), 3 Contact Information, 4 Minor Variations, and 5 Self-Assessment Review. The 'License to Operate' section contains three input fields: 'License Number', 'Date of Validity', and 'Security Code'. Below these fields is a note: 'Please scan the QR Code in the document. For previously issued LTO, enter the sequence number located at the bottom right corner of the document (e.g. FDA-123456)'. To the right of the input fields is a reCAPTCHA widget with the text 'I'm not a robot' and a 'reCAPTCHA' logo. At the bottom right, there are two buttons: 'Back' and 'Next'.

6. Provide an updated contact information if applicable.
7. Key in the required fields. To upload documents, click the File Upload. Fill out the necessary variations (ex. Transfer of Location of Offices, Change of Distributor Activity, additional warehouse, and expansion of office establishments, change of business name, qualified person, or authorized person).
8. User may review if all details are correct in the “Self-Assessment Review”.
9. Once reviewed, the User shall confirm the correctness of data given and click on “**Confirm**” to submit the application.

F. APPLICATION FOR VARIATION IN LTO FOR WATER TREATMENT DEVICE/SYSTEM TRADER

Proceed as in Step No. 1 to Step No. 7 of Item E (**Application for Variation in LTO for Water Treatment Device/System Distributor**). Make sure to click the appropriate type of product and establishment under Step No. 2.

G. APPLICATION FOR INITIAL LTO FOR DISTRIBUTOR OF DEVICES USED FOR TREATING SHARPS, PATHOLOGICAL, AND INFECTIOUS WASTE

1. Access the online portal through 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 Device and the type of health product (Health-Related Devices – Devices Used for Treating Sharps, Pathological, and Infectious Waste) and Business Establishment (Distributor).



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



Device

For establishments that handle device products



Device



Medical Device

For establishments that handle Medical Device products



Health Related Device

For establishments that handle Health-Related Device products



Health Related Device



Water Treatment Device/System

For establishments that handle water treatment devices/systems



Devices used for Sharps, Pathological and Infectious Waste

For establishments that handle devices used for treating sharps, pathological, and infectious waste

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Health / Water

Health Related Device



Application Status
Check the current status of your application



Distributor
License authorization for distributor establishments




Trader
License authorization for trader establishments

3. Click the Initial Application.


FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Health / Steps Distributor


Health-Related Device Distributor



Initial
Apply for a new License to Operate



Renewal
Renew existing License to Operate



Variations
Apply for changes in the existing License to Operate

4. Read carefully the “**Declaration and Undertaking**” before proceeding with the application process. Make sure to check the box found below and click on “**Start Application**”.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Health / Steps Distributor / Initial

Health-Related Device Distributor Initial

- 1 Declaration & Undertaking
- 2 General Information
- 3 Product Line/s
- 4 Establishment Information
- 5 Office Address
- 6 Warehouse Addresses
- 7 Authorized Officer
- 8 Qualified Personnel
- 9 Documentary Requirements
- 10 Self-Assessment Review

Declaration & Undertaking

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 Qualified Person (PRC registered professional or graduates in the field of allied health profession) or authorized personnel at all times;
- II. The Qualified Person, upon and during employment in the establishment, is 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-approval shall be a ground for the appropriate ~~sanctions including the revocation of the license or, and/or the filing of the appropriate legal action against me, the owner, its~~

I agree to the declaration and undertaking

[Start Application](#)

5. Fill out the necessary information accurately based on establishment's activity/ies (Importer, Exporter, or Wholesaler). Make sure to properly tick the corresponding activity/ies before proceeding on the next step.

The screenshot shows the 'Health-Related Device Distributor Initial' form in the FDA eService Portal. The breadcrumb trail is 'Home / Applications / License to Operate / Device / Health / Sharps / Distributor / Initial'. The form is divided into a left sidebar with steps 1-10 and a main content area. Step 2, 'General Information', is highlighted with a red oval. The main content area includes the following fields:

- Type of Application:** Initial
- Product Type:** Health-Related Device
- Distributor:** Distributor
- Distributor Activities:** Importer, Exporter, Wholesaler (all three are circled in red)

Buttons for 'Back' and 'Next' are visible at the bottom right.

6. Indicate the Health-Related Device Product Line (Equipment or Devices Used for Treating Sharps, Pathological, and Infectious Waste) and its description. If there are two or more product lines, click on the "Add Product Line".

The screenshot shows the 'Health-Related Device Distributor Initial' form in the FDA eService Portal. The breadcrumb trail is 'Home / Applications / License to Operate / Device / Sharps / Distributor / Initial'. The form is divided into a left sidebar with steps 1-10 and a main content area. Step 3, 'Product Line/s', is highlighted with a red oval. The main content area includes the following fields:

- Product Line #1:** Product Line #1
- Product Type:** Please Select (dropdown menu)
- Product Description:** (text input field)
- Add Product Line:** (button with a plus icon, circled in red)

Buttons for 'Back' and 'Next' are visible at the bottom right.

- The e-mail address shall be official and the applicant shall make sure that it is within the scope and access of the Authorized Representative/s.

Please take note that all the fields marked with asterisks (*) are required to be filled out.

The screenshot shows the 'Health-Related Device Distributor Initial' form. The left sidebar contains a list of steps from 1 to 10. Step 4, 'Establishment Information', is circled in red. The main form area is divided into two sections: 'Establishment Information' and 'Contact Information'. Under 'Establishment Information', there are fields for '* Name of Establishment', '* Owner of Establishment', and '* Tax Identification Number'. Under 'Contact Information', there are fields for '* Email Address', '* Mobile Number', and 'Landline Number'. The 'Email Address' field is also circled in red. At the bottom right, there are 'Back' and 'Next' buttons.

- Click the “Get GPS Coordinates” to determine the exact location of the Office Address. Pin accurately the location on the map.

The screenshot shows the 'Health-Related Device Distributor Initial' form. The left sidebar contains a list of steps from 1 to 10. Step 6, 'Office Address', is circled in red. The main form area is divided into two sections: 'Office Address' and 'GPS Coordinates'. Under 'Office Address', there are fields for '* Region', '* Province', '* City or Town', '* Street Address', '* GPS Latitude', and '* GPS Longitude'. Under 'GPS Coordinates', there is a field for 'Get GPS Coordinates' which is circled in red. At the bottom right, there are 'Back' and 'Next' buttons.

- 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.

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

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device Distributor / Initial

Health-Related Device Distributor Initial

- 1 Declaration & Undertaking
- 2 General Information
- 3 Product Line/s
- 4 Establishment Information
- 5 Office Address
- 6 Warehouse Addresses**
- 7 Authorized Officer
- 8 Qualified Personnel
- 9 Documentary Requirements
- 10 Self-Assessment Review

Warehouse Addresses

Warehouse #1

* Region: Please Select

* Province: Please Select

* City or Town: Please Select

* Street Address: Street Address

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

* GPS Latitude: GPS Latitude

* GPS Longitude: GPS Longitude

Get GPS Coordinates

Add Warehouse Address

Back Next

10. The declared name of the Authorized Officer is understood to be the one transacting with FDA and shall only have the authority to transact on behalf of the establishment (i.e., follow ups, received result, etc.).

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device Distributor / Initial

Health-Related Device Distributor Initial

The declared name of the authorized officer is understood to be the one transacting with FDA and shall only have the authority to transact on behalf of the establishment (i.e. follow-ups, receives result)

- 1 Declaration & Undertaking
- 2 General Information
- 3 Product Line
- 4 Establishment Information
- 5 Office Address
- 6 Warehouse Addresses
- 7 Authorized Officer**
- 8 Qualified Personnel
- 9 Documentary Requirements
- 10 Self-Assessment Review

Details of Authorized Officer

* First Name: First Name

include suffix name on first name

Middle Name: Middle Name

* Last Name: Last Name

* Designation: Please Select

select owner for sole proprietorships

Government Issued Identification Document

* Type: Please Select

* Identification Number: Identification Number

Back Next

11. Fill out the details of the Qualified Personnel.

1 Declaration & Undertaking **Details of the Qualified Personnel**

2 General Information

3 Product Line

4 Establishment Information

5 Toll Manufacturer

6 Office Address

7 Warehouse Addresses

8 Authorized Officer

9 **Qualified Personnel**

Personnel Details

* First Name

Middle Name

* Last Name

* Designation

* Profession

Government Issued Identification Document

* Type

* Identification Number

12. Upload the necessary documents.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / **DTI** / Distributor / Initial

Health-Related Device Distributor Initial

1 Declaration & Undertaking **Documentary Requirements**

2 General Information

3 Product Line

4 Establishment Information

5 Office Address

6 Warehouse Addresses

7 Authorized Officer

8 Qualified Personnel

9 **Documentary Requirements**

10 Self-Assessment Review

* 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
Please upload a business/mayor's permit or barangay clearance if the declared site address is different on the proof of business name registration document.

13. The applicant may review all the details of the applications in the “Self-Assessment Review”.

The screenshot shows the 'Self-Assessment Review' page for a 'Health-Related Device Distributor Initial' application. On the left, a vertical navigation menu lists steps 1 through 10. Step 10, 'Self-Assessment Review', is highlighted with a red circle. The main content area is titled 'Self-Assessment Review' and contains two sections: 'General Information' and 'Health-Related Device Product Line'. In the 'General Information' section, the following fields are filled: 'Type of Application' is 'Initial', 'Product Type' is 'Medical Device', 'Primary Activity' is 'Distributor', and 'Distributor Activities' has 'Importer' checked, with 'Exporter' and 'Wholesaler' unchecked. The 'Health-Related Device Product Line' section shows 'Product Line 1' with 'Product Type' set to 'Medical Device' and a 'Product Description' field containing the letter 'e'. Below this is an 'Add Product Line' button. The top of the page includes the FDA eServices Portal logo and navigation links for 'Home' and 'Applications'.

14. After the self-assessment review, the applicant shall confirm the correctness of the data and uploaded documents and click on “Confirm” to submit the application.

The screenshot shows the final confirmation page of the application process. At the top left, there is a reCAPTCHA widget with the text 'I'm not a robot' and a red circle around it. Below this is a confirmation checkbox: I hereby confirm that all information I have provided are true and correct to the best of my knowledge. Underneath the checkbox, there are two lines of text: 'I understand that any errors that I have committed in this online form may be considered grounds for refusal or cancellation of my application.' and 'I consent to the use of 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 of the page, there are two buttons: a grey 'Back' button and a blue 'Confirm' button, with the 'Confirm' button circled in red.

H. APPLICATION FOR INITIAL LTO FOR TRADER OF DEVICES USED FOR TREATING SHARPS, PATHOLOGICAL AND INFECTIOUS WASTE

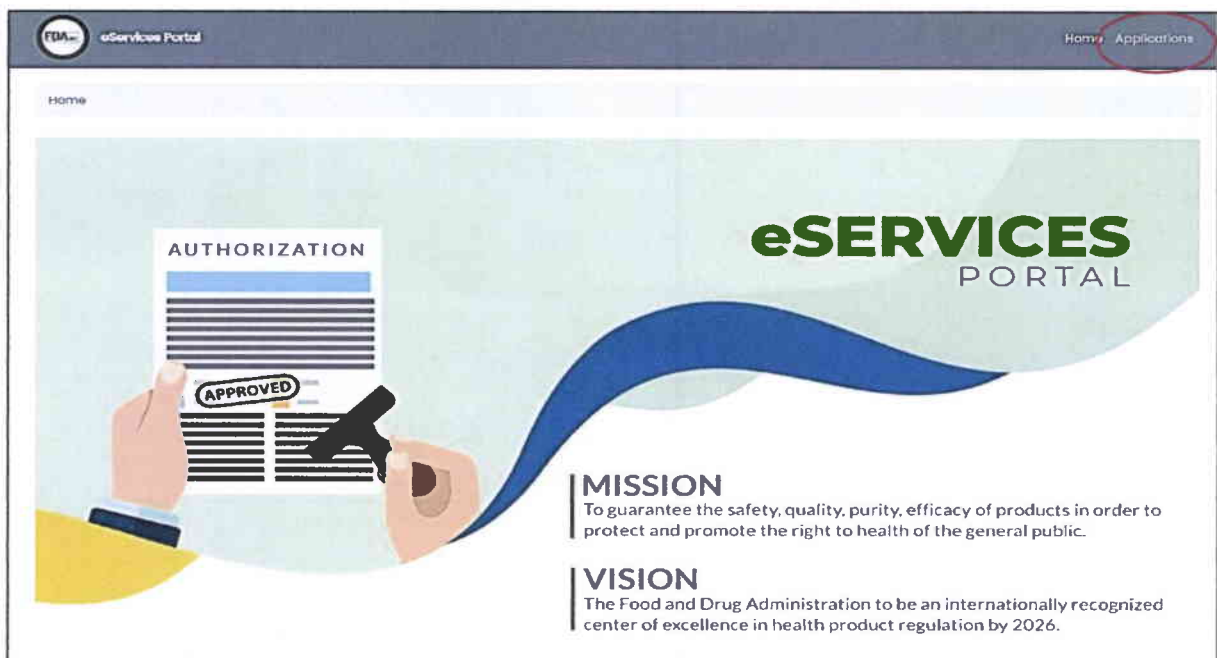
Proceed as in Step No. 1 to Step No. 7 of Item G (**Application for Initial LTO for Distributor of Devices Used for Treating Sharps, Pathological and Infectious Waste**). Make sure to click the appropriate type of product and establishment under Step No. 2.

Fill out the Toll Manufacturer details including the address and contract validity.

The screenshot shows a web form titled "Toll Manufacturer Details". On the left, a vertical navigation menu contains seven steps: 1. Declaration & Undertaking, 2. General Information, 3. Product Line, 4. Establishment Information, 5. Toll Manufacturer (highlighted with a red oval), 6. Office Address, and 7. Warehouse Addresses. The main form area contains three input fields: "Name of Toll Manufacturer" with a placeholder "Company Name", "Address", and "Contract Validity". Below these fields are two buttons: "Back" (grey) and "Next" (blue).

I. APPLICATION FOR RENEWAL OF LTO FOR DISTRIBUTOR OF DEVICES USED FOR TREATING SHARPS, PATHOLOGICAL AND INFECTIOUS WASTE

1. Access the online portal through eservices.fda.gov.ph and click “Applications” found on the upper right corner of the eServices landing page.






1. Click the License to Operate for Device and the type of health product (Health-Related Device – Devices Used for Treating Sharps, Pathological, and Infectious Waste) and Business Establishment (Distributor).

FDA eServices Portal Home Applications

Home / Applications

Applications

 <p>License to Operate Authorization permits for health establishments</p>	 <p>Certificate of Product Registration Authorization Permit for Health Products</p>	 <p>Compassionate Special Permit Permits granted to individuals or institutions to have access to investigational or unregistered drug products</p>
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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>Device For establishments that handle device products</p>		

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device


Device

 <p>Medical Device For establishments that handle Medical Device products</p>	 <p>Health Related Device For establishments that handle Health-Related Device products</p>
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FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Health

Health Related Device



Water Treatment Device/System
For establishments that handle water treatment devices/systems



Devices used for Sharps, Pathological and Infectious Waste
For establishments that handle devices used for treating sharps, pathological, and infectious waste

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Health / Water

Health Related Device



Application Status
Check the current status of your application



Distributor
License authorization for distributor establishments




Trader
License authorization for trader establishments

3. Click the Renewal Application.


FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Health Sharps Distributor


Health-Related Device Distributor



Initial
Apply for a new License to Operate



Renewal
Renew existing License to Operate



Variations
Apply for changes in the existing License to Operate

4. Read carefully the **“Declaration and Undertaking”** before proceeding with the application process. Make sure to check the box found below and click on **“Start Application”**.

Health-Related Device Distributor Renewal

Declaration & Undertaking

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 Qualified Person (PRC registered professional or graduates in the field of allied health profession) or authorized personnel at all times;
- II. The Qualified Person, upon and during employment in the establishment, is 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-approval shall be a ground for the appropriate sanctions including the revocation of the license or, and/or the filing of the appropriate legal action against me, the owner, its officers or the establishment whenever possible.

I agree to the declaration and undertaking

Start Application

5. Fill out the necessary details such as the valid License Number, its date of validity, and security code.

The security code is generated by scanning the QR Code found in the document. If everything is in order, tick the Captcha box and click “Next” to proceed to Contact Information.

Health-Related Device Distributor Renewal

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

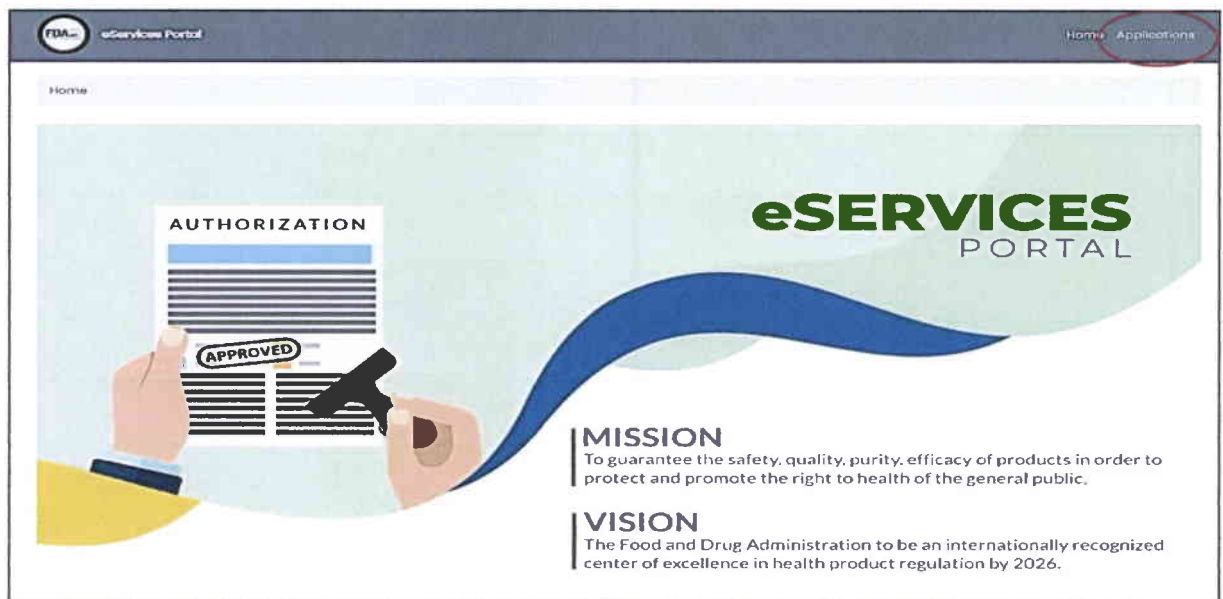
6. Update the contact number if necessary. Click “Next” to proceed to “Self-Assessment Review”.
7. The applicant may review all the details of the applications in the “Self-Assessment Review”.

J. APPLICATION FOR RENEWAL OF LTO FOR TRADER OF DEVICES USED FOR TREATING SHARPS, PATHOLOGICAL AND INFECTIOUS WASTE

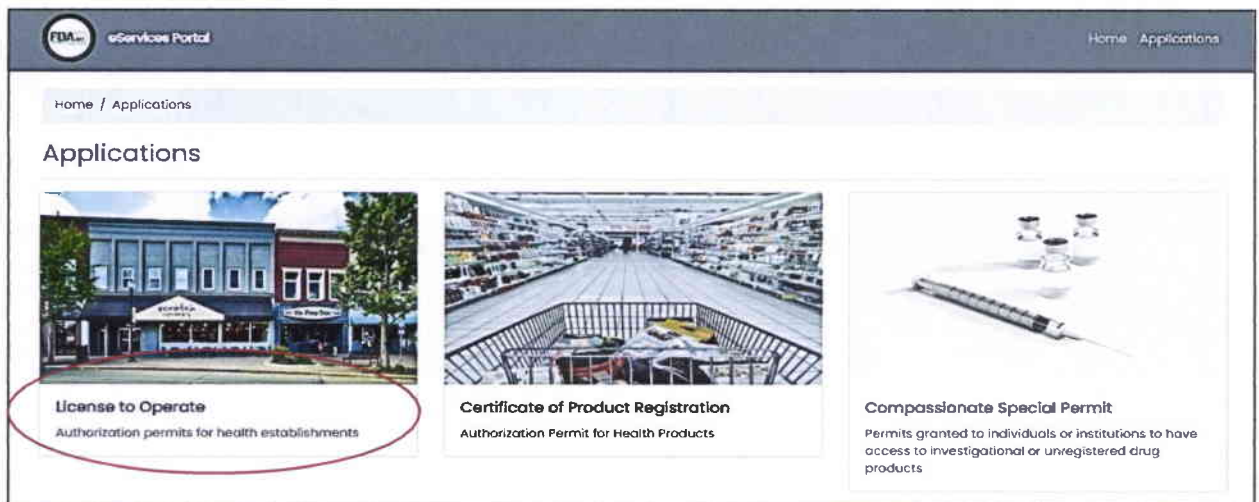
Proceed as in Step No. 1 to Step No. 7 of Item I (**Application for Renewal LTO for Distributor of Devices Used for Treating Sharps, Pathological and Infectious Waste**). Make sure to click the appropriate type of product and establishment under Step No. 2.

K. APPLICATION FOR VARIATION IN LTO FOR DISTRIBUTOR OF DEVICES USED FOR TREATING SHARPS, PATHOLOGICAL, AND INFECTIOUS WASTE

1. Access the online portal through 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 Device and the type of health product (Health-Related Device – Devices Used for Treating Sharps, Pathological, and Infectious Waste) and Business Establishment (Distributor).



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



Device

For establishments that handle device products

Device



Medical Device

For establishments that handle Medical Device products



Health Related Device

For establishments that handle Health-Related Device products

Health Related Device



Water Treatment Device/System

For establishments that handle water treatment devices/systems



Devices used for Sharps, Pathological and Infectious Waste

For establishments that handle devices used for treating sharps, pathological, and infectious waste

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Health / Water

Health Related Device



Application Status
Check the current status of your application



Distributor
License authorization for distributor establishments




Trader
License authorization for trader establishments

3. Click the Variation Application.


FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Health , [Steps](#) / Distributor


Health-Related Device Distributor



Initial
Apply for a new License to Operate



Renewal
Renew existing License to Operate



Variations
Apply for changes in the existing License to Operate

4. Read carefully the “**Declaration and Undertaking**” before proceeding with the application process. Make sure to check the box found below and click on “**Start Application**”.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Device / Medical / Distributor / Variations

Health-Related Device Distributor Variation

- 1
- Declaration & Undertaking
- 2
- License to Operate
- 3
- Contact Information
- 4
- Minor Variations
- 5
- Self-Assessment Review

Declaration & Undertaking

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 Qualified Person (PRC) registered professional or graduates in the field of allied health profession) or authorized personnel at all times;
- II. The Qualified Person, upon and during employment in the establishment, is 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-approval shall be a ground for the appropriate actions including the revocation of the license and for the filing of the appropriate legal action against me.

I agree to the declaration and undertaking
In order to proceed with your application, you need to agree with the declaration and undertaking.

[Start Application](#)

5. 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.

The screenshot shows the FDA eServices Portal interface for a 'Health-Related Device Distributor Variation'. The breadcrumb trail is: Home / Applications / License to Operate / Device / Medical / Distributor / Variations. The main heading is 'Health-Related Device Distributor Variation'. On the left, a navigation menu includes: Declaration & Undertaking, License to Operate (highlighted with a red circle), Contact Information, Minor Variations, and Self-Assessment Review. The 'License to Operate' section contains three required fields: License Number, Date of Validity, and Security Code. Below the Security Code field, there is a note: 'Please scan the QR Code in the document. For previously issued LTO, enter the sequence number located at the bottom right corner of the document (e.g. FDA-123456)'. At the bottom right, there is a reCAPTCHA 'I'm not a robot' checkbox and a 'Next' button.

6. Provide an updated contact information if applicable.
7. Key in the required fields. To upload documents, click the File Upload. Fill out the necessary variations (ex. Transfer of Location of Offices, Change of Distributor Activity, additional warehouse, and expansion of office establishments, change of business name, qualified person, or authorized person).
8. User may review if all details are correct in the “Self-Assessment Review”.
9. Once reviewed, the User shall confirm the correctness of data given and click on “**Confirm**” to submit the application.

L. APPLICATION FOR VARIATION IN LTO FOR TRADER OF DEVICES USED FOR TREATING SHARPS, PATHOLOGICAL, AND INFECTIOUS WASTE

Proceed as in Step No. 1 to Step No. 9 of Item K (**Application for Variation in LTO for Distributor of Devices Used for Treating Sharps, Pathological and Infectious Waste**). Make sure to click the appropriate type of product and establishment under Step No. 2.

ANNEX C

PROCEDURE FOR CHECKING OF APPLICATION STATUS IN THE eSERVICES PORTAL SYSTEM

1. To check the status of the application, click “Application Status”.



2. Enter the Reference Number and click “Submit”.

The screenshot shows the 'Application Status' page in the FDA eServices Portal. The top navigation bar is the same as in the previous image. The breadcrumb trail is 'Home / Applications / License to Operate / Device / Medical / Status'. The main heading is 'Application Status'. Below the heading is a progress indicator with three steps: 1. Reference Number (circled in green), 2. Verification Code, and 3. Application Status. Below the progress indicator is a blue box with the instruction: 'Enter the reference number indicated in your application.' Below this is a form with a label 'Reference Number' and a text input field containing 'Reference Number' and an example 'e.g. FDA-100000001234'. A blue 'Submit' button is located below the input field.

3. A verification code will be sent to applicant’s registered e-mail address.
4. Enter the verification code to view the progress.