Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2020-2054

25 NOV 2020

TO : **MEDICAL DEVICE ESTABLISHMENTS WITHIN NCR AND THE GENERAL PUBLIC**

SUBJECT : **Pilot Implementation of Food and Drug Administration (FDA) eServices Portal System for License to Operate (LTO) Application of Medical Device Establishments**

The Food and Drug Administration (FDA) is currently developing the FDA eServices Portal System – an online platform for a streamlined License to Operate (LTO) application of FDA-regulated establishments.

In this regard, FDA is issuing this Advisory to inform all stakeholders that the application for eLTO for **Medical Device Establishments** within National Capital Region (NCR) is now on its pilot implementation. The eServices Portal is accessible through this link eservices.fda.gov.ph/, with the scope of the application is limited for the time being:

FDA eServices Portal for LTO Application for Medical Device Establishments	
Location of Establishment	National Capital Region (Metro Manila)
LTO Establishment Application	Distributor (Wholesaler, Importer, Exporter), and Trader of Medical Devices, in-vitro diagnostic device, reagents, equipment or devices used for treating sharps, pathological and infectious waste and water purification system
Type of LTO Application	Initial, Renewal, and Variation
Fees to be Paid	Based on current issuance on Fees and Charges (Reference: DOH Administrative Order No. 50 s. 2001)
Validity of Initial LTO	Two (2) years
Start of Pilot Implementation	23 November 2020
End of Pilot Implementation	07 December 2020

For this Pilot Run, applications for Renewal and Variation in the LTO using the eServices Portal are only functional if the approved initial LTO is applied using the eServices Portal.

For those with existing LTO application via ePortal, you may opt to apply to the eServices Portal for a new fee. Previous payment will be forfeited as the application has already been processed.

The implementation of eServices Portal for **Manufacturers, including Refurbishers** of all health products shall be on November 2020.

Retailers of Medical Devices, Radiation Facilities and Installer of water treatment systems providing installation, repair and maintenance services to operators of water refilling stations and other users of water treatment systems shall be governed by separate rules and regulations.

Please follow Annex A of this Advisory for the Guideline and Checklist of Requirements, and Annex B for the Step-by-Step Guide in applying via eServices Portal and the procedure for checking of application status.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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ANNEX A
General Guideline and Requirements for LTO Application Using eServices Portal

A. General Guideline

1. All Medical Device Establishments, whether public or private entity, engaged in business or operation on medical devices shall first secure a License to Operate (LTO) issued by the FDA and when applicable, product market authorizations, i.e. Certificate of Medical Device Registration (CMDR), Certificate of Medical Device Notification (CMDN), or Certificate of Medical Device Listing (CMDL) based on Medical Device Classification, before engaging in the importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship activities.

2. All FDA regulated Medical Device Establishments applying for LTO shall be required to accomplish online application through the eServices Portal (eservices.fda.gov.ph/). Creation of account and password is no longer a requirement to obtain access to the online portal.

3. The declared e-mail address under the Contact Information is **unalterable**. The applicant shall make 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. Thus, the FDA shall not be held liable in any way for loss of access to the declared e-mail address.

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

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

4. All information filled-out by the applicant during the process shall be reflected in the final output based on the consistency with uploaded documents. Thus, it is imperative for the client to be diligent in filing out all required information.

5. All Importers, Exporters, Distributors, Wholesalers, and Traders shall submit notification of sources immediately after the approval of LTO.

6. No more LTO exemption shall be issued by the CDRRHR. Establishments engaged in doing research, educational establishments, service providers (repair and maintenance) are not required to apply for an LTO.

7. Medical Device Establishments that are due for renewal but have some changes regarding information in the system should apply first for a renewal. The renewal application should be approved first before applying for the variation. The clients should be guided on these actions that there should be two (2) separate applications. Further, the clients should be informed that the LTO to be issued upon renewal will reflect the previous information and the updating should be done thru 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.

8. For any variation, the establishment is required to file for a new notification.

9. There shall be a change in the format of LTO number as such;
   Old: **300000XXXXXX**
   New: **CDRRHR-(Region)-(Activity)- (Sequence Number)**

10. The FDA shall have the authority to enter any FDA-licensed establishments selling FDA-regulated health products during operating hours to conduct routine or spot check inspections.

11. Upon approval of application, regulated establishments shall print the generated e-LTO on standard A4 size (21 cm x 29.7 cm) bond paper, on full-colored page and in portrait orientation. It shall be positioned on the most conspicuous place within the business establishments.

B. LTO Application Requirements

Type of Application	Requirements
Initial LTO	1. Accomplished e-Application form with Declaration of Undertaking a. Location Plan b. Global Positioning System (GPS) Coordinates c. Name of the Qualified Person, depending on the type of health product establishment 2. Proof of Business Name Registration a. For Single Proprietorship, Certificate of Business Registration issued by the Department of Trade and Industry (DTI) b. For Corporation, Partnership and other Juridical Person, the Certificate of Registration issued by the Security and Exchange Commission (SEC) and Articles of Incorporation c. For Government owned and Controlled Corporation, the law creating the establishment, if with original charter, or its

	Certificate of Registration issued by the SEC and articles of Incorporation, if without original charter. d. For Cooperatives, proof of Business Name Registration issued by the Cooperative Development Authority 3. 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, duly notarized Statement/Certification of Initial Capitalization must be submitted 4. Payment of Fees based on latest FDA issuance 5. 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.
Renewal of LTO	1. Accomplished e-Application Form with Declaration of Undertaking 2. Payment of Fees
Variation in LTO	1. Accomplished e-Application Form with Declaration of Undertaking 2. Documentary requirements depending on the variation of circumstances of the establishment or the product 3. Payment of Fees

The detailed application requirements are indicated in Administrative Order No. 2020-0017 (Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003)

C. Qualification and Credential Requirements of the Qualified Person

Qualification	Training Requirements
• 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 to the device to be distributed and imported • Engineering profession (includes the following course but not limited to EE, ECE, ME, CoE, CHE, SE), Computer Science, and Chemistry	a. PRC ID for professions with Board/Licensure Exam or Diploma for profession without Board/Licensure Exam 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

D. Payment

1. The FDA shall inform the applicant through the registered email address the result of 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. If the application did not pass the pre-assessment step, the FDA shall notify the reason/s for non-acceptance e.g. deficiency/s found and prompt the applicant to apply again through the eServices Portal.

2. 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. Always indicate the Reference Number reflected in the OP. Clients will be informed of other available channels of payment through an FDA issuance.

   For renewal of application, the client must pay within the prescribed validity date of Order of Payment. Surcharge or penalty may be imposed if there is no payment made on one (1) working day after the expiration *(The percentage of penalty shall accordingly increase by 10% for every month until a maximum of four (4) months or one-hundred twenty (120) days).*

3. 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) working 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 for bank and online payments may take a minimum of two (2) days, depending on the volume of paid applications received.

4. 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. This also means that the application will not proceed to the next step of the process.

5. 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, email will contain Acknowledgment Receipt, otherwise, a notification on payment deficiency.

6. If the establishment has failed to pay for the applicable fees within the specified date, a new order of payment should be generated by filing another case application.

E. Evaluation

1. The veracity of the application and compliance with all the documentary requirements and appropriate standards shall be further assessed.

2. The action on the application shall be Approval or Disapproval as provided by Republic Act (RA) No. 11032 otherwise known as the Ease of Doing Business and Efficient Government Service Delivery Act of 2018.

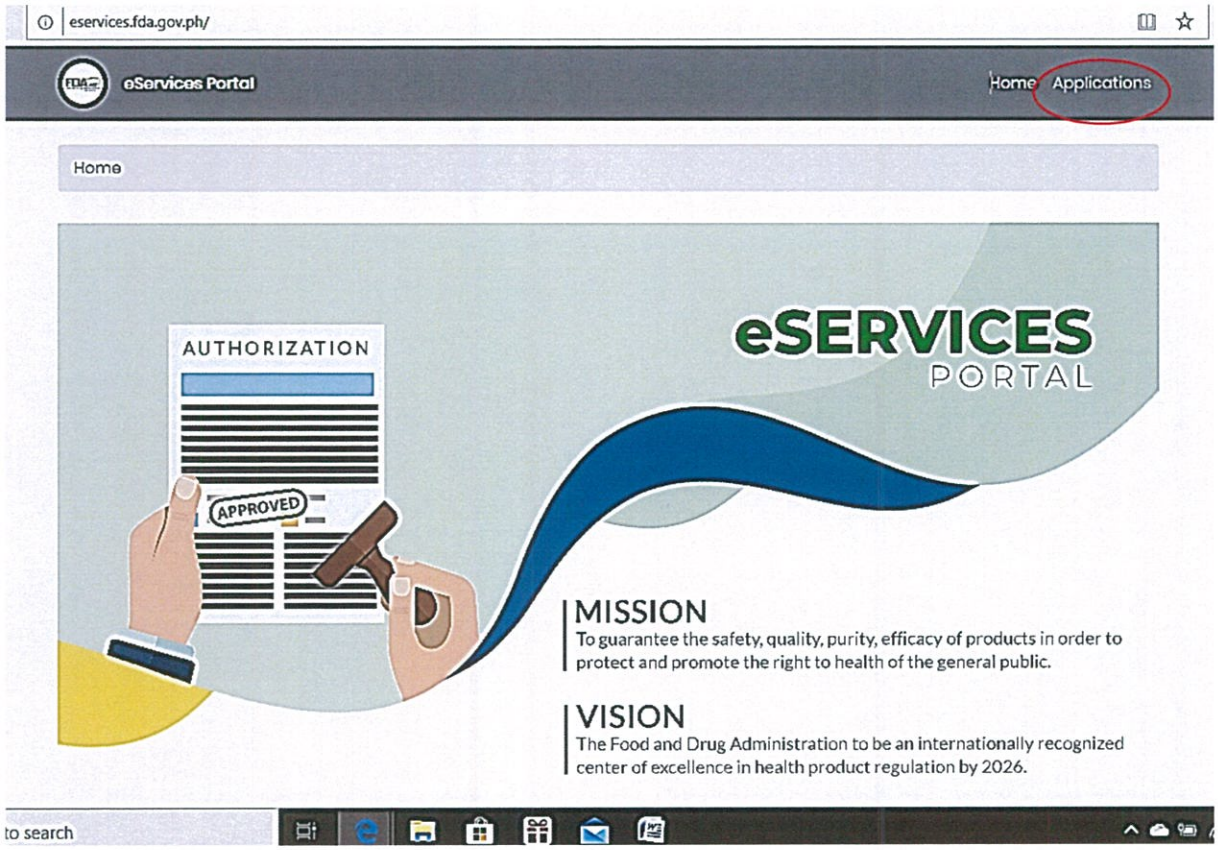
3. Automatic renewal as provided for by the Implementing Rules and Regulations (IRR) of RA 11032 specifically Rule VIII. Section 1. *On When Shall Automatic Approval of an Original Application or Request be Granted,* shall apply.

4. Evaluation shall be done within the prescribed working days and office hours. Applications filed after the working hours and during weekends/holidays shall be considered filed on the next working day.

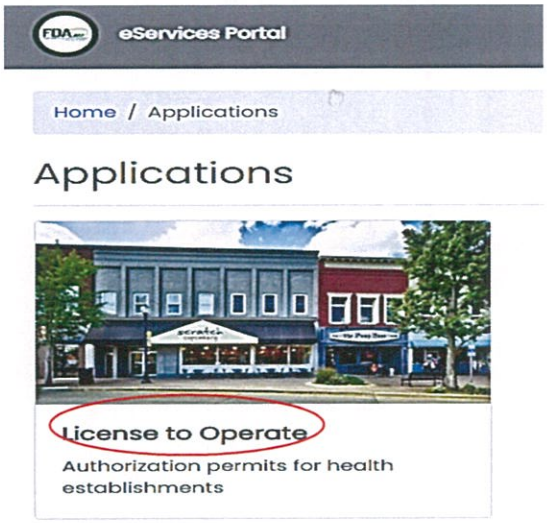
ANNEX B
Procedure for the Use of the FDA eServices Portal for License to Operate (LTO) Application

A. Application for Initial LTO for Medical Device Distributor

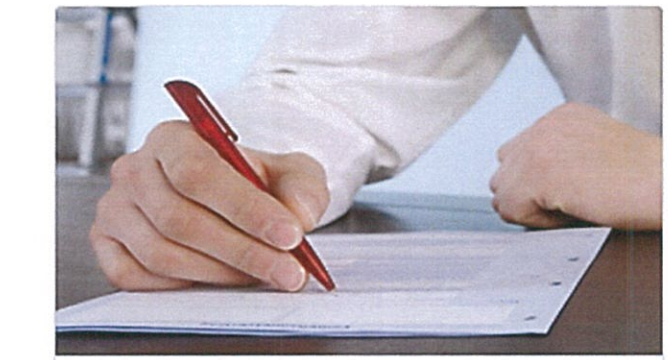
1. Access the online portal through eservices.fda.gov.ph and click **"Applications"** found on the upper right corner of the system.



2. Click on the License to Operate for Medical Device and the type of Business Establishment (Distributor).



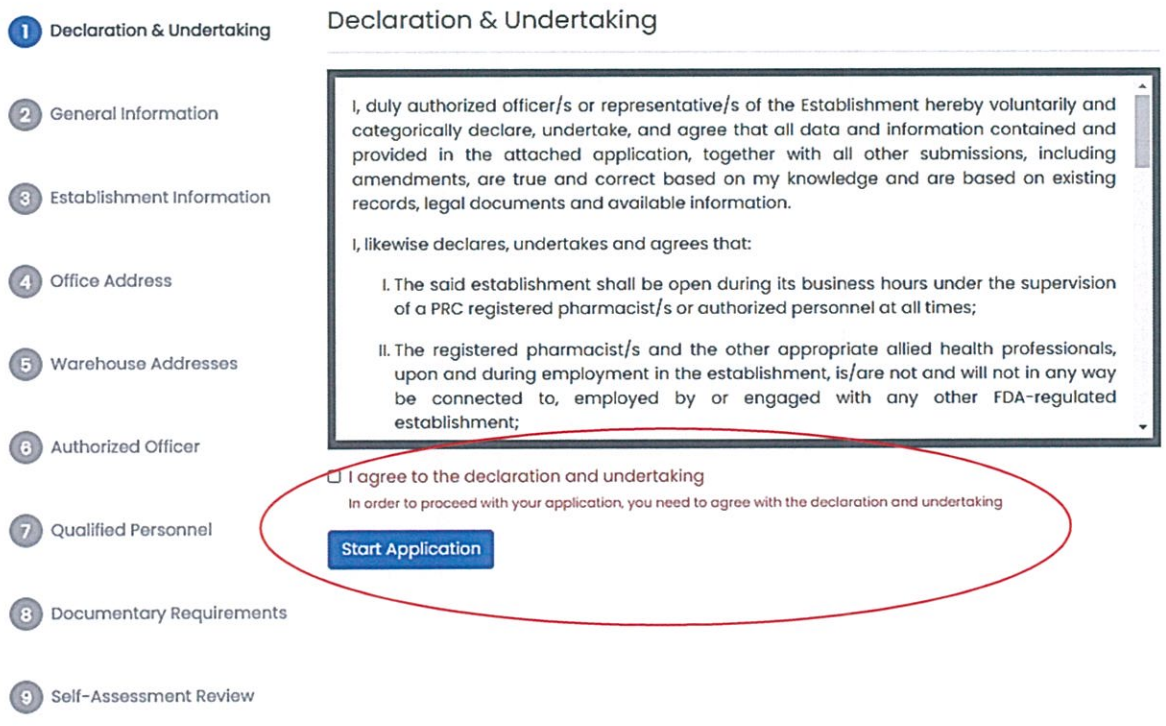
3. Click on the Initial Application.



Initial

Apply for a new License to Operate

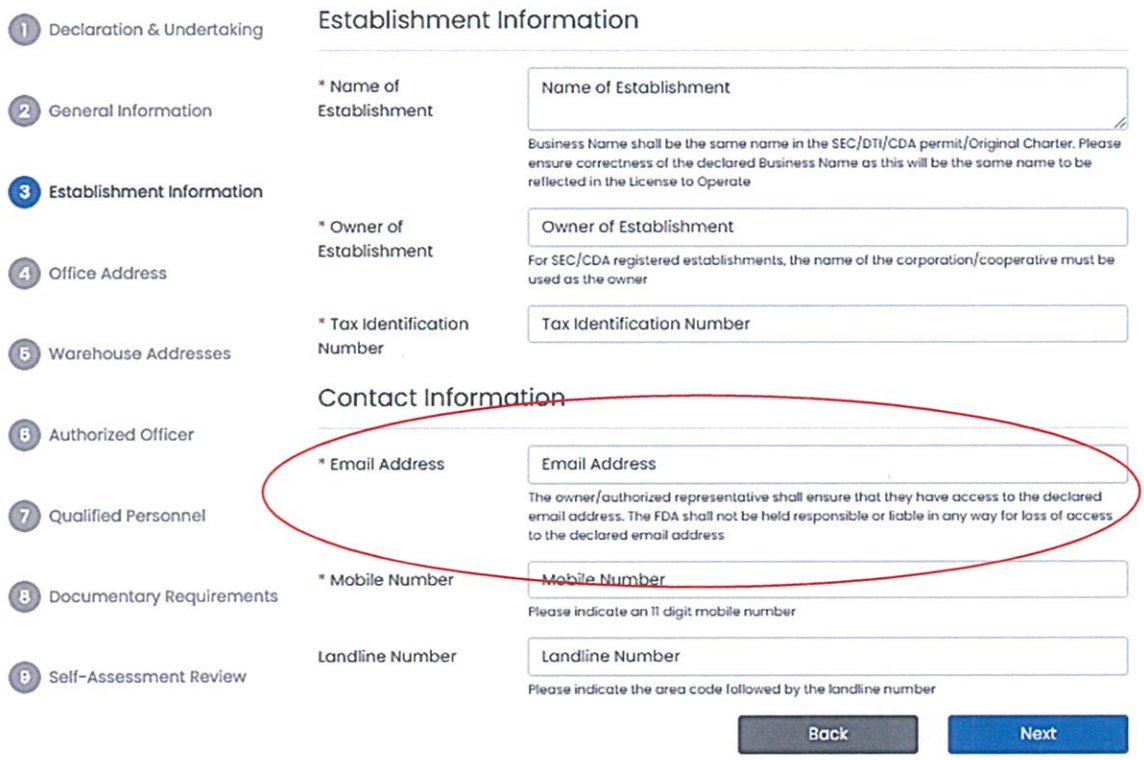
4. Read carefully the "Declaration and Undertaking" before proceeding with the application process. Make sure to check the box found below and click on **"Start Application".**



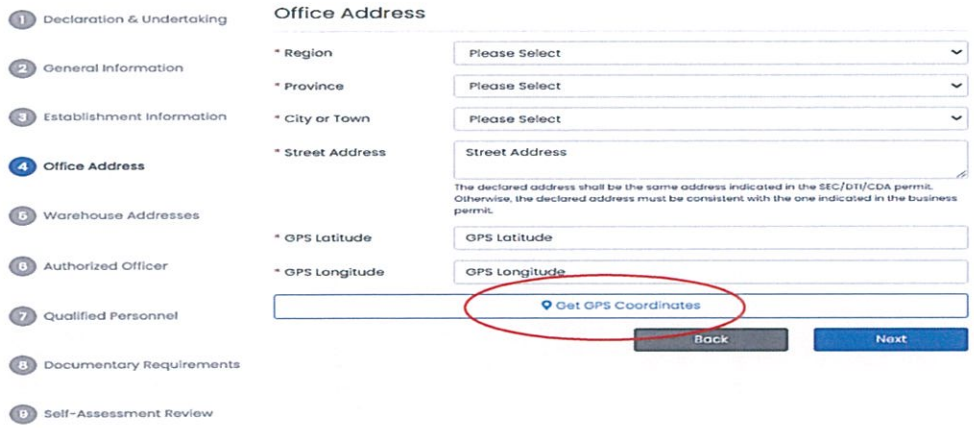
5. Fill-out the necessary information accurately based on establishment's activity/ies (Importer, Exporter, or Wholesaler). Make sure to properly tick the corresponding activity/ies to proceed on the next step.

6. 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 asterisk (*) are required to be filled-out.



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



8. The declared office 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.

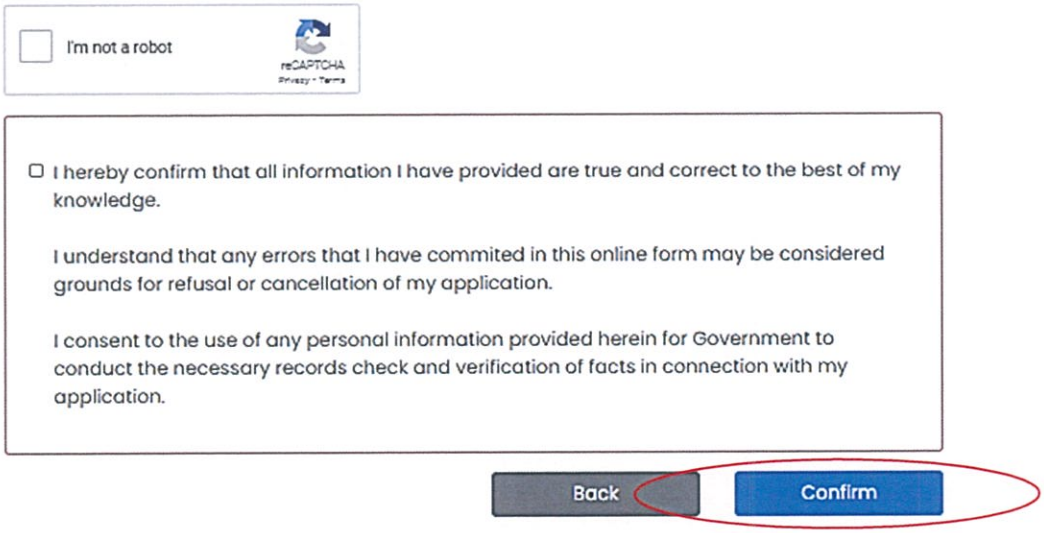
If there are two or more warehouses provided, it shall indicate in the application with respective GPS coordinates generated on the Geo-Coding Map.

9.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).

10. Upload the necessary documents.

11. User may review if all details are correct in the "Self-Assessment Review".

12. Once reviewed, the User shall confirm the correctness of data given and click on **"Confirm"** to submit the application.

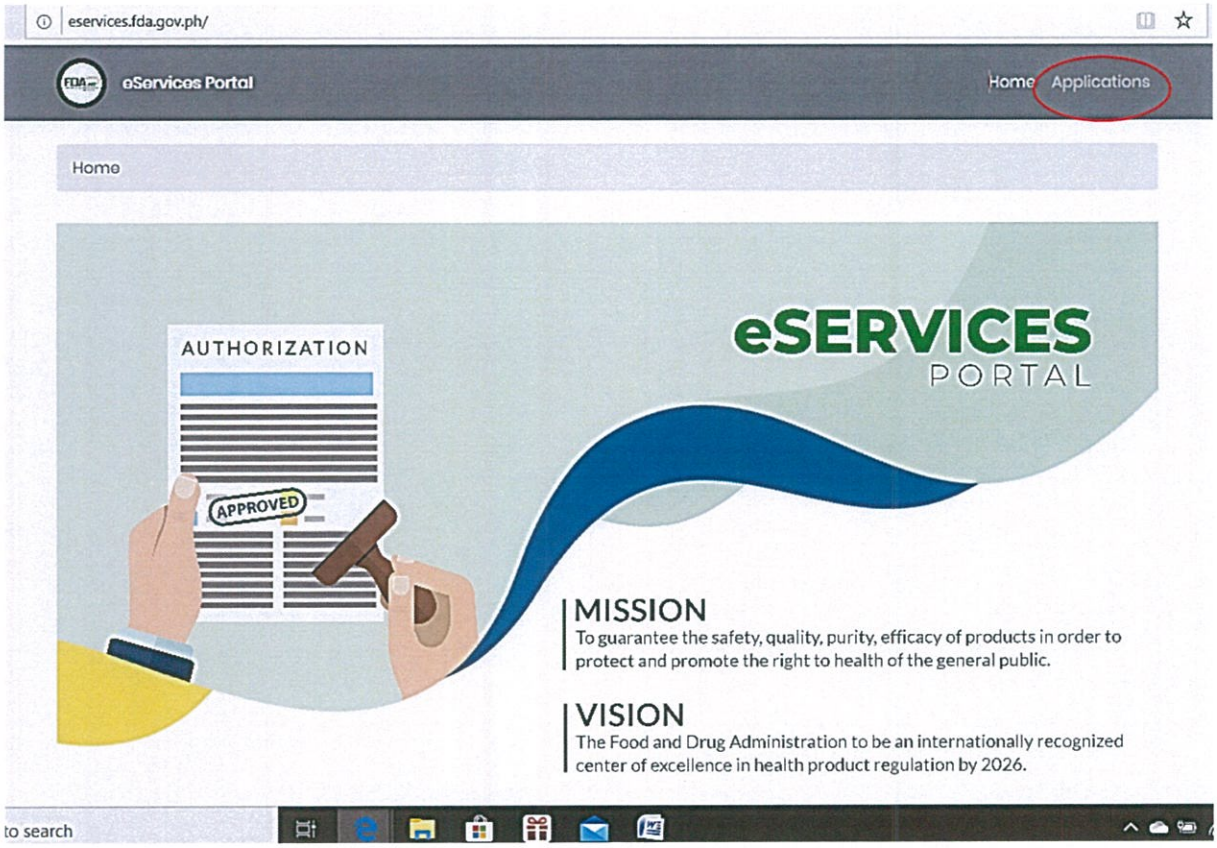


B. Application for Initial LTO for Medical Device Trader

Proceed as in Steps one (1) to twelve (12) of Item A (Application for Initial LTO for Medical Device Distributor). Make sure to click the appropriate type of establishment under Step # 2.

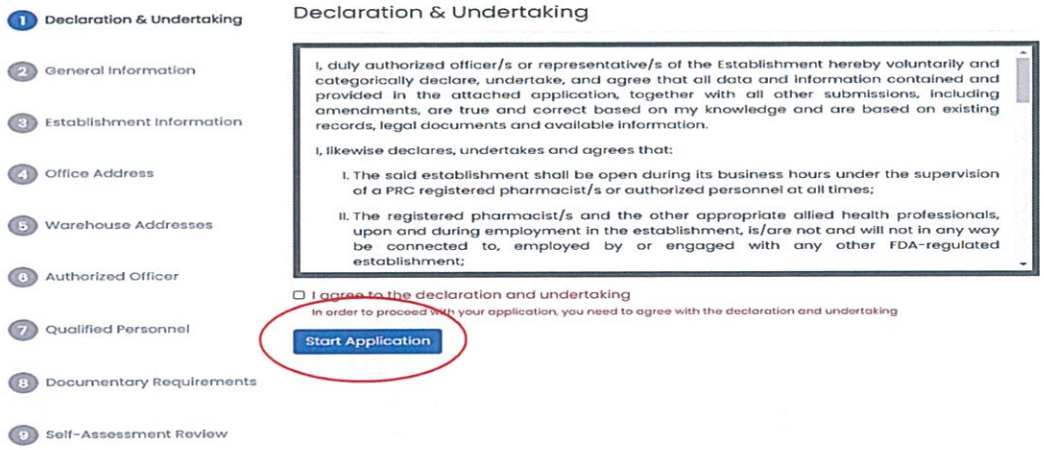
C. Application for Renewal of LTO for Medical Device Distributor

1. Access the online portal through eservices.fda.gov.ph and click **"Applications"** found on the upper right corner of the system.



2. Click on the License to Operate for Medical Device and the type of Business Establishment (Distributor). Click on the "Renewal".

3. 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"**.



4.Fill out the required fields. Security code is generated by scanning the QR code in the document. If everything is in order, tick the Captcha box and click Next to proceed to Contact Information.

5.Update contact numbers if necessary. Click Next to proceed to Self-Assessment Review.

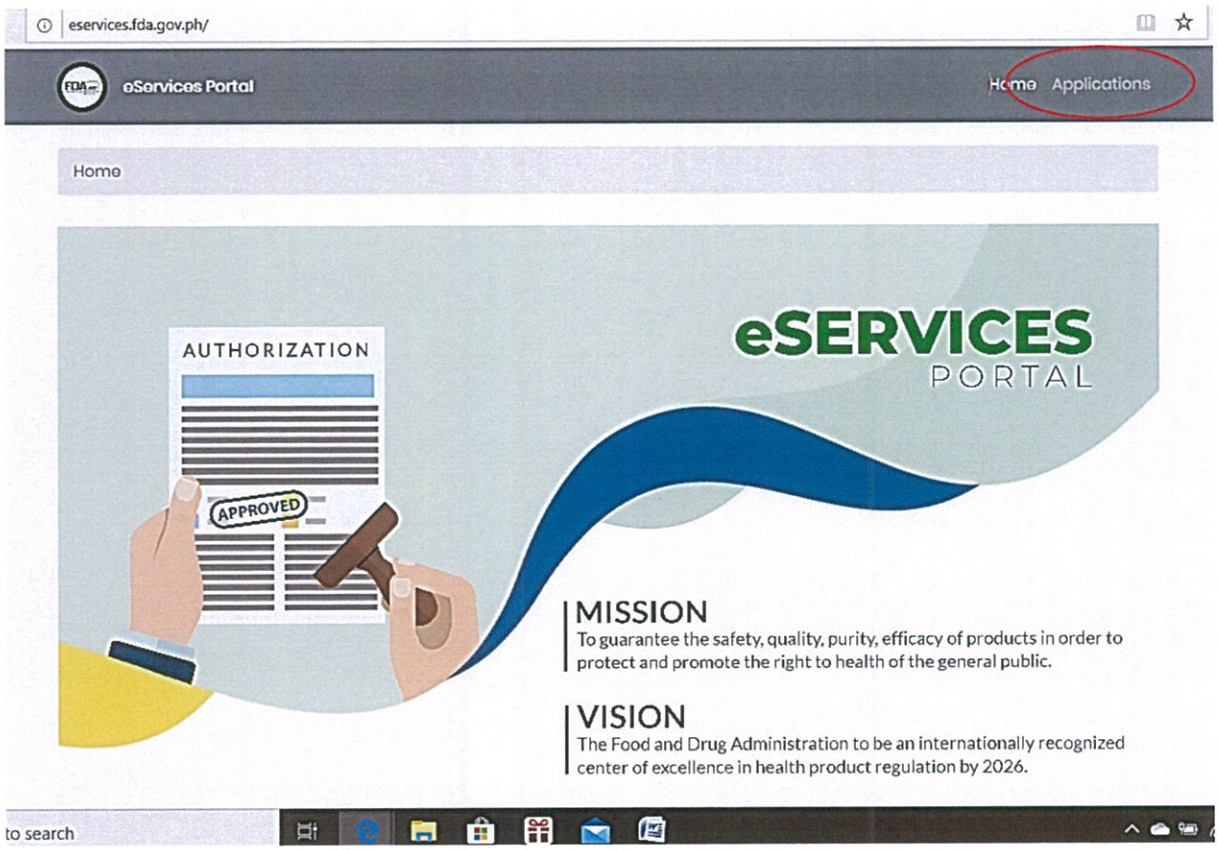
6.User may review if all details are correct in the "Self-Assessment Review".

D. Application for Renewal of LTO for Medical Device Trader

Proceed as in Steps one (1) to six (6) of Item C (Application for Renewal of LTO for Medical Device Distributor). Make sure to click the appropriate type of establishment under Step # 2.

E. Application for Variation in LTO for Medical Device Distributor

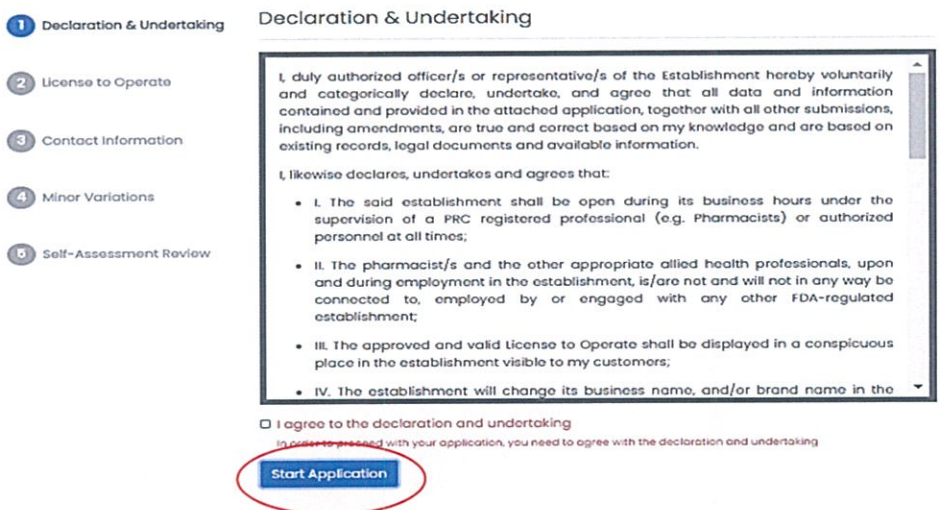
1. Access the online portal through eservices.fda.gov.ph and click **"Applications"** found on the upper right corner of the system.



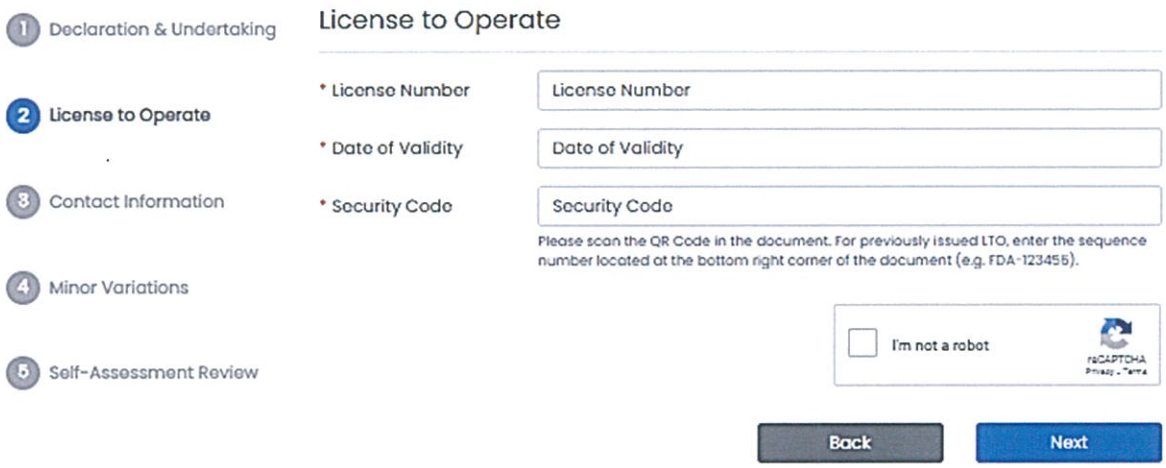
2. Click on the License to Operate for Medical Device and the type of Business Establishment (Distributor).

3. Click on the **"Variations"**.

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"**.



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.



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 Medical Device Trader

Proceed as in Steps one (1) to nine (9) of Item E (Application for Variation in LTO for Medical Device Distributor). Make sure to click the appropriate type of establishment under Step # 2.

G. Procedure for Checking of Application Status in the eServices Portal

1. To check the status of your application, click "Application Status.

2. Enter the Reference Number and click "submit".

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

4. Enter the verification code to view the progress of your application.