

# Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



0 7 MAY 2020

FDA ADVISORY No. 2020~781

TO

ALL NCR STAKEHOLDERS AND THE GENERAL PUBLIC

SUBJECT

Pilot Implementation of FDA eServices Portal for License to Operate (LTO) Application for Drugstores, RONPD, Drug

Distributor, and Drug Traders

The Food and Drug Administration, in its commitment to provide stakeholders with streamlined and improved government services, is developing the **FDA eServices Portal** – online platform for FDA Market Authorization applications.

The FDA wishes to invite stakeholders located within the National Capital Region (Metro Manila) who intend to apply for License to Operate (LTO) as Drug Distributor, Drug Trader, Drugstore, Retail Outlet for Non-Presciption Drugs (RONPD) only, to use the FDA eServices Portal through this link: <a href="http://eservices.fda.gov.ph/">http://eservices.fda.gov.ph/</a>. The eServices Portal is in its Pilot Implementation, hence the scope of the application is limited for the time being:

FDA eServices Portal Pilot Implementation			
Location of Establishment	National Capital Region (Metro Manila)		
LTO Establishment	Drug Distributor, Drug Trader, Drugstore, Retail Outlet for		
Application	Non-Prescription Drugs (RONPD)		
Type of LTO Application	Initial and Variation only		
Fees to be Paid	Based on Current Issuance on Fees and Charges		
	(Reference: DOH Administrative Order No. 50, s. 2001)		
Validity of Initial LTO	Current Validity Period Given by FDA - one (1) year		
Start of Pilot	07 May 2020		
Implementation			

Applications for 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.

Please follow Annex A of this Advisory for the Guideline and Checklist of Requirements, and Annex B of this Advisory for the Step-by-Step Guide in applying in the **FDA eServices Portal**.

ROLANDO ENRIQUE D. DOMINGO, MD.
Director General

Civic Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa, Philippines Trunk Line +63 2 857 1900 Fax +63 2 807 0751 Website: www.fda.gov.ph Email: info@fda.gov.ph



#### ANNEX A

### General Guideline and Requirements for LTO Application Using eServices Portal

#### General Guideline:

- 1. All establishments, whether public or private entity, engaged in business or operation on health products shall first secure a License to Operate (LTO) issued by the FDA and, when applicable, product market authorizations, i.e. Certificate of Product Registration (CPR), Certificate of Product Notification (CPN), before engaging in the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship activities.
- 2. All FDA regulated establishments applying for LTO shall be required to accomplish online application form through the E-Services Portal (eservices.fda.gov.ph). Creation of account and password is no longer a requirement to obtain access to the online portal.
- 3. The establishment shall use its company e-mail address to lodge an application on the E-Services Portal.
- 4. 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, FDA shall not be held liable in any way for loss of access to the declared e-mail address.
- 5. All fields on the online application form have written warnings/pop-ups/reminders before proceeding to the next step to ensure accuracy of information provided. The establishment applying for LTO shall ensure that the declared information in the web-based form are consistent with the uploaded supporting documents, i.e. business name and owner, establishment's address and others.
- 6. 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 the FDA or discuss or clarify matters with the FDA when submitting technical requirements or engage the FDA officials when conducting inspection or post-market surveillance activities. The qualified person may also be the duly Authorized Person of the establishment.
- 7. All drug establishments, including drugstores, whether privately owned or governmentowned, shall be under the supervision of a registered pharmacist when operating or open for business, unless otherwise allowed by other pertinent laws or regulations.
- 8. It is the responsibility of the licensed establishments to immediately recall, withdraw or remove health products from the market that is banned or declared injurious, unsafe or dangerous by the FDA or products or batches of product that have been found to pose imminent danger to public health or consumer safety.
- 9. FDA inspection shall be conducted after the issuance of the LTO (post-licensing approval).
- 10. The FDA shall have the authority to enter any FDA-licensed establishments and establishments selling FDA-regulated health products during operating hours to conduct routine or spot check inspections.
- 11. All FDA-required information, education, and communication campaign materials shall be displayed in the establishment's conspicuous area.

12. 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.

#### **Application Requirements:**

#### A. Initial LTO

- 1. Accomplished e-Application Form with Declaration of Undertaking (eservices.fda.gov.ph)
- 2. Proof of Business Name Registration (in pdf, 5MB maximum file size)
  Any one of the following shall be submitted as proof of business name registration (in pdf):
  - a. For single proprietorship, the 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 Securities and Exchange Commission (SEC) and Articles of Incorporation;
  - c. For Cooperative, the Certificate of Registration issued by the Cooperative Authority and Articles of Cooperation; or
  - d. For Government-Owned or Controlled Corporation, the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter.
- 3. If the business or establishment address is different from the business name registration address, the applicant shall submit a copy of the Business Permit (e.g. Mayor's Permit).
- 4. Proof of Income for Drug Trader (in pdf, 5MB maximum file size) such as 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.
- 5. Standard Operating Procedures (SOP)
- 6. Risk Management Plan (RMP) shall be presented to FDA during inspection of establishment; please refer to current FDA issuance for the detailed RMP guideline
- 7. Site Master File (SMF) shall be presented to FDA during inspection of establishment; please refer to current FDA issuance for the detailed SMF guideline

#### B. Variation in LTO

- 1. Accomplished e-Application Form with Declaration of Undertaking;
- 2. Documentary requirements depending on the variation or circumstances of the establishment or the product as shown in Annex C of this Order; and
- 3. Payment of Fees

Type of Variation	Requirement
Transfer of Location of Offices	Business permit reflecting new location
- Physical transfer of the office of the	office
establishment (which may also entail	
changes in the previously approved	
address)	
Transfer of Location of Drug Retailers	Business permit reflecting new address
- Physical transfer of the drug retailer	
(which may also entail changes in the	
previously approved address)	<i>i</i>

Change of Distributor Activity - Shall refer to an additional/deletion of/change inactivity that the distributor engage in	Contract Agreements showing change in activity		
Transfer/Addition of Warehouse - Physical transfer and addition of the warehouse of the establishment (which may also entail changes in the previously approved address)	Business permit reflecting new warehouse		
Additional Drugstore Activities	<ul> <li>a. Additional Credentials of Pharmacist, as applicable</li> <li>b. Other documents related or specific to the additional activity, such as but not limited to: <ul> <li>Adult Vaccination - Standard Operating Procedure</li> <li>Dispense Vaccines and Biologicals - Standard Operating Procedure</li> <li>Mobile Pharmacy - Standard Operating Procedure</li> <li>Online Ordering and Delivery - Standard Operating Procedure and Website Screenshot</li> <li>Sterile Compounding and Non-Sterile Complex Compounding - Standard Operating Procedure</li> <li>Other additional activities that may require appropriate regulation.</li> </ul> </li> </ul>		
Expansion of Office Establishments and Drug Retailers - Shall refer to expansion made which is adjacent to the existing location of the establishment	Expansion floor plan		
Change of Ownership  - Change in ownership of the licensed establishment	<ul> <li>a. Business name registration reflecting new ownership</li> <li>b. Any proof on the transfer of ownership such as any of the following: <ul> <li>Deed of sale or assignment or transfer of rights/ownership;</li> <li>Memorandum of Agreement; or</li> <li>Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer</li> </ul> </li> </ul>		
Change of Business Name - Change only in the business name of the establishment	Business permit reflecting the new name		
Zonal Change in Address  - Change of the name/number of the street/building without physical transfer of the establishment	Certificate of Zonal Change		

Change of Qualified Person	a. Name of new qualified person
- Change in the identified qualified person	b. Applicable requirements as specified in
initially registered with the FDA	Annex B
Change of Authorized Person	a. Name of new qualified person
- Change in the authorized person initially	b. Updated contact details
registered with the FDA	

C. Qualified Person Qualification and Credential Requirements

<b>Qualified Person</b>	Qualifications/Requirements	
Registered Pharmacists (RA 10918)	<ul> <li>a. Professional Regulatory Commission (PRC) Identification Card (ID)</li> <li>b. Certificate of Attendance to seminars, training, learning and development activities on drug safety, quality, and efficacy and other applicable trainings (e.g. Training for Pharmacy Assistant, Basic and Advance Course on Good Clinical Practice for Clinical Research Organizations (CRO)/sponsors</li> </ul>	

#### Payment:

Payment of prescribed fees as indicated in the Order of Payment may be done through the FDA Cashier, the bank (i.e. Landbank of the Philippines, Development Bank of the Philippines, Bancnet), or online thru Bancnet based on the existing FDA issuances. Incomplete payment will not be accepted and the application will not proceed to the next step of the process.

# FDA Evaluation of the Application:

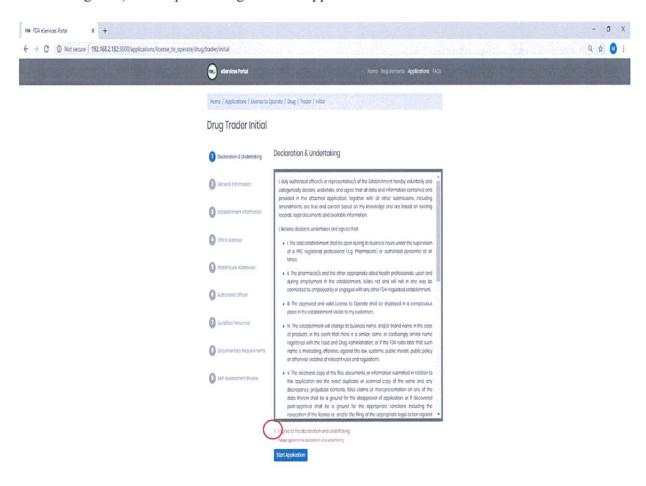
- 1. The veracity of the application and compliance with all the documentary requirements and appropriate standards shall be further assessed.
- 2. Any of the following or similar instances shall be a ground for disapproval:
  - a. The documentary requirements submitted show that the establishment does not meet the required technical requirements and/or appropriate standards;
  - b. The applicant made misrepresentations, false entries, or withhold any relevant data contrary to the provisions of the law or appropriate standards;
  - c. The owner has violated any of the terms and conditions of its license; and
  - d. Such other analogous grounds or causes as determined by the FDA.
- 3. The action on the application shall be Approval or Disapproval as provided by RA No. 11032.
- 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

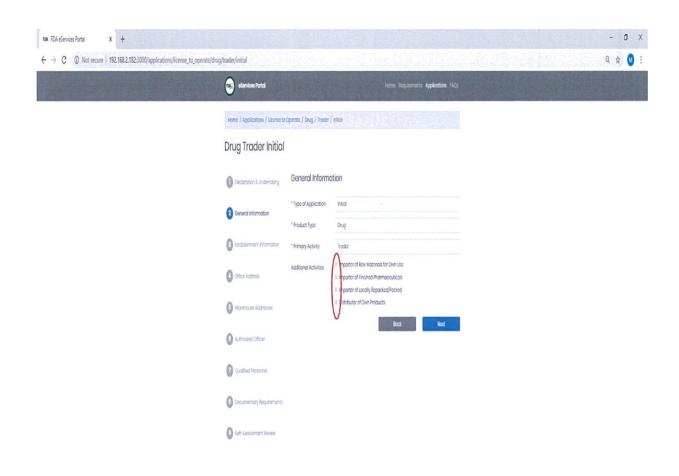
# Procedure for the Use of the FDA eServices Portal for License to Operate (LTO) Application

# A. Application for Initial LTO for Drug Trader

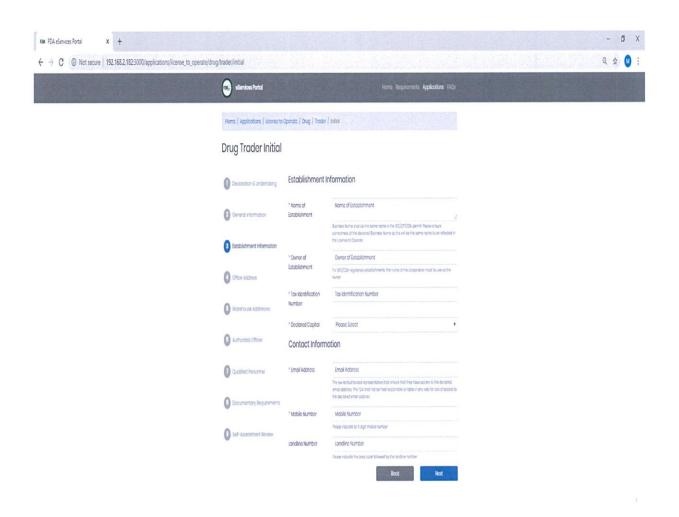
- 1. To start the application, access the online portal through https://www.eservices.fda.gov.ph and click "Applications".
- 2. Select the product category (Drug) and the type of business establishment (Distributor, Trader,, or Drugstore) before proceeding to Initial application.



3. Read and understand the Declaration and Undertaking. If no objection, click Start Application.



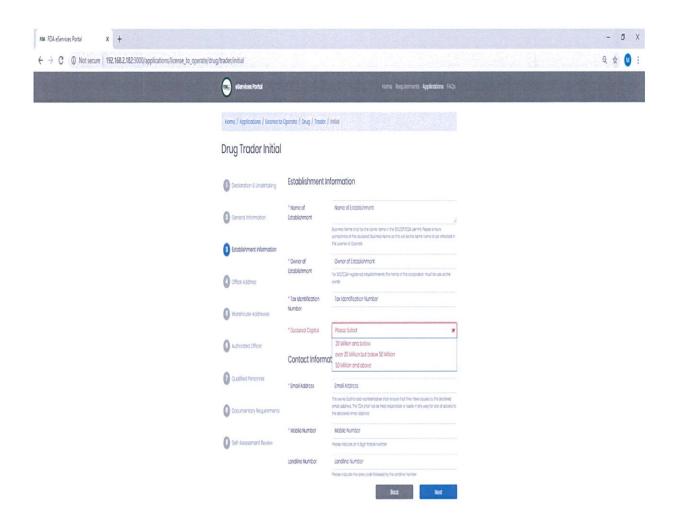
4. Tick the appropriate box/es listed for Additional Activities (if any). Click Next to proceed to Establishment Information. All fields marked with (\*) asterisk must be duly filled-out.



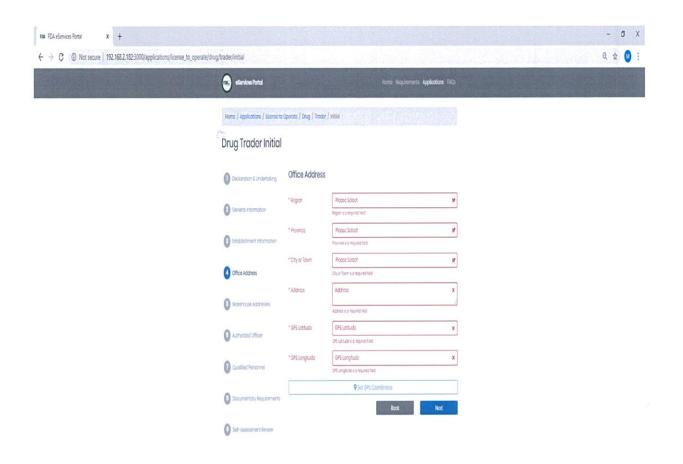
© 2020 Food and Drug Administration Philippines

Privacy Policy

3. Key in the required fields.

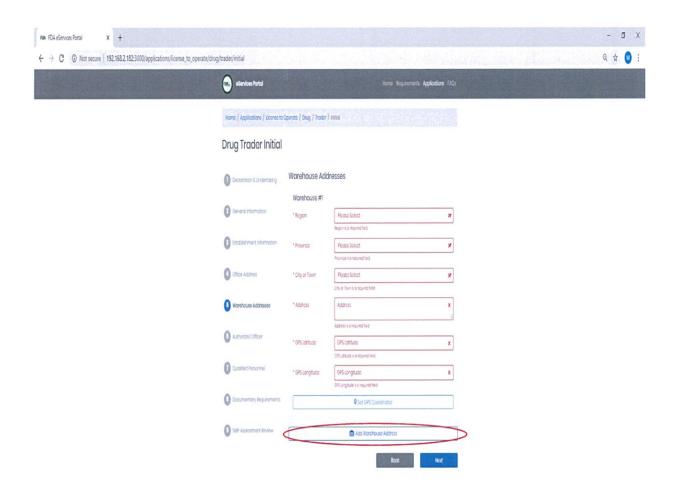


Select the applicable range for the Declared Capital. If everything is in order, click Next to proceed to office address.

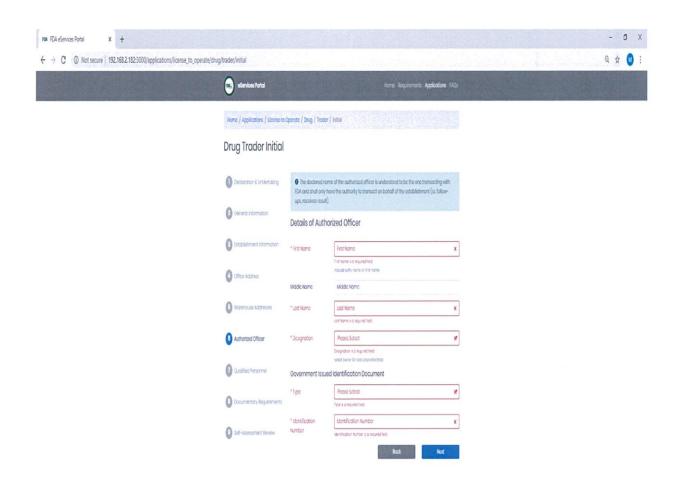


2001 Food and Ding Administration Philippines
 Phinosy Yolicy

4. Fill out the required fields. Click get GPS coordinates to automatically generate GPS Latitude and Longitude. If everything is in order, click Next to proceed to Warehouse Address.

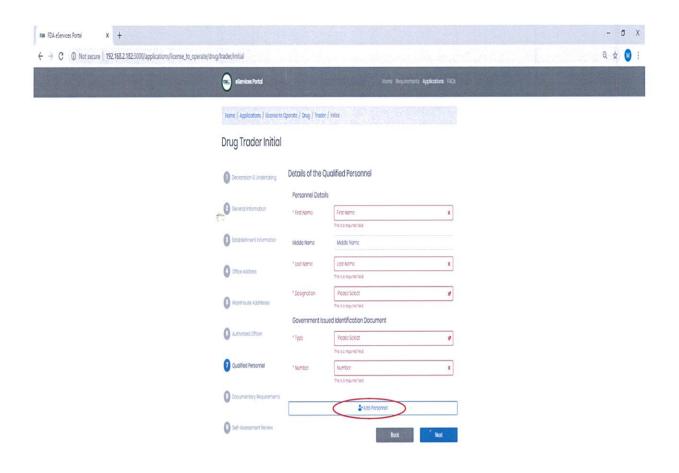


5. Fill out the required fields for the Warehouse Addresses. To add warehouse, click add Warehouse Address encircled in red. If everything is order, click Next to proceed to Authorized Officer.

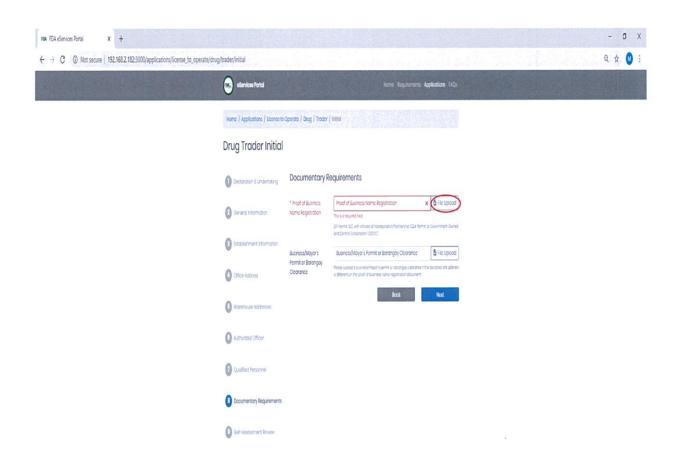


8 2021 Food and Drug Main inhabation Philippines Phinoxy Rulay

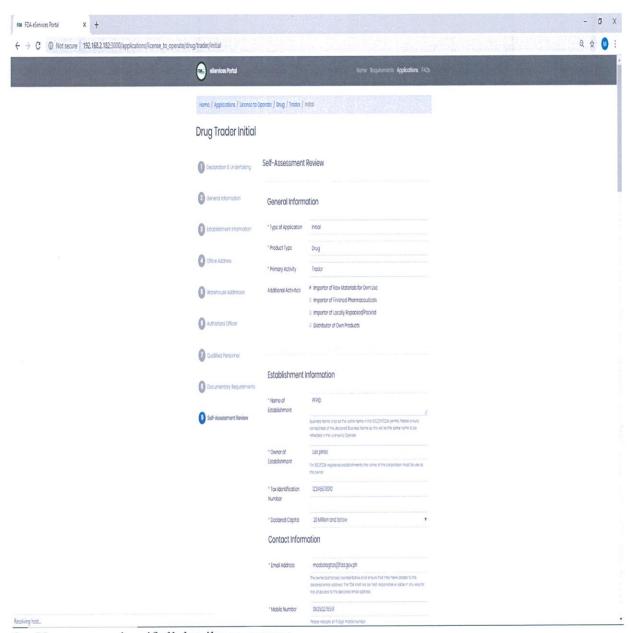
6. Fill out the required fields for Authorized officer and click Next to proceed to Qualified Personnel.



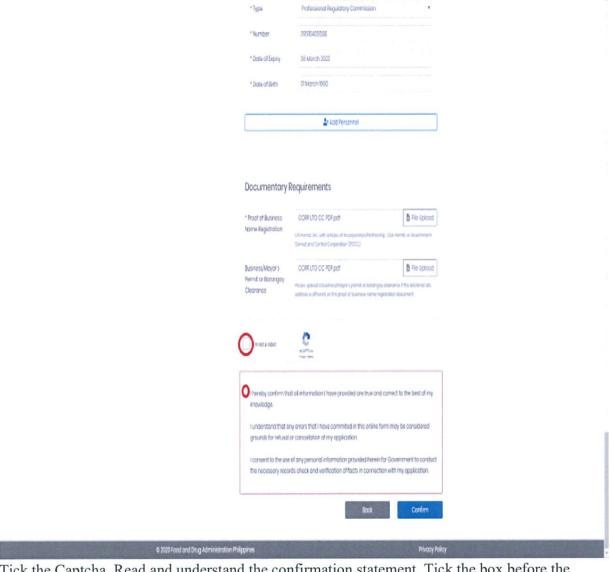
7. Fill out the required fields for the Details of the Qualified Personnel. To add more personnel, click Add Personnel encircled in red. If everything is in order, click Next to proceed to Documentary Requirements.



8. To upload documents, click the File Upload icon encircled in red. Once done, click Next to proceed to Self-Assessment Review.



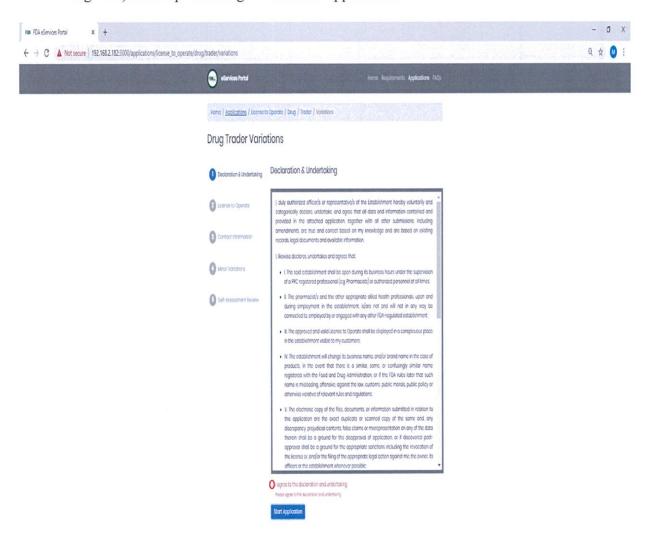
9. User may review if all details are correct.



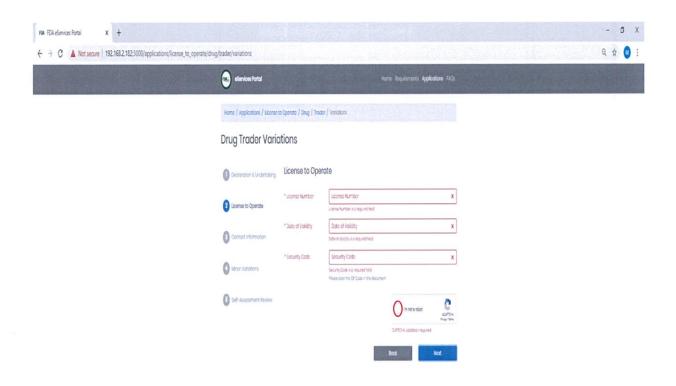
Tick the Captcha. Read and understand the confirmation statement. Tick the box before the sentence and click Confirm.

# B. Application for Variation in the LTO

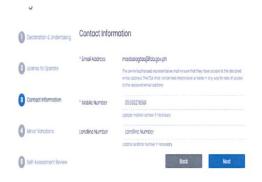
- 5. To start the application, access the online portal through https://www.eservices.fda.gov.ph and click "Applications".
- 6. Select the product category (Drug) and the type of business establishment (Distributor, Trader,, or Drugstore) before proceeding to Variation application.



1. To start the application, read and understand the Declaration and Undertaking. If no objection, tick the box and click Start Application.



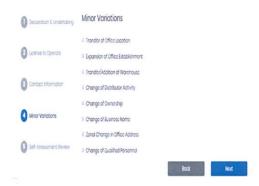
2. Fill out the required fields. Security code is generated by scanning the QR code in the document. If everything is in order, tick the Captcha box and click Next to proceed to Contact Information.



2020 Food and Drug Administration Philippines

Privacy Po

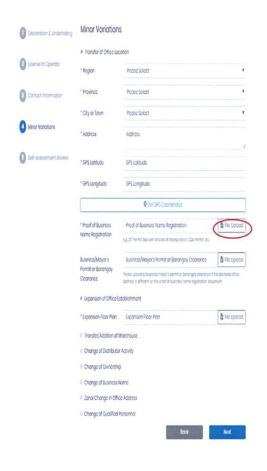
3. Update contact numbers if necessary. Click Next to proceed to Self-Assessment Review.



© 2020 Rood and Drug Administration Philippin

Privacy Polic

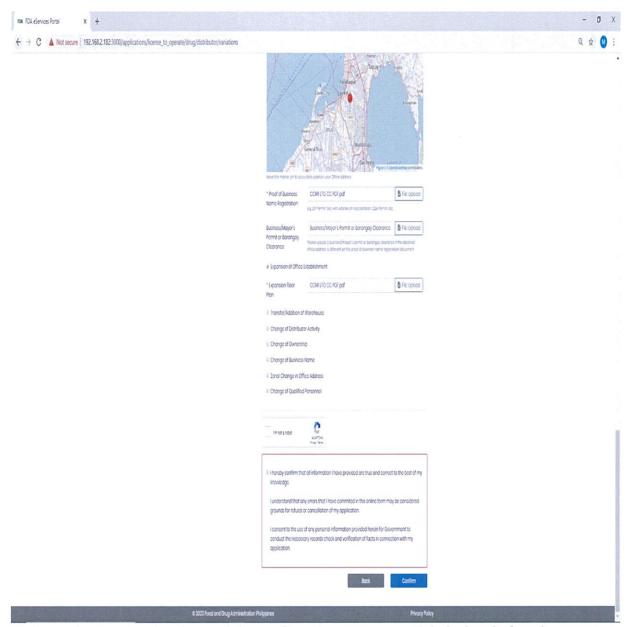
4. Choose the applicable variation(s) by ticking the box.



5. Key in the required fields. To upload documents, click the File Upload icon encircled in red. If everything is in order, click Next to proceed to Self-Assessment Review.

Declaration & Undertaking	Self-Assessment Review		
(2) License to Operate	License to Operate		
Contact Information	* License Number	CDR9-NCH-DE-2382	
	* Date of Volidity	09 March 2022	
Mrcr Variations	" Security Code	EDUCKEN/201	
Self-Assessment Review		Please scan the CR Code in the document	
	Contact Infor	mation	
	*Emoil Address	mosbolagtas@fda.gov.ph	
		The comentium draph expressions and ensure that they make access to the discount email address. The IDA and not be need responsible or label in any any for test of access to the decorate email address of access to the decorate email address.	
	* Mobile Number	0936027698	
		Cpdat-rable number ( recessory	
	Landine Number	Landline Number  space under humber I recessary	
	General Information		
	* Type of Application	Variation	
	* Primary Activity	Distributor	
	* Additional Activities	Exportor	
	Establishment	t Information	

6. User may review if all details are correct.



Tick captcha. Read and understand the confirmation statement. Tick the box before the sentence and click Confirm.