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-Prescription Drugs (RONPD) only, to use the FDA eServices Portal through this link: http://eservices.fda.gov.ph/. The eServices Portal is in its Pilot Implementation, hence the scope of the application is limited for the time being:

<table>
<thead>
<tr>
<th><strong>FDA eServices Portal Pilot Implementation</strong></th>
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<tr>
<td><strong>Location of Establishment</strong></td>
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<tr>
<td><strong>LTO Establishment Application</strong></td>
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<tr>
<td><strong>Type of LTO Application</strong></td>
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<td><strong>Fees to be Paid</strong></td>
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<tr>
<td><strong>Validity of Initial LTO</strong></td>
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<td><strong>Start of Pilot Implementation</strong></td>
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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
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 government-owned, 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

<table>
<thead>
<tr>
<th>Type of Variation</th>
<th>Requirement</th>
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| Transfer of Location of Offices  
- Physical transfer of the office of the establishment (which may also entail changes in the previously approved address) | Business permit reflecting new location office |
| Transfer of Location of Drug Retailers  
- Physical transfer of the drug retailer (which may also entail changes in the previously approved address) | Business permit reflecting new address |
<table>
<thead>
<tr>
<th>Change of Distributor Activity</th>
<th>Contract Agreements showing change in activity</th>
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<tbody>
<tr>
<td>- Shall refer to an additional/deletion of/change inactivity that the distributor engage in</td>
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<tr>
<th>Transfer/Addition of Warehouse</th>
<th>Business permit reflecting new warehouse</th>
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<tr>
<td>- Physical transfer and addition of the warehouse of the establishment (which may also entail changes in the previously approved address)</td>
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<tr>
<th>Additional Drugstore Activities</th>
<th>a. Additional Credentials of Pharmacist, as applicable</th>
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<tr>
<td></td>
<td>b. Other documents related or specific to the additional activity, such as but not limited to:</td>
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<td></td>
<td>- Adult Vaccination - Standard Operating Procedure</td>
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<td></td>
<td>- Dispense Vaccines and Biologicals - Standard Operating Procedure</td>
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<td></td>
<td>- Mobile Pharmacy - Standard Operating Procedure</td>
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<td></td>
<td>- Online Ordering and Delivery - Standard Operating Procedure and Website Screenshot</td>
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<td></td>
<td>- Sterile Compounding and Non-Sterile Complex Compounding - Standard Operating Procedure</td>
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<td>- Other additional activities that may require appropriate regulation.</td>
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<tr>
<th>Expansion of Office Establishments and Drug Retailers</th>
<th>Expansion floor plan</th>
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<td>- Shall refer to expansion made which is adjacent to the existing location of the establishment</td>
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<tr>
<th>Change of Ownership</th>
<th>a. Business name registration reflecting new ownership</th>
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<tr>
<td>- Change in ownership of the licensed establishment</td>
<td>b. Any proof on the transfer of ownership such as any of the following:</td>
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<td></td>
<td>- Deed of sale or assignment or transfer of rights/ownership;</td>
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<td></td>
<td>- Memorandum of Agreement; or</td>
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<td></td>
<td>- Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer</td>
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<tr>
<th>Change of Business Name</th>
<th>Business permit reflecting the new name</th>
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<tbody>
<tr>
<td>- Change only in the business name of the establishment</td>
<td></td>
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<tr>
<th>Zonal Change in Address</th>
<th>Certificate of Zonal Change</th>
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<tbody>
<tr>
<td>- Change of the name/number of the street/building without physical transfer of the establishment</td>
<td></td>
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</table>
Change of Qualified Person
- Change in the identified qualified person initially registered with the FDA
  a. Name of new qualified person
  b. Applicable requirements as specified in Annex B
Change of Authorized Person
- Change in the authorized person initially registered with the FDA
  a. Name of new qualified person
  b. Updated contact details

C. Qualified Person Qualification and Credential Requirements

<table>
<thead>
<tr>
<th>Qualified Person</th>
<th>Qualifications/Requirements</th>
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<tbody>
<tr>
<td>Registered Pharmacists (RA 10918)</td>
<td>a. Professional Regulatory Commission (PRC) Identification Card (ID)</td>
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<td></td>
<td>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</td>
</tr>
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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.
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.
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.
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.
Drug Trader Initial

Self-Assessment Review

General Information

- Name of Establishment: [Name]
- Address: [Address]
- Contact Person: [Name]
- Email: [Email]
- Phone: [Phone]

Establishment Information

- Name of Establishment: [Name]
- Address: [Address]
- Contact Person: [Name]
- Email: [Email]
- Phone: [Phone]

Establishment Information

- Name of Establishment: [Name]
- Address: [Address]
- Contact Person: [Name]
- Email: [Email]
- Phone: [Phone]

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