Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

LICENSING OF DRUG ESTABLISHMENTS

Frequently Asked Questions (FAQs)

Version 3.0

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1. LICENSE TO OPERATE (LTO)

1.1. General Procedures

1.1.1. What are the guidelines for an LTO application?

Administrative Order (A.O.) No. 2020-0017 or the Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003 dated 08 May 2020 and effective on 05 June 2020. (link: https://www.fda.gov.ph/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/.

1.1.2. How is the A.O. No. 2020-0017 different from the previous guidelines, A.O. No. 2016-0003?

A.O. No. 2020-0017 provides more streamlined application processes and requirements with some of the following significant changes:

a. The client does not need to request for a User Account and Password from the Food and Drug Action Center (FDAC) to log in to their account.
b. The application process is reduced to only five (5) steps.
c. The documentary requirements are lessened to only two (2) or three (3) documents, as applicable.
d. On the Pre-Assessment stage, there is no fee to be paid if the application is denied. The client can re-apply and there is no limit on the number of re-applications to be done. Thereafter, if done with the Pre-Assessment stage, the step proceeds to the Payment stage.
e. The client will print their own FDA LTO.

1.1.3. Is there a portal that we need to use?

In line with the provision of A.O. No. 2020-0017, the FDA launched the eServices Portal System, the new online system for the processing of LTO applications, with pilot implementation that has started on 07 May 2020 (as per FDA Advisory No. 2020-781).

1.1.4. Where can I view the list of requirements?

The list of requirements is provided in the Annex of A.O. No. 2020-0017 and can be accessed through this link: https://www.fda.gov.ph/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/.

HOWEVER, all applications filed and received by the FDA before 05 June 2020 are required to comply with the requirements stated in A.O. No. 2016-0003 or the "Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration" which can be accessed through this link:

https://ww2.fda.gov.ph/issuances-2/pharml-1/pharml-administrative-order/303720ao2016-003.

1.1.5. What are the available payment methods?

The payment can be made through the FDA Cashier, any branch of the Land Bank of the Philippines, and Bancnet.

1.1.6. What is the next step after payment?

All payments are cleared by the cashier and thereafter, the application is routed to the Center for evaluation.

1.1.7. When should I renew my LTO?

An LTO must be renewed within ninety (90) days or within three (3) months before its validity date, as stipulated in the issued LTO applied through the e-Portal system.

If an LTO is not renewed after one hundred twenty (120) days or after four (4 months) from its validity, the application shall be treated as a "turned initial" application with the corresponding fees and validity (2 years) of an initial application.

1.1.8. If we need to file for a variation, how do we determine if it is a major or minor variation application?

The list of variations is provided in Annex C of A.O. No. 2020-0017 and can be accessed through this link: https://www.fda.gov.ph/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/.

1.1.9. What is the turnaround time (TAT) for LTO evaluation and issuance?

As provided in the Citizen's Charter, the TAT for both LTO evaluation and issuance is thirty (30) calendar days upon receipt of the application by the Center.

1.1.10. What is the validity of an LTO?

An initial LTO is valid for two (2) years and a renewed LTO is valid for three (3) years.

1.1.11. What are the fees for an LTO application?

All of the fees have an additional 1% Legal Research Fee (LRF) and are according to the A.O. No. 2020-0017:

LTO APPLICATION		
ESTABLISHMENT	**INITIAL APPLICATION + LRF**	**RENEWAL APPLICATION + LRF**
Drugstore	₱ 2,020.00	₱ 3,030.00
Retail Outlet for Non-Prescription Drugs (RONPD)	₱ 2,020.00	₱ 3,030.00

Drug Distributor	₱ 10,100.00	₱ 15,150.00
Contract Research Organization and Sponsor (Capital: 20 million and below)	₱ 6,060.00	₱ 9,090.00
Contract Research Organization and Sponsor (Capital: 20 million but below 50 million)	₱ 10,100.00	₱ 15,150.00
Contract Research Organization and Sponsor (Capital: 50 million and above)	₱ 14,140.00	₱ 21,210.00
Drug Trader (Capital: 20 million and below)	₱ 6,060.00	₱ 9,090.00
Drug Trader (Capital: 20 million but below 50 million)	₱ 10,100.00	₱ 15,150.00
Drug Trader (Capital: 50 million and above)	₱ 14,140.00	₱ 21,210.00
Drug Manufacturer (Capital: 20 million and below)	₱ 20,200.00	₱ 30,300.00
Drug Manufacturer (Capital: 20 million but below 50 million)	₱ 30,300.00	₱ 45,450.00
Drug Manufacturer (Capital: 50 million and above)	₱ 40,400.00	₱ 60,600.00

VARIATION APPLICATION	
ESTABLISHMENT	**VARIATION + LRF**
Drugstore	₱ 510.00 ***Note**: As per A.O. No. 2020-0017, there is no more delineation if a variation is major or minor, all variations are considered as just "variation" applications.*
RONPD	
Drug Distributor	
Contract Research Organization and Sponsor	
Drug Trader	
Drug Manufacturer	

1.1.12. How is the surcharge computed if we filed a renewal application a day after the expiration of an LTO?

The e-Portal automatically computes for the surcharge; but as per Republic Act No. 9711, computation of surcharge is equivalent to twice the renewal fee plus an additional 10% per month or a fraction thereof of continuing non-submission of such application up to a maximum of one hundred twenty (120) days or four (4) months (40%). Renewal applications filed after 120 days from its expiration date shall be considered turned initial. Please note that the surcharge will still be added to the renewal fee of the establishment plus 1% Legal Research Fund. Fees are based on A.O. No. 50 s. 2001 or the "Revised 2001

Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs."

An example of a computation if renewal is filed one (1) day after the LTO validity:
= (3,000 x 2) + (3,000 x 10%) + 3,000 + (3,000 x 1%)
= 6,000 + 300 + 3,000 + 30
= ₱ 9,330.00

1.1.13. If an application is disapproved, where and how can we re-apply?

The Letter of Disapproval (LOD) of an application filed through the e-Portal can be seen in the message received in the inbox of your e-Portal account.

Re-application can be done by clicking "New Case" in the e-Portal. Payment made for the application that merited a disapproval is already FORFEITED. Therefore, for the re-application, the client must pay again. In consideration of the disapproved application, the Licensing Section of the Center may prioritize the decking/evaluation of your re-application by providing a new Case Number. You may also contact the Licensing Section at (02) 8857-1900 local 1331**.**

1.1.14. What are the requirements for closing an establishment?

A Letter of Intent with the attached original copy of the LTO is submitted through the FDAC's Letters lane.

1.1.15. If there is a request for the list of registered drug establishments, what are the requirements?

Letter of Intent, blank DVD-R, and payment of a total fee + LRF of ₱ 510.00 are submitted through the FDAC's Letters lane.

1.2. LTO APPLICATION VIA E-PORTAL SYSTEM

1.2.1. How do we apply for an LTO through the e-Portal?

For an Initial LTO application in the National Capital Region (NCR), it is advised that the filing of application be made through the eServices portal system as per FDA Advisory No. 2020-781. However, for Renewal and Variation LTO applications, these are applied through the e-Portal system.

The processes and requirements for application using the e-Portal are provided in the FDA Circular No. 2016-004, "Procedure on the Use of the New Application Form for License to Operate (LTO) through the Food and Drug Administration (FDA) Electronic Portal (ePortal)". The LTO application through the e-Portal System is applicable for all establishments nationwide and without restrictions unlike the eServices portal system. The following are the step by step procedure:

i. Secure username and password from the FDAC.

ii. If you already have your username and password, go to www.fda.gov.ph and click "e-Portal" found on the homepage.
iii. Type your username and password.
iv. Click "New Case".
v. Read the Undertaking and select "I Agree" in the drop-down box. Then, click continue.
vi. Fill-in the required details and upload the documents as instructed in the next steps. The last step would be the order of payment which can be downloaded by the client.
vii. Proceed to payment then click "Next" to route the application to the FDA cashier for clearance.

1.2.2. How is the status of an LTO application tracked?

If the application is filed thru the e-Portal, the client may log-in to their e-Portal account, click "Information", choose "Process Map" (red color indicates current process while green color indicates completed or acted process).

If the application is submitted at the FDAC receiving area, you may use the document tracking or "doctrack" status feature in the website (link: https://ww2.fda.gov.ph/doctrack-status-know-the-status-of-your-application).

1.2.3. My eLTO does not have a signature, what should I do?

Since it is electronically generated, eLTOs do not contain a signature. This is already stipulated at the footnote of the License.

1.2.4. What are the steps to reactivate my user account on e-Portal?

As per FDA Circular No. 2016-004, reactivation request should be sent to fdac@fda.gov.ph within three (3) months before the expiration of the user account. Refer to the public assistance officer for assistance. The reactivation of account is handled by the FDAC and not by the CDRR.

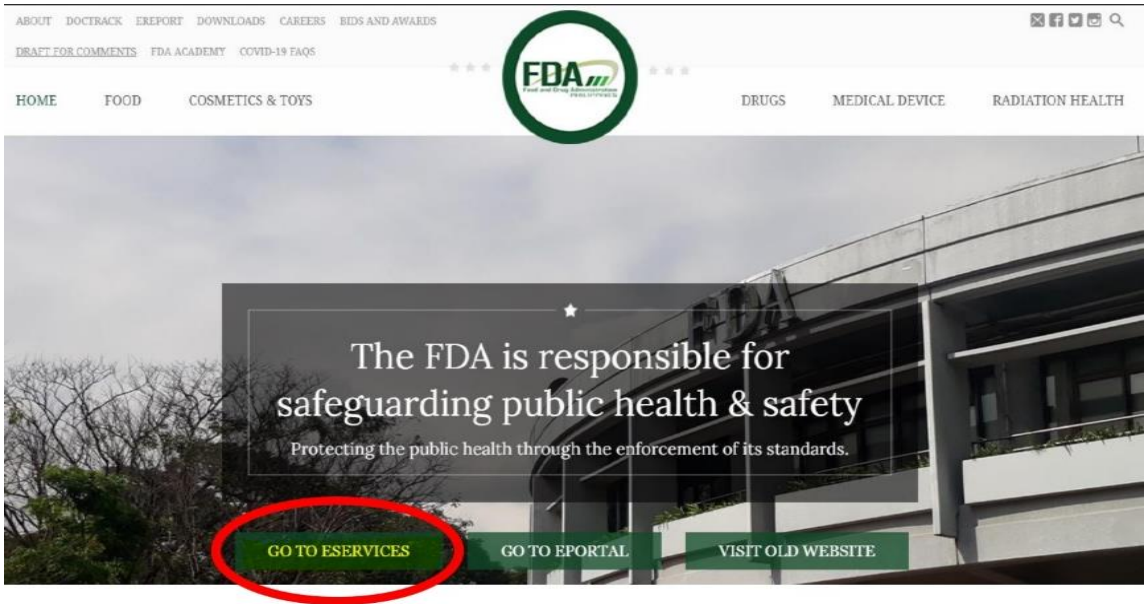
1.2.5. Can we add documents in the e-Portal?

Yes. After uploading the first three (3) documents in the e-Portal, click "Next" then a "List of Requirements" will appear on the screen. On the upper left portion, you'll see the option **'Attach' button**. From there, you can add/upload additional documents.

1.3. LTO APPLICATION VIA ESERVICES PORTAL SYSTEM

1.3.1. How do we apply for an LTO using the eServices portal?

Stakeholders can apply through the FDA website (www.fda.gov.ph) by clicking "GO TO SERVICES" or through this link: http://eservices.fda.gov.ph.



1.3.2. What is the process for applying through the eServices portal?

LTO application is only through five (5) steps: Application, Pre-Assessment, Payment, Checking, and Approval. Steps are lessened as compared to the filing of an LTO application through the e-Portal system. It must be noted that during the Pre-Assessment step, the technical evaluators of the Center evaluate for the completeness and correctness of the details on the online application form and uploaded documentary requirements. If approval is given, the LTO should be displayed in a conspicuous area of the establishment for public viewing.

The complete step-by-step procedures for the use of the FDA eServices portal is as follows or this information can be accessed in Annex B of the FDA Advisory No. 2020-781:

a. <u>Application for Initial LTO of a Drugstore, RONPD, Drug Distributor or Drug Trader</u>

i. Access the eServices portal system through http://eservices.fda.gov.ph or through the FDA website (www.fda.gov.ph) by clicking "GO TO SERVICES". Select "Applications".
ii. Select the product category (Drug) and the type of business establishment (Distributor, Trader, Drugstore or RONPD) before proceeding to Initial Application.
iii. Read and understand the Declaration and Undertaking. If there is no objection, tick the check box "I agree to the declaration and undertaking" and click "Start Application".
iv. Fill out the required fields.
v. Tick the appropriate box/es listed for Additional Activities (if any). Click "Next" to proceed to Establishment Information. All fields marked with an asterisk (*) must be duly filled out. Select the applicable range for the Declared Capital. If everything is in order, click "Next" to proceed to the office address.
vi. Fill out the required fields. Click get Global Positioning System (GPS) coordinates to automatically generate GPS Latitude ang Longitude. If everything is in order, click

"Next" to proceed to Warehouse Address. (Note: Drugstores and RONPDs does not have the Warehouse Address Page).

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

viii. Fill out the required fields for the Authorized Officer and click "Next" to proceed to the Qualified Personnel.

ix. Fill out the required fields for the details of the Qualified Personnel. To add more personnel, click Add Personnel. If everything is in order, click "Next" to proceed to Documentary Requirements.

x. To upload documents, click the File Upload icon. Once done, click "Next" to proceed to Self-Assessment Review.

xi. User may review all details if correct.

xii. Tick the Captcha. Read and understand the Confirmation Statement. Tick the box before the sentence and click "Confirm".

b. <u>Application for Variation in the LTO</u>

i. Access the eServices portal system through http://eservices.fda.gov.ph or through the FDA website (www.fda.gov.ph) by clicking "GO TO SERVICES". Select "Applications".

ii. Select the product category (Drug) and the type of business establishment (Distributor, Trader, Drugstore or RONPD) before proceeding to Variation Application.

iii. To start the application, read and understand the Declaration and Undertaking. If there is no objection, tick the check box "I agree to the declaration and undertaking" and click "Start Application"

iv. Fill out the required fields. Security Code is generated by scanning the Quick Response (QR) Code in the document. If everything is on order, tick the Captcha box and click "Next" to proceed to Contact Information.

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

vi. Choose the applicable variation/s by ticking the box/es.

vii. Fill out the required fields. To upload documents, click the File Upload icon. If everything is in order, click "Next" to proceed to Self-Assessment Review.

viii. User may review all details if correct.

ix. Tick Captcha. Read and understand the Confirmation Statement. Tick the box before the sentence and click "Confirm".

c. After the Approval step, a soft copy of the LTO is sent to the e-mail address of the applicant ready to be printed.

1.3.3. What are the requirements for an LTO application through the eServices portal?

The requirements for an LTO application is seen in the FDA Advisory No. 2020-781, FDA Advisory No. 2020-0781-A, and in A.O. No. 2020-0017.

a. <u>Initial LTO Application Requirements</u>

i. Accomplished e-Application Form with Declaration of Undertaking at http://eservices.fda.gov.ph
ii. Proof of Business Name Registration in portable document format (PDF) and maximum file size of 5 megabyte (MB)
   - For Single Proprietorship: the Certificate of Business Registration issued by the Department of Trade and Industry (DTI);
   - For Corporation, Partnership, and other Judicial Person: the Certificate of Registration issued by the Securities and Exchange Commission (SEC) with Article of Incorporation;
   - For Cooperative: the Certificate of Registration issued by the Cooperative Authority with Articles of Cooperation; or
   - For Government-Owned or Controlled Corporation: the law creating the establishment, if with original charter, or its Certificate of Registration issued by the SEC with Articles of Incorporation, if without original charter.
iii. 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., Business Permit).
iv. Proof of Income for Drug Trader (in PDF format, 5 MB maximum file size) such as latest audited Financial Statement with Balance Sheet (in PDF format) shall be submitted. This is to verify the capitalization of the establishment to their corresponding application fee.
v. Standard Operating Procedures (SOP) for the Additional Activities (if applicable).
vi. Risk Management Plan (RMP) shall be presented to the FDA during inspection of establishment. Refer to the FDA Circular No. 2018-013.
vii. Site Master File (SMF) shall be presented to the FDA during inspection of establishment. Refer to Bureau Circular No. 10-2001.

b. <u>Variation LTO Application Requirements</u>

i. Accomplished e-Application Form with Declaration of Undertaking at http://eservices.fda.gov.ph
ii. Documentary requirements depending on the variation or circumstances of the establishment or the product
iii. Payment of fees

Type of Variation	Document Requirement
Transfer of Location of Offices - Physical transfer of the office of the establishment (which may also entail	1. Business permit/registration reflecting new office location; **For Single Proprietorship: Business Permit/Mayor's Permit or Barangay**
changes in the previously approved address)	**Business Permit/Clearance reflecting the new office location;** **2. For SEC-registered establishments:** **a. submit the Amended Articles of Incorporation (if transferred from one city/ municipality/province); *or*** **b. updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality/province)** **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**
Transfer of Location of Drug Retailers - Physical transfer of the drug retailer (which may also entail changes in the previously approved address)	1. Business permit/registration reflecting new location of drug retailers; **For Single Proprietorship: Business Permit/Mayor's Permit or Barangay Business Permit/Clearance reflecting the new location of drug retailer;** **2. For SEC-registered establishments:** **a. submit the Amended Articles of Incorporation (if transferred from one city/ municipality/province); *or*** **b. updated General Information Sheet (GIS) from SEC (if transferred within the same city/municipality/province)** **3. Mayor's Permit or Barangay Business Permit/Clearance reflecting new location of drug retailer**
Change of Distributor Activity - Shall refer to an additional/deletion of/change inactivity that the distributor engage in	Contract Agreement 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)	**Mayor's Permit of Barangay Business Permit/Clearance reflecting new warehouse location**
Additional Drugstore Activities	a. Additional Credentials of Pharmacist, as applicable b. Other documents related or specific to the additional activity, such as but not limited to: • Adult Vaccination - Standard Operating Procedure • Dispense Vaccines and Biologicals - Standard Operating Procedure • Mobile Pharmacy – Standard Operating Procedure
	• Online Ordering and Delivery - Standard Operating Procedure and Website Screenshot • Sterile Compounding and Non-Sterile Complex Compounding - Standard Operating Procedure • Other additional activities that may require appropriate regulation.
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	a. Business name registration reflecting new ownership b. Any proof on the transfer of ownership such as any of the following: • Deed of sale or assignment or transfer of rights/ownership; • Memorandum of Agreement; or • Notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer
Change of Business Name - Change only in the business name of the establishment	**Business name registration reflecting the new business name**
Zonal Change in Address - Change of the name/number of the street/building without physical transfer of the establishment	a. Certificate of Zonal Change **b. Certification from Local Government Unit (City/Municipality) stating no physical transfer of the establishment**

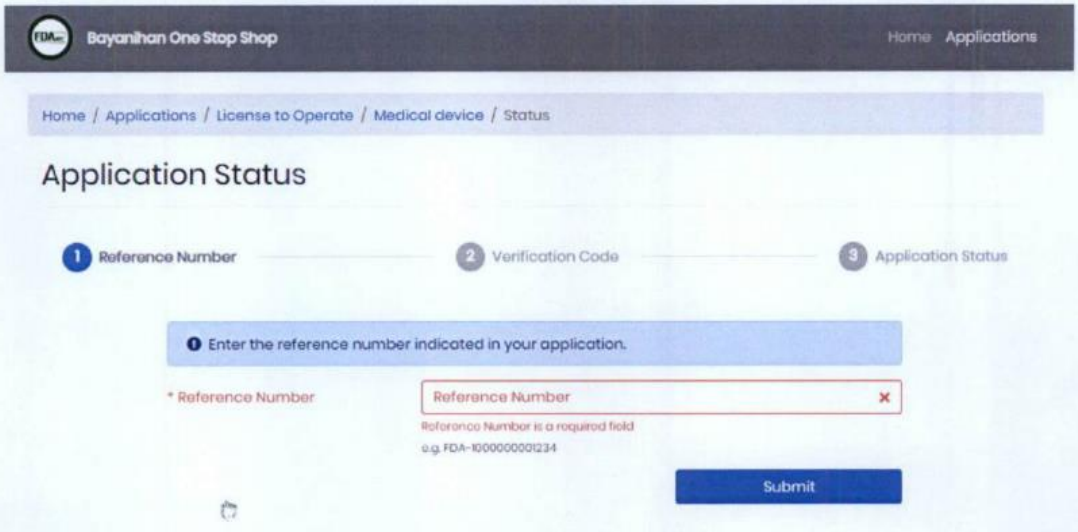
Change of Qualified Person - Change in the identified qualified person (Pharmacist) initially registered with the FDA	a. Name of new qualified person b. Valid Professional Regulation Commission (PRC) ID c. Signed Letter of Resignation, if previously connected with another pharmacy/establishment
Change of Authorized Person - Change in the authorized person initially registered with the FDA	a. Name of new qualified person b. Updated contact details

1.3.4. How to check the status of my application through the eServices portal?

The procedures for checking of an application status in the eServices portal is in Annex B of the FDA Advisory No. 2020-0781-A or as follows:

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 shall be sent to the registered e-mail address in your application.
4. Enter the verification code to view the progress of your application.

1.3.5. Are there any restrictions on the type of application that can be applied through the eServices portal?

For the pilot implementation of the eServices portal, only stakeholders from the NCR are allowed to apply for an LTO Initial or Variation application using the eServices portal. With regard to these applications, only a Drugstore, RONPD, Drug Distributor, or Drug

Trader can file its initial application through the eServices portal. Other establishments, such as Drug Manufacturer, Packer, or Repacker are not yet included. Thereafter, an LTO Variation application to be filed through the eServices portal is only functional if the approved initial LTO was applied using the eServices portal.

1.3.6. What will happen to the applications filed under the e-Portal system?

All data from the e-Portal system will be transferred to the eServices portal system. However, due to the pilot implementation, stakeholders may still use the e-Portal system for other applications, e.g., Initial LTO for Drug Manufacturer, Packer, or Repacker; Renewal LTO; Variation if LTO was approved through the e-Portal, since the eServices portal is currently applicable only for LTO Initial and Variation applications as stated in Section 1.3.5 of this document.

1.3.7. What is the validity of an LTO applied through the eServices portal?

An initial LTO is valid for two (2) years and a renewed LTO is valid for three (3) years.

1.3.8. When can we file a variation application at the eServices portal?

Variation application can be filed if the initial LTO was approved using the eServices portal and the variation must be filed within the validity of the LTO. However, any variation application must not be done if the establishment has a pending application for renewal of its LTO.

1.3.9. What if I have a pending application through the e-Portal system and preferred to apply at the eServices portal, is the payment transferrable?

As stated in the FDA Advisory No. 2020-781, "For those with existing application via e-Portal, you may opt to apply to the eServices portal for a new fee. Previous payment (via e-Portal) will be forfeited." Therefore, it is best for stakeholders to continue their compliance with their pending application via the e-Portal system rather than transferring or shifting to the eServices portal system for efficiency sake.

1.3.10. How is an LTO released through the eServices portal?

The approved LTO is sent to the registered e-mail address of the applicant. The applicant may also access the approved LTO through the eServices portal system in the FDA website (www.fda.gov.ph).

2. DRUG MANUFACTURERS (DM) AND GOOD MANUFACTURING PRACTICE (LOCAL AND FOREIGN)

2.1. General Procedures

2.1.1. Who can apply for a local Good Manufacturing Practice (GMP) Certification, i.e., Certificate of Current GMP?

All local DMs need to apply since GMP Certification is required with the renewal of an LTO of a DM.

2.1.2. When can a DM apply for a local GMP Certification?

Local GMP Certification is applied simultaneously with the renewal of an LTO of a DM.

2.1.3. What are the requirements for a local GMP Certification of a DM?

Letter of Intent and proof of payment are the requirements and must be submitted to the FDAC.

2.1.4. How much is the payment for a local GMP Certification?

The total fee + LRF is ₱ 510.00 per year or a total of ₱ 1,530.00 for the full validity (3 years) of a renewed LTO.

2.1.5. What is the validity of a local GMP Certification?

The validity of a GMP Certification is three (3) years which is the same with the LTO validity.

2.1.6. Who can apply for a Foreign GMP Clearance, e.g., Certificate of GMP Compliance?

All Drug Importers can apply for a Foreign GMP Clearance as per A.O. No. 2013-0022.

2.1.7. How much is the initial fee for a Foreign GMP clearance?

The total initial fee + LRF is ₱ 10,100.00.

2.1.8. How much is the renewal fee for a Foreign GMP clearance?

The total renewal fee + LRF is ₱ 2,020.00

2.1.9. Where can I submit an application for a Foreign GMP clearance?

The application for a Foreign GMP Clearance with the complete requirements must be submitted through the letter lane at the FDAC receiving area.

2.1.10. What are the requirements for a Foreign GMP clearance?

a. Assessment Slip
b. Annex B – importer should tick the pharmaceutical dosage forms that they plan to import and register in the Philippines (Section C)

c. Annex E
d. GMP Evidence
e. Additional Annex C documentary requirements are for Non- Pharmaceutical Inspection Co-operation Scheme (PIC/S) members only. Annex C is a list of documents that the manufacturing site shall provide through the importer and be submitted at the FDA. This list is seen on page 16 of A.O. No. 2013-0022 (link: https://ww2.fda.gov.ph/index.php/issuances-2/pharml-1/pharml-administrative-order/95755-administrative-order-no-2013-0022).

2.1.11. How much is the foreign inspection fee for a Foreign GMP clearance?

The fee for Foreign Inspection varies depending on the geographical site location of the Foreign DM. Schedule of fees can be seen in Annex F of A.O. No. 2013-0022 (link: https://ww2.fda.gov.ph/index.php/issuances-2/pharml-1/pharml-administrative-order/95755-administrative-order-no-2013-0022). The total fee for Foreign Inspection Filing Fee + LRF which amounts to ₱ 3,030.00 needs to be paid separately.

Take note that there is no surcharge for a Foreign GMP clearance.

2.1.12. How will I renew my Foreign GMP clearance if the GMP evidence of the Foreign DM is still undergoing its renewal?

In the absence of the renewed GMP evidence, the client may at least submit a certification or evidence issued by the Drug Regulatory Authority (DRA) that the Foreign DM is undergoing renewal/re-inspection of its manufacturing site with the expected date of its inspection. Furthermore, client should also state the time frame in their commitment letter for the submission of the renewed GMP evidence.

2.2. LTO as Drug Manufacturer

2.2.1. If DM prefers to change labeling materials, do we need to apply for another LTO as a packer or re-packer?

If the product is manufactured by the same DM, there is no need to apply. However, if the product is imported, an application for additional activity as drug packer or repacker is needed.

2.2.2. What is the format to be followed for the Site Master File (SMF)?

The format for the Site Master File is available at the FDA website through this link: https://ww2.fda.gov.ph/attachments/article/224762/pe-008-4-site-master-file.pdf.

2.3. GMP (Local GMP Certificate and Foreign GMP Clearance)

2.3.1. Can we apply for a local GMP given that the LTO applied is on initial status?

Yes, the application for local GMP Certificate must be done after one (1) year since issuance of its initial LTO which has a validity of two (2) years.

2.3.2. Are DMs allowed to encapsulate herbal products for clients given that originally, they do not carry herbal products?

The DMs must apply for a Variation under the Additional Product Line through the FDA e-Portal system or eServices portal system, where applicable.

2.3.3. Where can I find the list of PIC/S member countries?

For the list of PIC/S member countries with their corresponding DRAs, kindly refer to the PIC/S website through this link: https://picscheme.org/en/members.

2.3.4. Is the GMP application done per manufacturing site or per importer?

Currently, the GMP application is per manufacturer, per manufacturing site, and per local importer. This means that if a manufacturer has multiple manufacturing sites, the local importer should apply for all of its sites.

2.3.5. What are the accepted GMP evidence?

a. GMP Certificate issued by member countries of the PIC/S and ASEAN MRA, and from the World Health Organization (WHO) Headquarters in Switzerland
b. Certificate of Pharmaceutical Product (CoPP)
c. Manufacturer's License, including the list of approved product line/s of the manufacturer
d. In other cases, the Establishment Inspection Report (EIReport) of the United States (US) FDA is accepted in cases when the CoPPs are unavailable, and also because the US FDA does not issue GMP Certificates. The EIReport should be a closed-out inspection report, meaning all deficiencies are addressed by the manufacturer and are accepted by the US FDA.

2.3.6. Should the GMP evidence be authenticated?

The GMP evidence should be authenticated by the issuing country, e.g., if Ukraine conducted an inspection in a manufacturer based in India, the authentication should be done in Ukraine and not in India, since Ukraine is the issuing country of the GMP evidence. Also, apostillization of GMP evidence is acceptable provided that the same scheme as the authentication process is applied. List of countries for apostillization can be viewed through this link: https://www.internationalapostille.com/hague-apostille-member-countries/.

2.3.7. Can we submit the original GMP evidence?

Yes, and the original GMP evidence is only accepted if submitted as a hard copy. Once submitted, the GMP evidence will no longer be returned to the client and shall be filed by the FDA.

2.3.8. What are the regulating bodies recognized by the FDA Philippines?

Acceptable GMP evidence may come from any of the following:

a. PIC/S
b. ASEAN MRA, i.e., Malaysia, Indonesia, Singapore, and Thailand which are also PIC/S members
c. WHO Headquarters in Switzerland (not any local WHO Regional Office)

2.3.9. What are the bases of the validity of the clearance?

Bases of the validity will come from any of the following:

a. Inspection date plus three (3) years;
b. Issuance date plus three (3) years (if no inspection date is declared); or
c. Expiration date stated on the certificate.

2.3.10. Where can we ask issues pertaining to foreign GMP inspection, such as schedule of inspection, logistics, etc.?

Concerns on foreign inspection, such as logistics, hotel accommodation of the inspectors, and schedule of foreign inspection must be directly referred to the Regional Field Office (RFO)-NCR.

3. DRUGSTORES (DS) AND HOSPITAL PHARMACIES

3.1. General Procedures

3.1.1. Where can hospital pharmacies apply for an LTO?

Application for hospital pharmacies (which includes Level 1 to Level 3 hospitals, infirmaries, and birthing homes) is now under the Department of Health (DOH)-Health Facilities and Services Regulatory Bureau (HFSRB) following the DOH A.O. No. 2018-0016. However, the FDA through the RFO of the FROO shall still submit the Certificate of Compliance (COC) or Recommendation Letter (RL) to the DOH-HFSRB for the issuance of the LTO.

3.1.2. What are the requirements for additional activities for drugstores?

The requirements are provided in Annex C of A.O. No. 2020-0017. Please take note that an additional requirement for adult vaccination includes the SOP on cold chain management.

3.1.3. Where can we file additional activities like vaccination, medical consultation, laboratory diagnostics ,and such activities?

All additional activities (minor variation-additional activity) can now be filed using the e-Portal system or eServices portal system, where applicable, as per Memorandum dated 05 February 2018 titled, "Additional Activity for Drugstore." Hence, no hard copies will be received by the FDA for the abovementioned activities. Upon renewal of these LTOs, these approved additional activities should still be declared in the e-Portal system or eServices portal system, where applicable, so that it will be incorporated in their renewed LTO.

3.2. LTO as Drugstore and Hospital Pharmacy

3.2.1. We are a hospital pharmacy, can we get the COC of our establishment?

The COC is not released to the client; it is endorsed by the FDA to the DOH-HFSRB.

3.2.2. Do we need to secure an authorization from the FDA if we want to conduct activities in the drugstore, such as blood pressure, and blood glucose monitoring?

In line with the A.O. No. 2020-0017 and as reiterated in the FDA Advisory No. 2017-131, "Public Warning Against Accessing Unauthorized Immunization Programs and Other Unauthorized Community Programs Sponsored by Drugstores," the drugstores should apply for an LTO Variation under Additional Drugstore Activities in order to conduct such activities on a regular basis.

For one-time activity sponsored by drugstores, a Special Permit should still be secured from FDA.

3.2.3. What do we need to submit if we want to apply for a Special Permit?

The applicant needs to submit the following at the FDAC receiving area:

a. Letter of Intent – indicate the dates of the activity, and the names of the administering physician, nurse, and other healthcare professionals involved in the activity
b. Purchase Order/List of Products with complete details (generic name, brand name, dosage strength, dosage form, and quantity)
c. Affidavit stating that the drug products shall be used for the constituents only and shall not be for sale or re-sale
d. Payment of a total fee + LRF of ₱ 510.00
e. Copy of valid LTO (if applicable)

4. DRUG DISTRIBUTORS/WHOLESALERS

4.1. LTO as Drug Distributor/Drug Wholesaler

4.1.1. What are the different classifications of an establishment under the Drug Distributor?

There are three (3) classes under Drug Distributors:

a. Drug Distributor-Exporter
b. Drug Distributor-Importer
c. Drug Distributor-Wholesaler

4.1.2. I want to import drug products but my LTO is for Drug Distributor-Wholesaler only. What should we do?

The Drug Distributor-Wholesaler can apply for additional activity as a Drug Distributor-Importer. Variation requirements are stated in the Annex C of A.O. No. 2020-0017 (link: https://www.fda.gov.ph/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/).

5. CONTRACT RESEARCH ORGANIZATIONS (CRO) OR SPONSORS

5.1. General Procedures

5.1.1. Can a CRO or Sponsor apply through the e-Portal system?

Yes, the CRO or sponsor can apply through the e-Portal.

5.2. LTO as CRO or Sponsor

5.2.1. Are CROs and Sponsors covered by the A.O. No. 2020-0017?

Yes. CROs and Sponsors are covered by the A.O. No. 2020-0017. The previous guidelines or A.O. No. 2014-0034, "Rules and Regulations on the Licensing of Establishments Engaged in the Manufacture, Conduct of Clinical Trial, Distribution, Importation, Exportation, and Retailing of Drug products, and Issuance of other Related Authorizations", has been superseded by this A.O.

5.2.2. What is the difference between a CRO and a Sponsor?

A CRO refers to a person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of the sponsor's trial-related duties and functions while a Sponsor is an individual, company, organization or an entity which takes the responsibility for the initiation, management, and/or financing of a clinical trial.

6. ABBREVIATIONS

AO	Administrative Order
ASEAN	Association of Southeast Asian Nations
CDRR	Center for Drug Regulation and Research
COC	Certificate of Compliance
CoPP/CPP	Certificate of Pharmaceutical Product
CRO	Contract Research Organization
DOH	Department of Health
DM	Drug Manufacturer
DRA	Drug Regulatory Authority
DTI	Department of Trade and Industry
DVD-R	Digital Versatile Disc—Recordable
eLTO	Electronic License to Operate
FDA	Food and Drug Administration
FDAC	Food and Drug Action Center
FROO	Field Regulatory Operations Office
GMP	Good Manufacturing Practice
GPS	Global Positioning System
HFSRB	Health Facilities and Services Regulatory Bureau
LOD	Letter of Disapproval
LRF	Legal Research Fee
LTO	License to Operate
MB	Megabyte
MRA	Mutual Recognition Agreement
NCR	National Capital Region
OSS	One Stop Shop
PDF	Portable document format
PIC/S	Pharmaceutical Inspection Co-operation Scheme
QR	Quick Response
RFO	Regional Field Office
RL	Recommendation Letter
RMP	Risk Management Plan
RONPD	Retail Outlet for Non-Prescription Drugs
SEC	Securities and Exchange Commission
SMF	Site Master File
SOP	Standard Operating Procedures
TAT	Turn-Around Time
US FDA	United States Food and Drug Administration
WHO	World Health Organization

REVISION HISTORY

Date	Version	Changes
13 February 2020	1.0	N/A
19 February 2020	2.0	Changed the size of the FDA logo in the header; Fixed the formatting of page number; Changed the formatting of "Table of Contents" to Times New Roman; Fixed meaning of RFO-NCR by lessening "-"
		1.1.12: Changed from "Add" to "Attach button"; 2.3.5: Added entry on letter c. "including the list of approved product line/s of the Manufacturer."; 2.3.6. Changed the answer to: GMP evidence should be authenticated by the issuing country. For example, if Ukraine conducted inspection to manufacturer based in India, then authentication should be done in Ukraine and not in India, since Ukraine is the issuing country of the GMP evidence. Also, apostillization of GMP evidences are acceptable provided that the same scheme as the authentication process is applied. List of countries for apostillization can be viewed through this link: https://www.internationalapostille.com/hague-apostille-member-countries/
18 August 2020	3.0	Changed on the cover page the version no., date of revision, and document no.; 1. Changed the title from "E-PORTAL & LICENSE TO OPERATE" to "LICENSE TO OPERATE (LTO)" and revised the contents; 1.2. Added a new topic as "LTO APPLICATION VIA E-PORTAL SYSTEM"; 1.3. Added a new topic as "LTO APPLICATION VIA ESERVICES PORTAL SYSTEM"; 2. Changed from "E-SERVICES PORTAL" to "DRUG MANUFACTURERS (DM) AND GOOD MANUFACTURING PRACTICE (LOCAL AND FOREIGN)" and revised the contents; 3. Changed from "DRUG MANUFACTURERS (DM) AND GOOD MANUFACTURING PRACTICE (LOCAL AND FOREIGN)" to "DRUGSTORES (DS) AND HOSPITAL PHARMACIES" and revised the contents; 4. Changed from "DRUGSTORES (DS) AND HOSPITAL PHARMACIES" to "DRUG

		DISTRIBUTORS/WHOLESALERS" and revised the contents; 5. Changed from "DRUG DISTRIBUTORS/WHOLESALERS" to "CONTRACT RESEARCH ORGANIZATIONS (CRO) OR SPONSORS" and revised the contents; 6. Changed from "CONTRACT RESEARCH ORGANIZATIONS (CRO) OR SPONSORS" to "ABBREVIATIONS" and revised the contents; 6. Added these abbreviations and their corresponding meanings: FROO, GPS, LRF, MB, PDF, QR, RL, RONPD, TAT, and US FDA; 6. Revised abbreviation "DOH-HFRSB" to separate entries as "DOH" and "HFRSB"; 6. Revised abbreviation "RFO-NCR" to separate entries as "RFO" and "NCR"; 7. Deleted this section; Updated the LTO guidelines from A.O. No. 2016-0003 to A.O. No. 2020-0017