



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. - **2021-0365**

22 FEB 2021,

TO : **FOOD PRODUCT ESTABLISHMENTS WITHIN NCR AND THE GENERAL PUBLIC**

SUBJECT : **Pilot Implementation of Food and Drug Administration (FDA) eServices Portal System for License to Operate Renewal and Variation Applications of Food Product Establishments in National Capital Region**

The 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 Variation and Renewal of LTO for **Food Product 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 as follows:

FDA eServices Portal for LTO Application of Food Establishments	
Location of Establishment	National Capital Region (NCR)
LTO Establishment Application	Distributor (Wholesaler, Importer, Exporter), and Trader of Processed Food Products, Food Supplements, Bottled Water, and Iodized Salt
Type of LTO Application	Initial ¹ , Renewal, Variation
Fees to be Paid	Based on current issuance on Fees and Charges (Reference: DOH Administrative Order [A.O.] No. 50 s. 2001) For Bottled Water – AO No. 18 s 1993 For Iodized Salt – Republic Act 8172 For surcharge, penalty and Legal Research Fee – FDA Circular No. 2011-004
LTO Validity for Renewal Application	Five (5) years
Start of Pilot Implementation	22 February 2021
End of Pilot Implementation	08 March 2021

Manufacturers, including Repackers/Packers of health products with on-going/in-process LTO applications shall use the old ePortal System.

For issues/concerns/inquiries you may contact the FDA-Food and Drug Action Center (FDA-FDAC) at 8821-1177, 8821-1162, 8821-1220 or e-mail at fdac@info.fda.gov.ph.

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

DTN: 20210105124450

¹ FDA Advisory No. 2020-1696 entitled, "Pilot Implementation of FDA eServices Portal System for Initial License to Operate (LTO) Applications of Food Product Establishments"



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

A. General Guideline

1. All Food Product Establishments, whether public or private entity, engaged in businesses or operations on food 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), before engaging in the importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship activities.
2. All FDA regulated Food Product Establishments applying for LTO shall be required to accomplish online application through the eServices Portal (<http://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**. Hence, the applicant shall be responsible in making sure that the e-mail address is within the scope and access of the Authorized Person/s, Qualified Personnel, and/or owner of the establishment. The FDA shall not be held liable in any way for loss of access to the declared e-mail address.

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. Variation and renewal applications must be applied separately. If a Food Product Establishment is due for renewal, but is expected to apply for changes in information that need to be reflected in the system or registry, then a renewal application must first be submitted.

The clients should be informed that the LTO to be issued upon renewal will reflect the previous information and the updating should be done through filing of a separate

variation. In addition, the clients cannot apply for a renewal of application if not within ninety (90) days before the expiration date of the LTO.

6. For applications filed through the FDA eServices Portal System, there shall be a change in the format of LTO number as such;
 Old: **300000XXXXXX**
 New: **CFRR-(Region)-(Activity)- (Sequence Number)**
7. All technical specifications of food products for importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship are provided and based in Administrative Order No. 2014-0029 (*Rules and Regulations on the Licensing of Food Establishments and Registration of Processed Food, and other Food Products, and for other Purposes*).
8. Post-licensing inspection (PLI) shall be conducted within the validity period of the LTO and prior to renewal of application.
9. The FDA has the authority to enter any FDA-licensed establishments selling FDA-regulated health products during operating hours to conduct routine or spot check inspections.
10. 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 Renewal and Variation Application Requirements

Type of Application	Requirements
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
Company Regulatory Officer and Food Safety Compliance Officer who is preferably a graduate of food-related courses including but not limited to Food Technology, Food and Nutrition, Chemistry, Microbiology, Chemical/Sanitary Engineering,	Certificate of Attendance on seminar on food safety, GMP or HACCP given by the academe, WHO, FAO, NGOs, cooperative, food industry organizations, professional organizations, or the FDA Academy

D. Payment

1. The payment of the total application fee as indicated in the Order of Payment (OP) maybe done through Over-the-counter (OTC) payment at FDAC, On-coll payment at Land Bank of the Philippines (LBP) branches, or online payment thru Bancnet (including LBP bills payment), based on the existing FDA issuances. 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*).

2. Once the payment is made, the payment channel LBP or Bancnet (except for OTC at FDAC) will send a transaction report to FDA which usually takes a minimum of two (2) 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.
3. Incomplete payment (amount paid is less than that of OP amount) will not be posted until the full amount as indicated in OP is settled. As such, applications with incomplete or unsettled payments will not proceed to the next step of the process.
4. Applicants will receive a system-generated message through the registered e-mail address on the status of the payment made once posted or need further settlement. If full payment is made, the e-mail will contain Acknowledgment Receipt, otherwise, a notification on payment deficiency.
5. 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. Pre-assessment

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) 11032 otherwise known as the Ease of Doing Business and Efficient Government Service Delivery Act.
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.

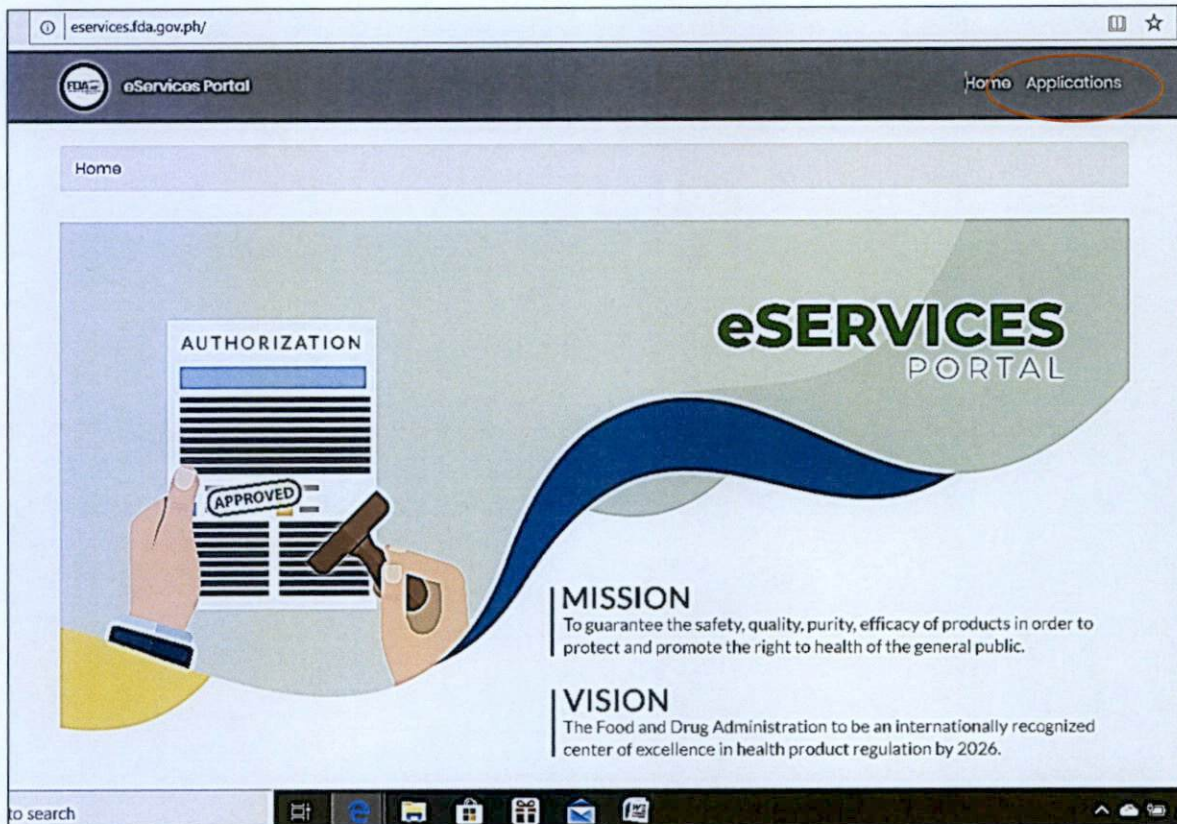
4. Pre-assessment shall be done within the prescribed working days and office hours. Applications filed after the working hours and during weekends/holidays shall be considered filed on the next working day.

ANNEX B

Procedure for the Use of the FDA eServices Portal for License to Operate (LTO) Renewal and Variation Application

A. Application for Renewal of LTO for Food 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 Food and the type of Business Establishment (Distributor). Then click on the “Renewal”.





Home / Applications / License to Operate

License to Operate



Bottled Water

For establishments that handles bottled water products



Drug

For establishments that handles drug products



Food

For establishments that handles food products



Medical Device

For establishments that handle medical device products



Home / Applications / License to Operate / Food

Food



Application Status

Check the current status of your application



Distributor

License authorization for distributor establishments



Trader

License authorization for trader establishments



Home / Applications / License to Operate / Food / Distributor

Food Distributor



Initial

Apply for a new License to Operate



Renewal

Renew existing License to Operate



Variations

Apply for changes in the existing License to Operate

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

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Food / Distributor / Renewal

Food Distributor Renewal

1 Declaration & Undertaking

Declaration & Undertaking

I, duly authorized officer/s or representative/s of the Establishment hereby voluntarily and categorically declare, undertake, and agree that all data and information contained and provided in the attached application, together with all other submissions, including amendments, are true and correct based on my knowledge and are based on existing records, legal documents and available information.

I, likewise declares, undertakes and agrees that:

- I. The said establishment shall be open during its business hours under the supervision of a PRC registered professional (e.g. Pharmacists) or authorized personnel at all times;
- II. The pharmacist/s and the other appropriate allied health professionals, upon and during employment in the establishment, is/are not and will not in any way be connected to, employed by or engaged with any other FDA-regulated establishment;
- III. The approved and valid license to Operate shall be displayed in a conspicuous place in the establishment visible to my customers;
- IV. The establishment will change its business name, and/or brand name in the case of products, in the event that there is a similar, same, or confusingly similar name registered with the Food and Drug Administration, or if the FDA rules later that such name is misleading, offensive, against the law, customs, public morals, public policy or otherwise violative of relevant rules and regulations;
- V. The electronic copy of the files, documents, or information submitted in relation to this application are the exact duplicate or scanned copy of the same and, any discrepancy, prejudicial contents, false claims or misrepresentation on any of the data therein shall be a ground for the disapproval of application, or if discovered post-approval shall be a ground for the appropriate sanctions including the revocation of the license or, and/or the filing of the appropriate legal action against me, the owner, its officers or the establishment whenever possible.

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

Start Application

- 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.

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Food / Distributor / Renewal

Food Distributor Renewal

2 License to Operate


License to Operate

* License Number

* Date of Validity

* Security Code

Please scan the QR Code in the document. For previously issued LTO, enter the sequence number located at the bottom right corner of the document (e.g. FDA-123456).

I'm not a robot 

Back **Next**

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

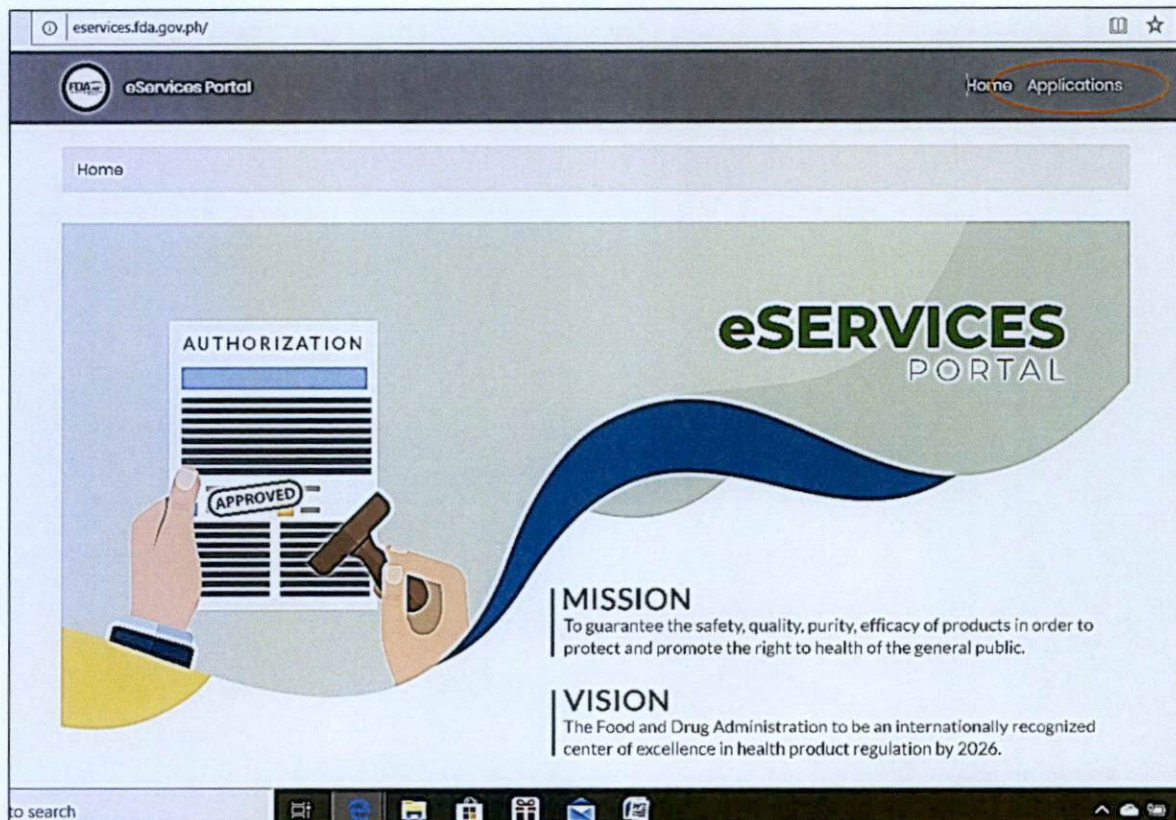
6.User may review if all details are correct in the “Self-Assessment Review”.

B. Application for Renewal of LTO for Food Trader

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

C. Application for Variation in LTO for Food Distributor

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




- Click on the License to Operate for Food and the type of Business Establishment (Distributor). Then click the "Variations".


FDA eServices Portal Home Applications

Home / Applications / License to Operate


License to Operate




Bottled Water
For establishments that handles bottled water products



Drug
For establishments that handles drug products



Food
For establishments that handles food products



Medical Device
For establishments that handle medical device products

FDA eServices Portal Home Applications

Home / Applications / License to Operate / Food

Food



Application Status
Check the current status of your application



Distributor
License authorization for distributor establishments




Trader
License authorization for trader establishments

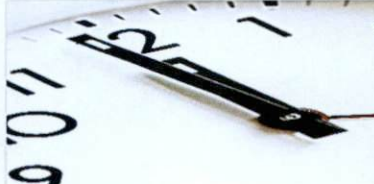
FDA eServices Portal Home Applications

Home / Applications / License to Operate / Food / Distributor


Food Distributor



Initial
Apply for a new License to Operate



Renewal
Renew existing License to Operate



Variations
Apply for changes in the existing license to Operate

- 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**”.

Home / Applications / License to Operate / Food / Distributor / Variations

Food Distributor Variations

1 Declaration & Undertaking

2 License to Operate

3 Contact Information

4 Minor Variations

5 Self-Assessment Review

I, duly authorized officer/s or representative/s of the Establishment hereby voluntarily and categorically declare, undertake, and agree that all data and information contained and provided in the attached application, together with all other submissions, including amendments, are true and correct based on my knowledge and are based on existing records, legal documents and available information.

I, likewise declares, undertakes and agrees that:

- I. The said establishment shall be open during its business hours under the supervision of a PRC registered professional (e.g. Pharmacists) or authorized personnel at all times;
- II. The pharmacist/s and the other appropriate allied health professionals, upon and during employment in the establishment, is/are not and will not in any way be connected to, employed by or engaged with any other FDA-regulated establishment;
- III. The approved and valid License to Operate shall be displayed in a conspicuous place in the establishment visible to my customers;
- IV. The establishment will change its business name, and/or brand name in the case of products, in the event that there is a similar, same, or confusingly similar name registered with the Food and Drug Administration, or if the FDA rules later that such name is misleading, offensive, against the law, customs, public morals, public policy or otherwise violative of relevant rules and regulations;
- V. The electronic copy of the files, documents, or information submitted in relation to this application are the exact duplicate or scanned copy of the same and, any discrepancy, prejudicial contents, false claims or misrepresentation on any of the data therein shall be a ground for the disapproval of application, or if discovered post-approval shall be a ground for the appropriate sanctions including the revocation of the license or, and/or the filing of the appropriate legal action against me.

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

Start Application

- 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.

Home / Applications / License to Operate / Food / Distributor / Variations

Food Distributor Variations

1 Declaration & Undertaking

2 License to Operate

3 Contact Information

4 Minor Variations

5 Self-Assessment Review


License to Operate

* License Number

* Date of Validity

* Security Code

Please scan the QR Code in the document. For previously issued LTO, enter the sequence number located at the bottom right corner of the document (e.g. FDA-123456).

I'm not a robot 

Back **Next**

5. Provide an updated contact information if applicable.
6. 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).
7. User may review if all details are correct in the "Self-Assessment Review".
8. Once reviewed, the User shall confirm the correctness of data given and click on "**Confirm**" to submit the application.

D. Application for Variation in LTO for Food Trader

Proceed as in Steps one (1) to nine (9) of Item C (Application for Variation in LTO for Food Distributor). Make sure to click the appropriate establishment on Step # 2.

E. 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.