

ANNEX

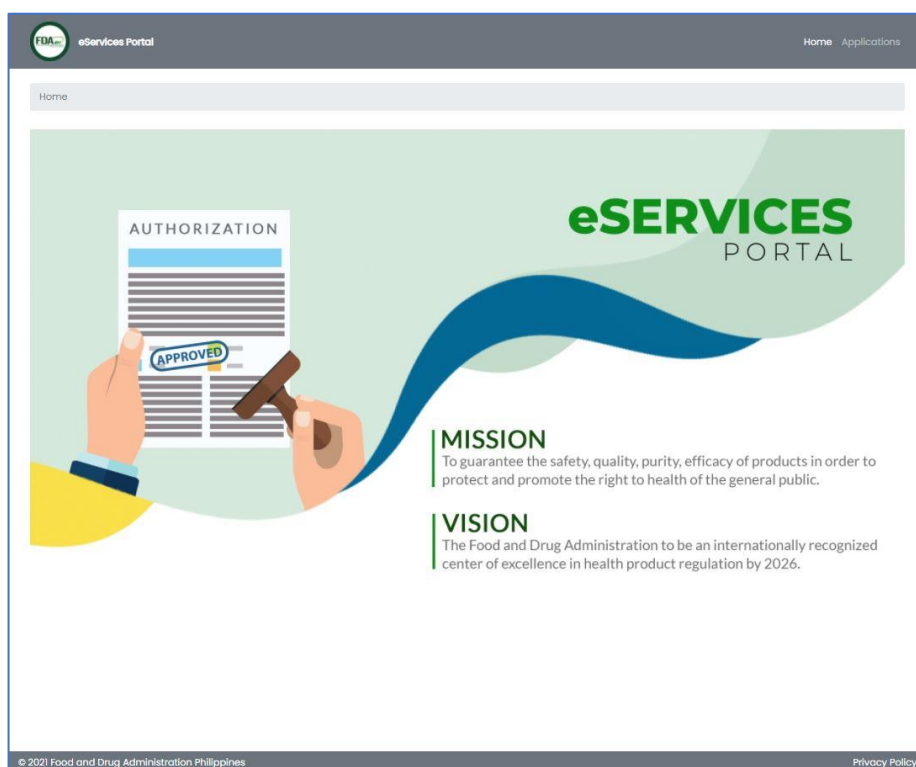
eServices Portal System Frequently Asked Questions

What is the FDA eServices Portal System?

The FDA eServices Portal System is an online application system for obtaining FDA market authorizations, such as License to Operate (LTO) for retailers of drugs and medical devices, distributors and traders of processed foods, drugs, medical and health-related devices. It also caters to the establishments for applications of Compassionate Special Permit (CSP), Certificate of Product Registration for drug products including Automatic Renewal, Principal Certificate of Product Registration (PCPR) Conversion, and Certificate of Listing of Identical Drug Product (CLIDP).

How can I access the FDA eServices Portal System?

You may access the FDA eServices Portal System through <http://eservices.fda.gov.ph> or by the FDA website at www.fda.gov.ph. Just go to the website menu and click on Services found on the upper right corner of the FDA landing page.



Who can access the FDA eServices Portal System?

The FDA eServices Portal System is fully accessible to the general public, specifically to FDA stakeholders who intend to apply for FDA marketing authorizations available through the online system.

Do I need a user account to access the FDA eServices Portal System?

No. Creation of a user account is not necessary to apply through the FDA eServices Portal System.

What is the process for applying through the FDA eServices Portal System?

Go to <http://eservices.fda.gov.ph> and you will be prompted to eServices landing page. Click on the “Applications” found on the upper right corner then proceed with the type of application relative to your business. Fill out the online application form, upload the documentary requirements, and submit your application.

FDA will conduct pre-assessment of the submitted application and documentary requirements. If found acceptable, FDA will send an Order of Payment to client’s registered e-mail address.

What types of application can be submitted through the eServices Portal System?

For the time-being, the eServices Portal System is limited to the below applications:

- LTO application for Initial, Renewal, and Variation applicable to distributors and traders of drugs, foods, medical and health-related products and retailers of medical devices and pharmaceutical products;*
- Application for Automatic Renewal, CLIDP, and PCPR Conversion for drug products, including Biologicals, Vaccines, and Veterinary Products; and*
- CSP which grants individuals or institutions access to investigational drugs which are not yet registered or in the process of registration in the Philippines for the treatment of seriously ill patients.*

How can I check the status of my application?

Go to <http://eservices.fda.gov.ph> and you will be prompted to eServices landing page. Click on the “Applications” found on the upper right corner then proceed with the type of application relative to your business. Click on the “Application Status”. Enter the reference number and click on “submit”. A verification code will be sent to your registered e-mail address. Once received, enter the verification code to view the progress of your application.

If I experience issues while using the system, how do I reach someone to assist me?

For inquiries and/or other concerns, you may reach the FDA-Food and Drug Action Center (FDA-FDAC) at (8) 857- 1900 local 1000, (8) 842-5635, 0961-0574926, 0961-7709691, 0961-6845994 or through fdac@fda.gov.ph.

How can I pay for my application filed through the eServices Portal System?

Print the system-generated Order of Payment (OP), and pay the necessary fees on any of these payment channels;

- Landbank Over-the-Counter payment using the FDA Clearing Account Number based on FDA Memorandum Circular No. 2013-046 through this link, <https://bit.ly/36ChH4X>

Please input the following information on the Oncoll Payment Slip:

- Account Number (per category of the product/center)
- Reference No. 1 - Account Code (reflected in the Order of Payment)
- Reference No. 2 – Company Name
- Merchant Name – Food and Drug Administration

- BANCNET online (<https://bit.ly/3uB8PEL>)
- LBP Online Payment Link.Biz Portal based on FDA Advisory No. 2021-0246 (<https://bit.ly/3DmdPRv>)

How do I receive the result of my application?

You shall receive the FDA marketing authorizations in your registered e-mail address and may also be accessed through the FDA eServices Portal System. The declared e-mail address through the eServices is unalterable. You are responsible in making sure that the dedicated e-mail address is within the scope and access of the Authorized Person/s, Qualified Personnel, and/or owner of your establishment.

You are also responsible in printing the copy of the LTO. The FDA shall no longer issue and send hard copy of the LTO to the establishments.

What are the relevant issuances and guidelines for the FDA eServices System Portal System?

FDA Administrative Issuance	Scope of Implementation	Title	Date Issued/Implemented in the eServices Portal System
FDA Circular No. 2020-030	Nationwide	Guideline for the Use of the FDA eServices Portal System for License to Operate (LTO) Application of Drug Distributors, Drug Traders, Drugstores, Retail Outlet for Non-Prescription Drugs (RONPD), Clinical Research Organizations (CROs), and Sponsors	16 October 2020

FDA Advisory No. 2021-0697	Nationwide	Pilot Implementation of the Food and Drug Administration (FDA) eServices Portal System for Automatic Renewal Applications for Drug Products	06 April 2021
FDA Advisory No. 2021-0842	Nationwide	Implementation of FDA eServices Portal System for Compassionate Special Permit Application for Drug Products	23 April 2021
FDA Circular No. 2021-012	Nationwide	Guidelines for the Use of the FDA eServices Portal System for License to Operate Application of Food Traders, and Food Distributors including Wholesalers, Importers, and Exporters of Processed Food Products, Food Supplements, Bottled Water, and Iodized Salt	11 June 2021
FDA Circular No. 2021-014	Nationwide	Guidelines for the Use of the FDA eServices Portal System for License to Operate Application of Traders and Distributors including Wholesalers, Importers, Exporters of Medical Devices, Equipment or Devices Used for Treating Sharps, Pathological and	24 June 2021

		Infectious Waste and Water Treatment Devices/Systems	
FDA Advisory No. 2021-2634	National Capital Region	Pilot Implementation of the Food and Drug Administration eServices Portal System for License to Operate Application of Retailers of Medical Devices within the National Capital Region	02 November 2021
FDA Advisory No. 2022-0417	Nationwide	Implementation of the Food and Drug Administration eServices Portal System for Principal Certificate of Product Registration (PCPR) Conversion Applications for Drug Products	03 March 2022
FDA Advisory No. 2022-0418	Nationwide	Implementation of the Food and Drug Administration eServices Portal System for Certificate of Listing of Identical Drug Product (CLIDP) Applications	03 March 2022