



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2021-2634**

02 NOV 2021

TO : RETAILERS OF MEDICAL DEVICES WITHIN THE NATIONAL CAPITAL REGION (NCR) AND THE GENERAL PUBLIC

SUBJECT : Pilot Implementation of Food and Drug Administration eServices Portal System for License to Operate Application of Retailers of Medical Devices within the National Capital Region

The Food and Drug Administration (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, the FDA is issuing this Advisory to inform all stakeholders that the application for eLTO for **Retailers of Medical Devices** within the National Capital Region (NCR) is now on its pilot implementation. The eServices Portal is accessible through this link eservices.fda.gov.ph/, with the limited scope of the application for the time being, as follows:

FDA eServices Portal for LTO Application for Retailers of Medical Devices	
Location of Establishment	National Capital Region (Metro Manila)
LTO Establishment Application	<p>Retailers of Medical Devices including;</p> <ol style="list-style-type: none">(1) Retail stores for medical devices;(2) Clinics that sell products classified as medical devices except those that are covered by the DOH One Stop Shop Licensing System;(3) Sellers using online shopping website, social media platforms;(4) TV shopping companies that sell or offer to sell medical device directly to the general public;(5) Optical Shop; and(6) Drug outlets, such as drugstores and retail outlet for non-prescription drugs (RONPD) that also sell or offer to sell medical devices <p>For this pilot run, drug outlets, such as drugstores and RONPDs with multiple outlets/branches within the National Capital Region shall be allowed to apply for a maximum of ten (10) outlets/branches only.</p>



Type of LTO Application	Initial
Fees to be Paid	Based on current issuance on Fees and Charges (Reference: DOH Administrative Order No. 50 s. 2001) Initial: ₱2,000 valid for 2 years Renewal: ₱3,000 valid for 3 years Fee for Variation of LTO: ₱500 + 1% Legal Research Fee
Validity of Initial LTO	Two (2) years
Start of Pilot Implementation	03 November 2021
End of Pilot Implementation	31 January 2022

Radiation Facilities, Installer of water treatment systems providing repair and maintenance services to operators of water refilling stations and other users of water treatment systems, Distributor and Trader of Medical and Health Related Devices shall be governed by separate rules and regulations.

Please follow FDA Circular No. 2021-021 on the Guidelines on the Licensing of Retailers of Medical Devices in the Philippines, the copy of which is posted on the FDA website at www.fda.gov.ph.

The nationwide implementation of the licensing of all the retailers of medical devices shall start on February 01, 2022.


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