

BUREAU OF CUSTOMS MAKABAGONG ADUANA, MATATAG NA EKONOMIYA



PROFESSIONALISM

ACCOUNTAB

MASTER COPY

July 15, 2021

customs memorandum circular no. 157-2021

To:

All Deputy Commissioners

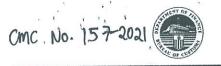
All Service Directors
All District/Port Collectors
All Others Concerned

SUBJECT: ELECTRONIC COPY OF MARKETING AUTHORIZATIONS ISSUED BY THE FOOD AND DRUG ADMINISTRATION (FDA)

With reference to the attached letter dated 30 June 2021 from Director General Rolando Enrique D. Domingo, FDA, please be informed of the following FDA's digitization initiatives to streamline the issuance of market authorizations for health products:

- a. eServices Portal System an online application system for obtaining FDA market authorizations, such as License to Operate (LTO) of establishments of health products. The said system is available to the following applications:
 - application for initial, renewal, and variation LTO of establishments, such as Drugstores, Retail Outlet for Non-Prescription Drugs, and Distributor (Wholesaler/Importer/Exporter) of drugs, foods, medical and health-related products;
 - application for automatic renewal for drug products, including biologicals, vaccines, and veterinary products; and
 - Compassionate Special Permit (CSP) which grants individuals or institutions access to investigational or unregistered drug products.
- b. Modified Electronic Registration System was launched for the application of Certificate of Product Registration (CPR) of processed food product. This covers initial, renewal, reapplication, and amendment registration of prepackaged processed food products such as raw materials or ingredients, low risk, medium risk and high risk.

A Modernized and Credible Customs Administration That is Among the World's Best
South Harbor, Gate 3, Port Area, Manila 1099
8527-4537, 8527-1935 | www.customs.gov.ph | boc.cares@customs.gov.ph



BUREAU OF CUSTOMS





Through the said electronic systems, the LTO, CPR and CSP are issued through the valid and official e-mail addresses of FDA clients and stakeholders. Thus, security paper is no longer necessary, and FDA no longer prints the aforesaid certificates that were approved through above-mentioned platforms. Nonetheless, the FDA ensures that the certificates are secured and protected through the use of watermark and unique quick response (QR) code embedded therein.

In addition, the FDA also established the **FDA Verification Portal**, an online system that provides lists of licensed health establishments and registered health products available in the market that fall within the jurisdiction of the FDA. The said portal can be accessed through <u>verification.fda.gov.ph</u>. However, for verification related to CSP, it can be verified by sending an e-mail to **clinicalresearch@fda.gov.ph**.

Attached are sample copies of LTO and CPR generated through the use of both aforementioned systems.

For information and reference.

For record purposes, please confirm the dissemination of this Circular throughout your offices within fifteen (15) days from receipt.

Commissioner NUL 22 2021







BUREAU OF CUSTOMS MESSAGECENTER F F V E I

JUL 0 8 2021



HING GROUP



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



30 June 2021

REY LEONARDO GUERRERO

Commissioner Bureau of Customs (BOC) Port Area, Manila

Subject:

Electronic Copy of Marketing Authorizations issued by the Food

and Drug Administration



Greetings!

In keeping with the mandate to safe, quality, and efficacious health products twailable for the general public, the Food and Drug Administration (FDA) developed online platforms to streamline the issuance of market authorizations for the said health products. Relative thereto, the FDA would like to respectfully update your good office with the following agency's digitization initiatives for your information and guidance.

 On the first quarter of 2020, the FDA started developing the eServices Portal System, an online application system for obtaining FDA market authorizations, such as License to Operate (LTO) of establishments of health products.

For the time-being, the eServices Portal System is available to the following applications:

- a. Application for Initial, Renewal, and Variation LTO of establishments, such as Drugstores, Retail Outlet for Non-Prescription Drugs, and Distributor (Wholesaler/Importer/Exporter) of drugs, foods, medical and health-related products;
- b. Application for Automatic Renewal for drug products, including Biologicals, Vaccines, and Veterinary Products; and
- c. Compassionate Special Permit (CSP) which grants individuals or institutions access to investigational or unregistered drug products.
- 2. On February 2021, the **Modified Electronic Registration System** was launched for the application of Certificate of Product Registration (CPR) of processed food product. This covers initial, renewal, reapplication, and amendment registration of prepackaged processed food products such as raw materials or ingredients, low risk, medium risk, and high risk.

Through the eServices Portal System and Modified Electronic Registration System, the LTO, CPR, and CSP are issued through the valid and official e-mail addresses of FDA clients and stakeholders. Thus, security paper is no longer necessary, and FDA no longer print the aforesaid certificates that were approved through the above platforms. Nonetheless, the FDA ensures that the certificates are secured and protected through the use of watermark and unique quick response (QR) code embedded therein.

Civic Drive, Filinvest Corporate City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900
Fax +63 2 807 0751
Website: www.fda.gov.ph
Email: info@fda.gov.ph



Management System ISO 9001:2015



cmc No. 157 - 2021 p.3



The FDA also established the FDA Verification Portal, an online system that provides lists of licensed health establishments and registered health products available in the market that fall within the jurisdiction of the FDA. It can be accessed through this link, verification.fda.gov.ph. However, for verification related to CSP, it can be verified by sending an e-mail to clinicalresearch@fda.gov.ph.

Enclosed are sample copies of LTO and CPR generated through the use of both aforementioned systems for your reference.

Rest assured that the FDA fully supports the mandate of the Bureau of Customs as we mutually endeavor to facilitate trade, while securing the borders from all unauthorized entry of prohibited imported goods in the Philippine market.

Should you have clarifications or questions, you may direct them to the FDA Policy and Planning Service at pps@fda.gov.ph.

Thank you very much.

Truly yours,

ROLANDO ENRIQUE D. DOMINGO, MD

Director General

DTN #20210610102822

cc: Food and Drug Action Center