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June 23, 2021

CUSTOMS MEMORANDUM CIRCULAR
NO. 139- 2021

To: All Deputy Commissioners
All Service Directors
All District/Port Collectors
All Others Concerned

SUBJECT: FOOD AND DRUG ADMINISTRATION (FDA) MEMORANDUM CIRCULAR 2021-0001

With reference to the letter dated May 28, 2021 from Jesusa Joyce N. Cirunay, RPh, Director IV, Center for Drug Regulation and Research, the Bureau of Customs (BOC) was furnished with a copy of FDA Memorandum Circular 2021-0001 entitled: "Extension of Validity of License To Operate (LTO) and other Market Authorizations Granted to Veterinary Establishments, Drugs, Biologicals And Products transferred from the Bureau Of Animal Industry (BAI) to the FDA".

Relative thereto, all concerned are informed that imported Veterinary Drugs and Products (Raw materials for drugs/non medicated products, Vaccines and Biologics) shall neither require Import or Phytosanitary (SPS) permit prior to entry into the country. The valid LTO and Certificate of Product Registration (CPR) issued by BAI shall be attached and presented to the BOC for the release of imported items until 31 December 2021. After which LTOs, CPRs, and authorizations issued by BAI will be deemed invalid.

Additionally, Joint Administrative Order (JAO) No. 2020-001 (Re-adoption of the JAO 2013-0026 entitled Rules on the Regulations of Veterinary Drugs and Products, Veterinary Biological Products, and Veterinary Drug Establishments) released on August 28, 2020 was cited which states that after a six month period, the FDA shall assume the function without need for further orders or issuances. The said JAO was mutually agreed/signed upon by both the Department of Agriculture (DA) and Department of Health (DOH) Secretaries.

Lastly, the regulation of veterinary drugs and products is under the mandate of FDA vested by the Republic Act (RA) No. 3720 or the Food, Drug and Cosmetic Act as amended by RA 9711 or the Food and Drug Administration Act.

For information and guidance.

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

REY LEONARDO B. GUERRERO
Commissioner

JUN 29 2021

CCC-21-070454

South Harbor, Gate 3, Port Area, Manila 1099
8527-4537, 8527-1935 | www.customs.gov.ph | boc.cares@customs.gov.ph

CMC NO. 139- 2021

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BUREAU OF CUSTOMS
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Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA
Food and Drug Administration
PHILIPPINES

CENTER FOR DRUG REGULATION AND RESEARCH

BUREAU OF CUSTOMS
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BY: TIME:

CCC-21-070454

28 May 2021

HON. REY LEONARDO B. GUERRERO
Commissioner
Bureau of Customs

Dear **Hon. Guerrero,**

This is to furnish you a copy of the FDA Memorandum Circular 2021-0001 Subject: Extension of Validity of License to Operate (LTO) and other Marketing Authorizations Granted to Veterinary Establishments, Drugs, Biologicals and Products transferred from the Bureau of Animal Industry (BAI) to the Food and Drug Administration (FDA).

Please be informed that imported Veterinary Drugs and Products (*Raw materials for drugs/non medicated products, Vaccines and Biologics*) shall neither require Import or Phytosanitary (SPS) permit prior to entry into the country. The valid LTO and CPRs issued by BAI with the said Circular shall be attached and presented to the Bureau of Customs (BOC) for the release of imported items **until 31 December 2021.** After which, LTOs, CPRs and authorizations issued by BAI are invalid.

Pursuant to Joint Administrative Order (JAO) No. 2020-001 (Re-adoption of the JAO 2013-0026 entitled Rules on the Regulation of Veterinary Drugs and Products, Veterinary Biological Products, and Veterinary Drug Establishments released on 28 August 2021, after a six month transition period, the FDA shall assume the function without the need for further orders or issuance. The said JAO are mutually agreed/signed by both the Department of Agriculture (DA) and Department of Health (DOH) Secretaries.

The regulation of veterinary drugs and products is under the mandate of FDA vested by Republic Act (RA) No. 3720 (*Food, Drug, and Cosmetic Act*) as amended by RA 9711 (*Food and Drug Administration Act*). Attached are other pertinent documents for your perusal.

OFFICE OF THE DIRECTOR
RELEASED
By:
Date: 6/7/21
Time: 1:08 pm

Should you have any concerns, please do not hesitate to contact us at cdrr.vetunit@fda.gov.ph or 8857-1900 loc. 1281/1282.

BUREAU OF CUSTOMS
RECEIVED
07 JUN 2021
2:00 PM

Thank you very much.

Sincerely yours,

JESUSA JOYCE N. CIRUNAY, RPh
Director IV
Center for Drug Regulation and Research

20210528100425

10:00 6/4

CMC No. 139- 2021

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Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

31 MAR 2021

FDA MEMORANDUM CIRCULAR
No. 2021- 001

TO : **ALL ESTABLISHMENTS OF VETERINARY DRUGS, VACCINES AND BIOLOGICAL PRODUCTS**

SUBJECT : **EXTENSION OF VALIDITY OF LICENSE TO OPERATE (LTO) AND OTHER MARKET AUTHORIZATIONS GRANTED TO VETERINARY ESTABLISHMENTS, DRUGS, BIOLOGICALS AND PRODUCTS TRANSFERRED FROM THE BUREAU OF ANIMAL INDUSTRY (BAI) TO THE FOOD AND DRUG ADMINISTRATION (FDA)**

In the interest of service and to ensure the continuous delivery of services during the transfer of regulation of veterinary establishments, drugs, biological products, from the BAI to FDA, this Office hereby issues the following transitory guidelines:

1. All valid Market Authorization (MAs) such as License to Operate (LTO), Certificate of Product Registration (CPR) and other MAs duly issued by BAI will be honored by the FDA.
2. All LTOs, CPRs and other MAs expiring from March to July 2021 will be given six (6) months validity extension upon filling of application to FDA.
3. This automatic validity extension of 6 months shall not preclude the FDA from revoking the relevant marketing authorization in case of violation.
4. For transactions with the Bureau of Customs (BOC) and other offices, this issuance may be presented together with valid LTOs and CPRs for importation purposes. No other authorization (e.g. import permit) shall be required for incoming shipments.
5. Initial and Renewal applications for LTOs and CPRs shall follow existing rules and regulations, systems, process, procedures and requirements of FDA for licensing of establishments, drug product registration and issuances of other MAs.

This Memorandum Circular shall take effect immediately upon approval and publication posting at the FDA website. Likewise, it shall be published in a national newspaper, endorsed and filed at the Office of the National Administrative Register (UP-ONAR) of the UP Law Center.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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CMC NO. 139- 2021

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DEPARTMENT OF AGRICULTURE
DEPARTMENT OF HEALTH

JOINT ADMINISTRATIVE ORDER
No. 2020 - 0001

SUBJECT: **Re-Adoption of the Joint Administrative Order No. 2013-0026**

Whereas, the Food and Drug Administration (FDA) invoking Section 30, paragraph 5 of Republic Act (RA) No. 3720 as amended by RA No. 9711, called upon the assistance of the Department of Agriculture (DA) through the Bureau of Animal Industry (BAI) in the Implementation of the said Acts;

Whereas, in order to effect the same, Joint DOH and DA Administrative Order No. 2013-0026 was issued with the objective, among others, "to facilitate the licensing and registration and for the effective regulation of the manufacture, distribution, and monitoring of veterinary drugs and products, veterinary biological products, and establishment selling the same to avoid overlapping of functions of the FDA and BAI";

Whereas, with the expiration of the said Joint Administrative Order, the BAI loses its authority to regulate veterinary drugs and products and veterinary biological products affecting our stakeholders particularly manufacturers and importers;

NOW, THEREFORE, BE IT RESOLVED AS IT IS HEREBY RESOLVED that in order to ensure unhampered delivery of services to our stakeholders, the JOINT DOH and DA ADMINISTRATIVE ORDER NO. 2013-0026 is hereby re-adopted for a period of six (6) months from the date of issuance of this Order. The 6 months shall serve as a transition period for the transfer of regulation of veterinary drugs and products, veterinary biological products, and establishments to the FDA. Upon lapse of the period, the FDA shall immediately assume such functions without need of further orders or issuances.

This Order shall be effective immediately.

Done this 27th day of August 2020.

CERTIFIED TRUE COPY
AUG 28 2020
CORAZON S. DELA CRUZ
KMITS - RECORDS SECTION
Department of Health

Department of Agriculture

WILLIAM D. DAR, PhD
Secretary of Agriculture

Department of Health

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health