Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-1175

03 JUN 2021

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

SUBJECT : **CLARIFICATION ON THE FDA MEMORANDUM CIRCULAR NO. 2021-001 - EXTENSION OF VALIDITY OF THE LICENSE TO OPERATE (LTO) AND OTHER MARKETING AUTHORIZATIONS (MAs) GRANTED TO VETERINARY ESTABLISHMENTS, DRUGS, BIOLOGICALS AND PRODUCTS TRANSFERRED FROM THE BUREAU OF ANIMAL INDUSTRY (BAI) TO THE FOOD AND DRUG ADMINISTRATION (FDA)**

Due to the increasing number of inquiries regarding the extension of the validity of LTO and other MAs transferred from the BAI to the FDA, this Office hereby clarifies the transition guidelines set in the FDA Memorandum Circular No. 2021-001 so as not to impede the supply of veterinary drug products in the market:

1. **All LTOs, Certificates of Product Registration (CPRs) and other MAs expiring from March to July 2021 will be given six (6) months validity extension upon filing of application to FDA.**

   All holders of existing LTO duly issued by the BAI which will expire from March to July 2021 are directed to submit their initial applications to the FDA, regardless of application type, together with the documents and fees required as per 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*) three (3) months before expiration of the FDA Memorandum Circular No. 2021-001.

   For Renewal of CPRs and other Authorizations, the applicant must file the application to the FDA within six (6) months, from March to December 2021, subject to submission of necessary requirements following the existing procedures and payment of appropriate fees. For this purpose, the original BAI-issued CPR and dossier must be surrendered, otherwise, the renewal application shall be denied outright.

The FDA will process and evaluate all initial applications together with the required documents for registration of veterinary drugs and licensed establishments which were submitted to the BAI after 28 February 2021.

2. **For transactions to with the Bureau of Customs (BOC) and other Offices, this issuance may be presented together with the valid LTOs and CPRs for importation purposes.**

Imported raw materials used or intended for use as component in the manufacture of veterinary drugs shall neither require registration nor Import/ Phytosanitary (SPS) permit prior to entry into the country. However, only valid LTO as Drug Manufacturer and CPRs issued by the BAI together with the FDA Memorandum Circular No. 2021-001 shall be attached and presented to the BOC for the release of imported materials only until 31 December 2021.

For guidance of all concerned. Dissemination of this advisory to all concerned is hereby requested.

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