Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. _____

SUBJECT : Implementing Guidelines of Joint Department of Health (DOH) and Department of Agriculture (DA) Administrative Order No. 2020-001: Re-Adoption of Joint DOH and DA Administrative Order No. 2013-0026

I. INTRODUCTION

Cognizant of the authority of the Food and Drug Administration (FDA) to call upon the assistance of any department, office or agency under Section 30, paragraph 5 of Republic Act (RA) No. 3720 as amended by RA No. 9711, a partnership was forged between FDA and the Department of Agriculture-Bureau of Animal Industry (DA-BAI) in the regulation of selected veterinary establishments, drugs, and products by virtue of the Joint Department of Agriculture (DA) and Department of Health (DOH) Administrative Order (JAO) No. 2013-0026: Rules on the Regulation of Veterinary Drugs and Products, Veterinary Biological Products, and Veterinary Drug Establishments. The JAO No. 2013-0026 was effective for five years, until its expiration last September 2018. The delegation of regulation of veterinary establishments and products under the jurisdiction of the FDA began way back in late 1990 through a JAO between the DOH and DA Secretaries.

In the interest of continuous public service and to avoid confusion among the stakeholders, The DOH Memorandum Circular No. 2020-0042 of the JAO No. 2020-0001: Re-Adoption of Joint DOH and DA Administrative Order No. 2013-0026 was both signed by the DA-BAI and DOH establishing the final date of effectivity on 28 February 2021. During the transition period, the FDA and the BAI agreed to develop guidelines for the return of applicable veterinary establishments, drugs, and products from back to FDA, and conduct information dissemination activities for the benefit of the stakeholders and consumers.

II. SCOPE

This Circular covers all veterinary establishments, drugs, and products that shall be returned from DA-BAI back to the FDA.

III. OBJECTIVES

This Circular aims to:

A. Establish the transitory guidelines for the application of market authorizations of veterinary establishments, drugs, and products from BAI to FDA; and
B. Ensure uninterrupted regulatory management services of veterinary establishments, drugs, and products thru information dissemination and dialogues.
C. Ensure continuous supply of veterinary products in the market that are essential and critical to animal health and production of livestock, poultry and other animals.

IV. GENERAL GUIDELINES

A. The provisions of JAO No. 2013-0026 shall be automatically extended with a transition period until 28 February 2021.

B. The FDA shall acknowledge the validity of License to Operate (LTO) and market authorizations issued by BAI. This however, shall not preclude the FDA from investigating and issuing regulatory actions and penalties if the establishment or product is found does not meet the standards or regulations on quality, safety, and efficacy.

V. SPECIFIC GUIDELINES

A. LTO and Market Authorizations

1. All applications (i.e. initial and renewal) for market authorizations of veterinary products and establishments covered in JAO No. 2013-0026 shall still be applied to the respective Office as delineated in the JAO No. 2013-0026.
    a. Market authorizations originally registered under BAI with validity until 28 February 2021 shall still apply for renewal application to their Office. Market authorizations that have failed to apply for renewal shall be considered by this Office as expired and will not be eligible for automatic extension.
    b. Market authorizations originally registered under BAI that will be transferred under the jurisdiction of FDA and will be expiring on 1 March 2021 onwards shall be automatically extended until 30 June 2021.
    c. Market authorizations that will be transferred under the jurisdiction of FDA and that will be expiring on 1 March 2021 until 30 June 2021 must apply for a renewal application to the FDA within the given period until 30 June 2021.
    d. The automatic validity extension shall not preclude the FDA from revoking the relevant market authorization if the evaluation of the application or investigation as warrants.
    e. For transactions with the Bureau of Customs (BOC), and other offices, this Circular maybe presented as proof of automatic extension for market authorizations covered under Section IV (A) (1) (b) of this Circular. No stamp extension shall be issued by this Office.

2. The validity and fees of market authorizations issued under this transition period shall still follow the existing rules and regulations from the issuing Office.
3. The authentications of market authorizations shall be under the jurisdiction of the Office that originally issued the authorization.
4. A new guideline shall be released regarding the re-issuance of LTO and market authorizations by FDA.

B. Post-Market Surveillance and Inspection of Establishments

The post-market surveillance and inspection of establishments of veterinary drugs, products and establishment shall follow the concerned Office in jurisdiction as delineated in JAO No. 2013-0026 until 28 February 2021.

C. Regulatory Information Dissemination

The FDA shall conduct information dissemination, including conduct of seminars for stakeholders (e.g. pharmacists and regulatory affairs officers in veterinary industry). The FDA shall also stakeholder's meetings and dialogues with the stakeholders during the transition. All stakeholders and related organizations are advised to send their contact information (e-mail address and phone number) at cdrr.od@fda.gov.ph to be listed for invitations for any seminars, updates, meetings, and other information dissemination by this Office.

D. Policy Development

The FDA Technical Working Group (TWG) shall develop definite guidelines, rules and regulations, and systems for the transfer of jurisdiction of regulations of applicable veterinary establishments, drugs, and products from BAI to FDA.

A risk-based approach shall be adopted in the establishment of policies and requirements to ensure that the national and international standards shall be met without increasing burden to the stakeholders.

E. Continuing Collaboration of FDA and BAI

The FDA and BAI shall continue to collaborate to ensure one government approach to the protection of animals and humans.

The FDA may still call upon the assistance of BAI for technical assistance, conduct of investigation and hearings, and other functions as allowed by RA No. 9711.

VI. REPEALING CLAUSE

Provisions in previous circulars and memoranda that are inconsistent with this Circular are hereby withdrawn, repealed and/or revoked accordingly.

If any provision in this Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this Circular shall not be affected.

VII. EFFECTIVITY

This Circular shall take effect immediately.

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Director General