Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA
Food and Drug Administration
PHILIPPINES

09 AUG 2021

FDA CIRCULAR
No. 2021-002-A

SUBJECT: **Addendum to FDA Circular No. 2021-002 Re: Full Implementation of Administrative Order No. 2018-0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements"**

I. BACKGROUND/RATIONALE

On 4 January 2021, FDA Circular (FC) No. 2021-002 was issued for the full implementation of Administrative Order (AO) No. 2018-0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements". FC No. 2021-002 stipulates guidelines for the filing of applications for and issuance of Certificate of Medical Device Notification (CMDN) and Certificate of Medical Device Registration (CMDR) for Class B, C and D medical devices which are considered non-registrable per FC No. 2020-001 re: Initial Implementation of Administrative Order No. 2018-0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements" as amended by FC No. 2020-001-A re: Amendment to Annex A of FC No. 2020-001.

FC No. 2021-002 does not specify provisions for the period wherein the companies may be allowed to manufacture, import, export, distribute, transfer, sell and/or offer for sale their medical device products covered under the said issuance without the CMDN. To provide guidelines on the transition period for the full implementation of AO 2018-002 and to ensure the continuous supply of the above medical devices in the local market, this Circular is hereby issued for implementation and compliance of all concerned.

II. OBJECTIVE

This Circular aims to provide guidelines for the transition period wherein the manufacturers, traders, and distributors/importers/exporters of medical devices covered by FC No. 2021-002 may apply for CMDN and may be allowed to manufacture, import, export, distribute, transfer, sell or offer for sale their medical device products pending the issuance of the CMDN.

III. SCOPE

These guidelines shall cover Class B, C and D medical devices that are not included in the list of registrable medical devices based on FDA Circular No. 2020-001-A.

IV. DEFINITION OF TERMS

The terms used in this Circular shall have the meaning as defined in R.A. 9711 and its Implementing Rules and Regulations, and related laws and regulations. However, for clarity and for purposes of these guidelines, the following terms are defined as follows:

1. Class B, C and D medical devices shall refer to medical devices that are not included in the list of registrable medical device products based on FDA Circular No. 2020-001-A.

2. Marketing authorization holder (MAH) shall refer to the medical device company, corporate or legal entity in whose name the Certificate of Product Registration (CPR), Certificate of Medical Device Registration (CMDR) or Certificate of Medical Device Notification (CMDN) for a medical device has been granted. The MAH is responsible for all aspects of the product, including quality and compliance with the conditions of the issued CPR/CMDR/CMDN. The MAH may be a manufacturer, trader, or distributor (exporter, importer or wholesaler) of medical devices.

V. GUIDELINES

1. All Class B, C and D medical devices that are already in the Philippine market prior to the effectivity of this issuance may continue to be manufactured, imported, exported, distributed, transferred, sold or offered for sale without CMDN until 31 March 2022. The License to Operate of the medical device establishment shall be provided at the point of entry and/or part of bidding requirements. However, starting 1 April 2022, only Class B, C and D medical devices with issued CMDN or with pending application for CMDN shall be allowed to be exported from the Philippines or manufactured, imported, distributed, transferred, sold or offered for sale in the country.

2. In line with the full implementation AO 2018-0002, application for CMDN for Class B, C and D medical devices shall be accepted until 31 March 2023 only. Receiving of application for CMDN for Class B, C and D medical devices shall cease starting 1 April 2023.

3. All manufacturers, traders, exporters, importers, and distributors of Class B, C and D medical devices shall secure a CMDR starting 1 April 2023.

4. For Class B, C and D medical devices with CMDN validity after 1 April 2023, the CMDN shall remain valid until its expiry. However, three (3) months prior to the expiration of the CMDN, the company shall apply for a CMDR for the product. While the CMDR is on process, the MAH may continue to manufacture, import, export, distribute and/or sell the product. The issued CMDN and proof application for CMDR shall be provided at the point of entry and/or part of bidding requirements.

5. Marketing authorization holder of Class B, C and D medical devices that are non-registrable but were issued with a registration certificate prior to the implementation of FDA Circular No. 2020-001 as amended by FDA Circular No. 2020-001-A shall continue to apply for renewal of the registration certificate. Initial application for

similar products shall comply with the CMDN requirements in accordance with the provisions of FDA Circular No. 2021-002 and this Circular.

6. All Certificate of Exemption (COE) for Class B, C and D medical devices that were issued from 25 February 2014 shall remain valid until 31 March 2022. This is to provide ample time for the industry to apply for CMDN for the said medical devices.

VI. PENALTY CLAUSE

Any establishment found to be in violation of the provisions of this issuance shall be subjected to sanctions and penalties as prescribed under RA 9711 otherwise known as the "Food and Drug Administration (FDA) Act of 2009", and its Implementing Rules and Regulations.

VII. SEPARABILITY CLAUSE

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

VIII. EFFECTIVITY

This Circular shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing three (3) certified copies to the University of the Philippines Law Center.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN: 20210222112655