Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. _____

TO: **ALL MEDICAL DEVICE MANUFACTURERS, TRADERS, AND DISTRIBUTORS AND OTHER CONCERNED PARTIES**

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 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 for Class B, C and D 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, 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, these guidelines is hereby issued for implementation and compliance of all concerned.

II. OBJECTIVES

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, 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 in FDA Circular No. 2020-001 as amended by FDA Circular No. 2020-001-A.

IV. GUIDELINES

1. All manufacturers, traders, and distributors/importers/exporters of medical devices issued with License to Operate (LTO) prior to effectivity of this issuance may continue to manufacture, import, export, distribute, sell or offer for sale their medical devices without CMDN until 31 March 2022. The LTO of the establishment shall be provided at the point of entry and/or part of bidding requirements. However, on 1 April 2022 only those with CMDN or with pending applications for CMDN shall be allowed to manufacture, import, distribute and/or sell their medical device products in the country.

2. All FDA licensed manufacturers, traders, and distributors/importers/exporters of Class B, C and D medical devices shall be given until 31 March 2023 to apply for CMDN for the said medical devices.

3. Receiving of application for CMDN for Class B, C and D medical devices shall cease starting 1 April 2023.

4. All manufacturers, traders, and distributors/importers/exporters are required to apply for CMDR for their Class B, C and D medical devices starting 1 April 2023. This provision does not apply to medical devices with valid CMDN that are within the scope of this issuance.

5. 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.

V. 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.

VI. 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.

VII. 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.

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Director General

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