Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

29 MAR 2023

FDA CIRCULAR
No. 2021-002-C

SUBJECT : **Guidelines on the Regulatory Flexibility for 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 entitled "Amendment to Annex A of FDA Circular No. 2020-001 re: Initial Implementation of Administrative Order NO. 2018-0002 "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements""**

I. RATIONALE

On 9 August 2021, FDA Circular (FC) No. 2021-002-A[1] was issued providing that 1) application for Certificate of Medical Device Notification (CMDN) for Class B, C and D medical devices that are not included in the list of registrable medical devices based on FC No. 2020-001-A shall be accepted until 31 March 2023; 2) receiving of application for CMDN for these medical devices shall cease starting 1 April 2023; and 3) all manufacturers, traders, exporters, importers, and distributors of the said medical devices shall secure a Certificate of Medical Device Registration (CMDR) starting 1 April 2023.

On 21 April 2022, FC No. 2021-002-B[2] was issued to extend the date wherein all Class B, C and D medical devices that are not included in the list of registrable medical devices based on FC No. 2020-001-A and that are already in the Philippine market prior to the effectivity of FC No. 2021-002-A (1 June 2022) may continue to be manufactured, imported, exported, distributed, transferred, sold or offered for sale without CMDN until 31 March 2023, after which the CMDN or at least with pending CMDN application requirement shall be enforced.

With the strict implementation of the above-mentioned requirements, there is a risk that supply of medical devices in the market will be negatively affected which may cause disruption in the health care service delivery in the country. In consideration of the challenges brought about by the full implementation of Administrative Order No. 2018-0002, the FDA recognizes that there is a need to provide medical device companies more time to prepare the technical documentary requirements based on the ASEAN common submission dossier template (CSDT) in applying for CMDR.

[1] 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"

[2] Amendment to FDA Circular No. 2021-002-A entitled "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""

II. OBJECTIVE

This Circular aims to provide guidelines on the regulatory flexibility for medical devices specified in Section III of this Circular.

III. SCOPE

This issuance shall apply to Class B, C and D medical devices that are not included in the list of registrable medical devices based on FC No. 2020-001-A.

IV. DEFINITION OF TERMS

As used in this Circular, the following terms shall be defined as follows:

A. **Regulatory flexibility** refers to temporary lifting of the authorization (CMDN) requirement within the specified period for Class B, C and D medical devices covered by this issuance.

B. **Marketing authorization holder (MAH)** refers to the medical device company, corporate or legal entity in whose name the CMDR or CMDN has been granted. The MAH may be a manufacturer, trader, or distributor (exporter, importer or wholesaler) of medical devices.

V. GUIDELINES

A. All Class B, C and D medical devices that are not included in the list of registrable medical devices based on FC No. 2021-001-A may continue to be manufactured, imported, exported, distributed, transferred, sold or offered for sale without CMDN until **31 March 2024**. The License to Operate of the medical device establishment shall be provided at the point of entry (presented to the Bureau of Customs officer) and/or part of bidding requirements.

B. Application for CMDN for Class B, C and D medical devices covered under this Circular shall be accepted until **31 March 2024**.

C. Receiving of application for CMDN for these medical devices shall cease starting **1 April 2024**. Companies may opt to apply for CMDR instead of CMDN for their products prior to this date.

D. All manufacturers, traders, exporters, importers and distributors shall apply for CMDR for Class B, C and D medical devices covered under this Circular starting **1 April 2024**.

E. Beginning **April 1, 2024**, the manufacture, importation, exportation, distribution, transfer, selling or offering for sale of all Class B, C and D medical devices covered under this Circular without CMDN/CDMR or with pending application for CMDN/CMDR shall be prohibited.

F. MAH with expiring CMDN for Class B, C and D medical devices shall apply for CMDR at least six (6) months prior to its expiration. 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 of application for CMDR shall be provided at the point of entry and/or part of bidding requirements.

VI. REPEALING CLAUSE

FC No. 2021-002-B and Section V (paragraphs 1, 2, 3 and 4) of FC No. 2021-002-A are hereby modified, repealed, and/or revoked accordingly.

VII. SEPARABILITY CLAUSE

All other provisions of FC NO. 2021-002-A not affected by this Circular shall remain in effect. In the event that any provision or part of this Circular is declared invalid, the other provisions hereof shall not be affected.

VIII. EFFECTIVITY

This Circular shall take effect immediately after its publication in the Official Gazette or in a newspaper of general circulation and filing three (3) certified true copies with the University of the Philippines – Office of the National Administrative Register.

DR. SAMUEL A. ZACATE
Director General

DTN: 20230216232907