FDA CIRCULAR
No. _____

SUBJECT : **Extension of 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

FDA Circular (FC) No. 2021-002-A was issued on 9 August 2021 to provide guidelines on the application for a Certificate of Medical Device Notification (CMDN) and a Certificate of Medical Device Registration (CMDR) 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[1]. This FC was issued as part of the full implementation of Administrative Order (AO) No. 2018-0002.

To prevent having a negative impact on the supply of medical devices on the market due to the implementation of the provisions of FC No. 2021-002-A, FC No. 2021-002-B[2] was issued in 21 April 2022, providing regulatory flexibility to 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 market prior to the effectivity of FC No. 2021-002-A.

Regulatory flexibility was extended further through the issuance of FC No. 2021-002-C[3] dated 29 March 2023. This issuance extended the dates for the application of a CMDN and CMDR for all Class B, C and D medical device that are not included in the list of registrable medical devices based on FC No. 2020-001-A. Hence, the medical device industries were given ample time to prepare the necessary technical documentary requirements to be used for applying for a CMDR to the aforementioned medical device products.

As the provided extensions stated in FC No. 2021-002-C are coming to an end, the FDA recognizes the importance of assuring that the availability of medical devices will not be affected. The FDA understands the need to extend the regulatory flexibility in order to assist

[1]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"

[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""

[3]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""

the medical device industry in complying with the regulatory requirements based on the ASEAN Common Submission Dossier Template (CSDT) in applying for CMDR.

II. OBJECTIVE

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

III. SCOPE

This issuance shall apply to 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.

IV. DEFINITION OF TERMS

For the purpose of implementing this Circular, the terms used herein shall have the meaning as defined in FC no. 2021-002-C, RA No. 9711, its IRR, and related laws and regulations. However, the term below is hereby defined for greater clarity:

Pending Application refers to an application that has passed the pre-assessment and are being evaluated for compliance.

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 **30 September 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 requirement.

B. Application for CMDN for Class B, C and D medical devices covered under this Circular shall be accepted until **30 September 2024**.

C. Receiving of application for CMDN for these medical devices shall cease starting **1 October 2024**. Establishments 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 October 2024**.

E. Beginning **1 October 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 / CMDR or without pending application for CMDN / CMDR shall be prohibited.

F. Market Authorization Holder (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. SEPARABILITY CLAUSE

If any part, term or provision of this Circular shall be declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions shall not be affected and this Circular shall be construed as if it did not contain the particular invalid or unenforceable or unconstitutional part, term or provision.

VII. REPEALING CLAUSE

Section V (Items A, B, C D, E and F) of FC No. 2021-002-C are hereby modified, repealed, and/or revoked accordingly.

VIII. EFFECTIVITY

This Circular shall take effect fifteen (15) days after its publication in the Official Gazette or in any newspaper of general circulation and upon filing with the University of the Philippines Law Center Office of the National Administrative Register.

DR. SAMUEL A. ZACATE
Director General

DTN: 20231128161822