FDA CIRCULAR
No. _____

SUBJECT : **Guidelines on the Use of the Food and Drug Administration eServices Portal System for the Initial Application of a Certificate of Medical Device Notification (CMDN)**

I. RATIONALE

Republic Act (RA) No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", has empowered the Food and Drug Administration (FDA) to regulate health products. Pursuant to this policy, FDA is mandated to enhance and strengthen its administrative and technical capacity with regard to the regulation of health products under its jurisdiction.

RA No. 11032, also known as the "Ease of Doing Business and Efficient Government Service Delivery Act of 2018", mandates all offices and agencies which provides government services to evaluate, improve, and if deemed necessary, reengineer their transaction systems and procedures to reduce bureaucratic red tape and processing time. In consonance with this, the FDA developed the eServices Portal System to streamline the FDA authorization applications.

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" has provided guidelines for the application of CMDN and Certificate of Medical Device Registration (CMDR) based on the risk level of the medical device. Detailed guidelines for the application for CMDN and CMDR of medical devices were further discussed in FDA Circular (FC) No. 2020-001 entitled "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"" and its amendment and FC No. 2021-002 entitled "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"" and its amendments.

Initial application for CMDN for medical devices is transacted online through the FDA ePortal System. Hence, the data and information about valid and existing CMDN are also stored in this system.

It is essential to make use of the eServices Portal System in the initial application for CMDN to benefit from the system's improvements. Thereby, this FC is issued to streamline the processing of initial application for CMDN and update the existing procedures through the eServices Portal System.

II. OBJECTIVE

This Circular aims to provide guidelines on the following:

A. Filing of initial application for a CMDN using the eServices Portal System

B. Checking of the status of the CMDN application

C. Downloading of the CMDN from the eServices Portal System

III. SCOPE

This Circular shall cover the process of CMDN initial application through the eServices Portal System for the following medical device products:

A. All Class A medical devices

B. 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 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"

This Circular shall not cover the renewal and variation applications for CMDN.

IV. DEFINITION OF TERMS

For the purpose of implementing this Circular, the terms used herein shall have the meaning as defined in RA No. 9711, its IRR, and related laws and regulations. However, the following terms are hereby defined for greater clarity:

Certificate of Medical Device Notification (CMDN) – is the authorization issued to all class A medical devices and to the initial application of 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.

ePortal System - is an online application system for securing FDA market authorizations including CMDN for medical devices.

eServices Portal System - is an online application system designed by the FDA that aims to improve and streamline the digital application, processing and issuance of FDA market authorizations.

V. GENERAL GUIDELINES

A. Initial application for a CMDN for medical devices shall be filed online through the eServices Portal System website through the link: https://eservices.fda.gov.ph/.

B. Filing of initial application for CMDN for medical devices through the ePortal System shall be deactivated upon effectivity of this Circular.

C. All on-going applications filed through the ePortal System prior to the implementation of this Circular shall continue to be processed through the ePortal System upon effectivity of this Circular.

D. The creation of an account or password is no longer a requirement to obtain access to the eServices Portal System.

E. The CMDN Number shall follow the existing format. (i.e., CDRRHR-CMDN-YYYY-XXXXXX)

VI. SPECIFIC GUIDELINES

A. The requirements for initial application for a CMDN for medical device shall be based on AO No. 2018-0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements" or its subsequent amendment.

B. Procedure for filing of initial application for CMDN shall follow the guidelines stated in Annex A of this Circular.

C. Checking of the application status and downloading of the approved CMDN shall follow the guidelines stated in Annex B of this Circular.

VII. MONITORING AND REVIEW

Within three (3) years of its implementation, this Circular shall be reviewed and evaluated to determine whether the Circular's objectives, impact, and effectiveness are achieved and whether the provisions of this Circular are still valid and enforceable.

VIII. 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.

IX. REPEALING CLAUSE

Provisions from previous issuances that are inconsistent with this Circular are hereby amended, withdrawn, repealed or revoked accordingly.

X. 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.

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