REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF FINANCE
BUREAU OF CUSTOMS
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18 September 2024

CUSTOMS MEMORANDUM CIRCULAR
NO. 166 -2024

TO: **ASSISTANT COMMISSIONER**
DEPUTY COMMISSIONERS
SERVICE DIRECTORS AND DIVISION CHIEFS
DISTRICT AND SUB-PORT COLLECTORS
ALL OTHERS CONCERNED

SUBJECT: **FOOD AND DRUG ADMINISTRATION (FDA) - CLARIFICATION REGARDING AUTHORIZATIONS NEEDED FOR THE IMPORTATION OF MEDICAL DEVICES**

This has reference to the letter with attachments dated 07 August 2024 from Dr. Samuel Zacate, Director General, FDA, bearing on the attached FDA Circular No. 2024-003 with 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 entitled: "Amendment to Annex A of FDA Circular No. 2020-001 re: "Initial Implementation of Administrative Order No. 2018-002: Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements".

Relative thereto, **all Class B, C and D medical devices that are not included in the list of registrable medical devices based on FDA Circular No. 2021-001-A may continue to be manufactured, imported, exported, distributed, transferred, sold or offered for sale without a Certificate of Medical Device Notification (CMDN) until 30 September 2024**. The License to Operate (LTO) as Medical Device Importer/Distributor of the establishment shall be required during importation.

To summarize, the following are the authorizations needed or required during the importation of medical devices:

a. LTO
   - Importers of Medical Devices and In Vitro Medical Devices, Registrable and Non-Registrable Products

b. Certificate of Product Registration - Only for Registrable Products
   - For Registrable Medical Device Products classified as Class B, Class C and Class D - Refer to the list in the FDA Circular No 2020-001, "Processing of Initial Implementation of Administrative Order No. 2018-002, Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements".

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- For Registrable IVD products - Refer for FDA Memorandum Circular No. 2014-005, "Updated List of Medical Devices Required to be Registered Prior to Sale Distribution and Use".

c. CMDN — For Class A Medical Devices
   - CMDN is the certification issued for Class A medical devices. *Certificates of Exemptions issued from 25 February 2014 are no longer valid.* Thus, all Class A should present a CMDN. FDA Circular No. 2021-017 is the Reference List of Class A Medical Devices.

d. Certificate of Medical Device Registration (CMDR) / Certificate of Medical Device Notification (CMDN) - For Class B, C and D Medical Devices that are Non-Registrable
   - The Marketing Authorization Holder (MAH) may file for CMDN or CMDR
   - 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.

e. Special Certification
   - Special Certification is being issued for new technologies or new test kits brought about by emerging disease or global outbreak of international and national concern. Example of this is FDA Memorandum No. 2020-006, "Issuance of Special Certification for Imported Test Kits of COVID - 19."

Lastly, for non-medical devices, no certification is needed from the FDA.

For records purposes, please disseminate throughout your respective offices and submit the necessary confirmation within fifteen (15) days from receipt hereof.

For your information and reference.

BIENVENIDO Y. RUBIO
Commissioner

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Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

BAGONG PILIPINAS

09-51191

07 August 2024

BUREAU OF CUSTOMS AOCG RECEIVED 4800 SEP 17 2024 BY: mapa TIME: 1:25

BIENVENIDO Y. RUBIO
Commissioner
Bureau of Customs
G/F, OCOM Bldg., 16th Street
South Harbor, Port Area, Manila

Subject: Clarification regarding authorizations needed for importation of medical devices

Dear Commissioner Rubio:

This refers to the guidelines and issuances issued by the Food and Drug Administration specifically on Medical Devices that are imported into the country. During several consultations with the stakeholders, issues have been raised with regards to required authorizations to be presented to the Bureau of Customs at points of entry. This serves as clarification on the appropriate authorizations to be presented to your office by the stakeholders.

With the issuance of FDA Circular No. 2024-003, "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"" signed on 26 March 2024, 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 (LTO) as Medical Device Importer/Distributor of the establishment shall be required during importation.

PORT OPERATIONS COORDINATION DIVISION AOCG BOC RECEIVED 17 SEP 2024 By: Time: 2:03

To summarize, the following are the authorizations needed to be required during the importation of medical devices:

A. LTO

a. Importers of Medical Devices and In Vitro Medical Devices, Registrable and Non-Registrable Products

B. Certificate of Product Registration – ONLY for Registrable Products

a. For Registrable Medical Device Products classified as Class B, Class C and Class D – Refer to the list in the FDA Circular No. 2020-001, "Processing of 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"

BUREAU OF CUSTOMS PORT OPERATIONS SERVICE RECEIVED SEP 17 2024 BY: TIME: 1:28

13 SEP 2024

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b. For Registrable IVD products - Refer to FDA Memorandum Circular No. 2014-005, "Updated List of Medical Devices Required to be Registered Prior to Sale, Distribution and Use".

C. Certificate of Medical Device Notification (CMDN) – For Class A Medical Devices

- CMDN is the certification issued for Class A medical devices. Certificates of Exemptions issued from 25 February 2014 are no longer valid. Thus, all Class A should present a CMDN. FDA Circular No. 2021-017 is the Reference List of Class A Medical Devices.

D. Certificate of Medical Device Registration (CMDR) / Certificate of Medical Device Notification (CMDN) – For Class B, C and D Medical Devices that are Non-Registrable

- The Marketing Authorization Holder (MAH) may file for CMDN or CMDR
- 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.

E. Special Certification

- Special Certification is being issued for new technologies or new test kits brought about by emerging disease or global outbreak of international and national concern. Example of this is FDA Memorandum No. 2020-006, "Issuance of Special Certification for Imported Test Kits of COVID -19".

For a non-medical device, no certification is needed to secure from the FDA.

Thank you very much for your usual support in ensuring the quality, safety and effectiveness of the medical devices.

For reference, copies of the relevant issuances are attached with this letter.

Very truly yours,

Digitally signed by
Zacate Samuel Arellano
Date: 2024.08.09
14:11:36 +08'00'

DR. SAMUEL ZACATE
Director General

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Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2024-003

26 MAR 2024

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.

[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""

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 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.

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 /

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CMDR shall be prohibited. Pending application refers to those applications with proof of payment and doc track number.

F. Market Authorization Holder (MAH) with valid CMDN for Class B, C and D medical devices shall apply for CMDR at anytime within its validity period to ensure continuous availability of market authorization during this transition. 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 payment for CMDR shall be provided at the point of entry and/or part of bidding requirements.

G. The MAH, during application for CMDR, shall provide a letter stating that the application is from CMDN to CMDR. The copy of the CMDN shall be attached to the letter.

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