



Virtual Public Hearing on the Proposed FDA Circulars:



“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”
and

“Reference List of Class A Medical Devices”

23 June 2021 | 9:00 AM –
12:00 NN

Virtual Public Hearing on the Following Proposed FDA Circulars:

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”, and
2. Reference List of Class A Medical Devices”

Date: 23 June 2021

Facilitated by: Center for
Device Regulation, Radiation
Health, and Research



OBJECTIVES

- ❑ **Solicit inputs and comments from the participants re: proposed policies**
- ❑ **Clarify issues and concerns of the diff. stakeholders on the proposed policies**



BACKGROUND

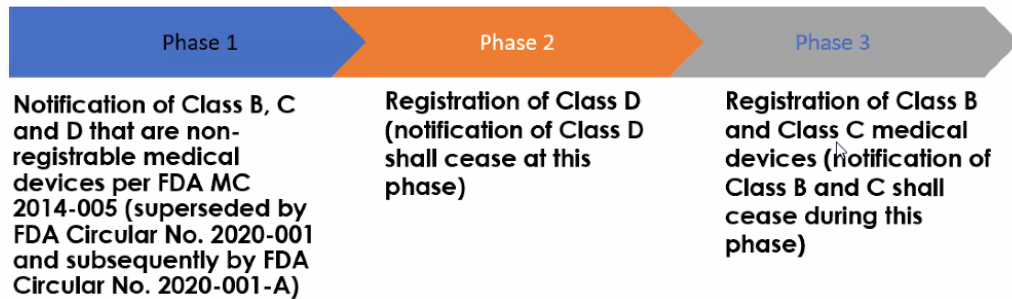
PHASES OF IMPLEMENTATION OF AO 2018-0002

Initial implementation (FDA Circular No. 2020-001, issued 23 January 2020)

- Issuance of CMDR for registrable medical devices specified in FDA MC 2014-005 (which was amended by FDA Circular No. 2020-001 and further amended by FDA Circular No. 2020-001-A)
- Issuance of CMDN for all Class A medical devices
- Issuance of CMDL for medical devices that will be used for research, clinical trial, exhibit, personal use and/or donated brand new medical devices
- All issued COEs for Class A medical devices are valid until 3 Nov 2021

BACKGROUND

PHASES OF IMPLEMENTATION OF AO 2018-0002

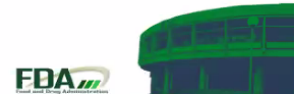


BACKGROUND

FDA Circular No. 2021-002

Approved on 4 January 2021

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”



OBJECTIVES of FDA Circular No. 2021-002

1

Implement Phases 1, 2 and 3 of AO 2018-002

2

To provide guidelines on the schedule of acceptance of applications for and issuance of CMDN for Class B, C and D medical devices under Phase I implementation

3

To provide guidelines on the submission of application for CMDR for Class B, C and D covered under Phase 2 and Phase 3 implementation



OBJECTIVES of FDA Circular No. 2021-002

1

Implement Phases 1, 2 and 3 of AO 2018-002

2

To provide guidelines on the schedule of acceptance of applications for and issuance of CMDN for Class B, C and D medical devices under Phase I implementation

3

To provide guidelines on the submission of application for CMDR for Class B, C and D covered under Phase 2 and Phase 3 implementation



FDA CIRCULAR NO. 2021-002

- The CDRRHR to accept applications for CMDN for Class B, C and D medical devices that are non-registrable per FDA Circular No. 2020-001 (as amended by FDA Circular No. 2020-001-A) upon effectivity

Effectivity

- 15 days after its publication in a newspaper of general circulation and upon acknowledgement of receipt of a copy hereof by the Office of the National Administrative Register
- 6 March 2021



FDA CIRCULAR NO. 2021-002

- The filing of application for CMDN for Class B, C and D medical devices shall follow the existing procedure for filing of application for CMDN for Class A medical devices
- Validity of CMDN for Class B, C and D medical devices is 2 years



FDA CIRCULAR NO. 2021-002

- When to apply for a CMDR for Class B, C and D issued with CMDN
 - ❖ 3 months prior to expiration of the CMDN, the MAH should apply for a CMDR based on existing procedures on filing of applications for CMDR
- Classification of medical devices that are not included in Annex A of FDA Circular No. 2020-001 and its amendment(s) shall follow the classification rules of AMDD



FDA CIRCULAR NO. 2021-002

- When to apply for a CMDR for Class B, C and D issued with CMDN
 - ❖ 3 months prior to expiration of the CMDN, the MAH should apply for a CMDR based on existing procedures on filing of applications for CMDR
- Classification of medical devices that are not included in Annex A of FDA Circular No. 2020-001 and its amendment(s) shall follow the classification rules of AMDD



FDA CIRCULAR NO. 2021-002

- The applicant shall submit the legal and technical requirements specified in Annex A and Annex B, respectively, of AO 2018-0002 when applying for CMDN for Class B, C and D medical devices covered in this Circular.

ANNEX A

Legal Requirements for Application for the Notification of Medical Devices under Class A and Registration of Medical Devices under Classes B, C and D

1. Notarized Application Form (Annex G or H)
2. Payment
3. Copy of Letter of Authorization. For imported medical devices, the copy of the Letter of Authorization shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the authorization is true and correct.
4. A government – issued certificate attesting to the status of the Manufacturer with regard to the competence and reliability of the personnel and facilities, a Quality Systems Certificate of approval, or a compliance certificate for ISO 13485. For imported medical devices, the copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.
5. For imported medical devices, the Certificate of Product Notification, Certificate of Product Registration, or any equivalent document attesting to the safety and effectiveness of the device issued by the regulatory agency or accredited notified body in the country of origin. The copy of the certificate shall be accompanied by an original copy of a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.
6. Colored picture of the device from all sides. However, the CDRRHR can require a representative sample or commercial presentation for verification purposes.

ANNEX B

Technical Requirements for Application for the Notification of Medical Devices under Class A

1. Device description consisting of the following:
 - a. Intended use
 - b. Instruction for use
 - c. List of all raw materials
 - d. Technical specification of the finished product
 - e. List of reference codes, sizes, colors, models and variance, whichever is applicable.
2. Certificate of Conformity (issued by government agency dealing with metrology) on the aspect of manufacture relating to metrology for devices with measuring functions, if applicable
3. Declaration of Conformity (self declaration by the manufacturer) with product standards, if applicable
4. Clear and complete colored pictures of label from all sides of the packaging (loose label or artworks of all layers of packaging)
5. Declaration of shelf life



BACKGROUND

Proposed Reference List of Class A Medical Devices

Subsection V (1) of AO 2018-0002 states that:

“A guidance document containing the list of medical devices per classification shall be issued.”

Subsection V (2) of AO 2018-0002 states that:

“The applicant shall classify the device based on the list of medical devices per classification issued by the CDRRHR.”



A. DRAFT ADDENDUM OF FDA CIRCULAR NO. 2021-002

Questions	Answers
BOC does not accept COE and LTO because there are similar products which have CMDN and CMDR already. What are we going to provide?	Reply of MCCM: FDA has provided the list to different govt agencies that they should abide. The company should have an audience with the BoC.
Can an extension be considered on CMDN application period? We suggest this for faster processing of CMDN. We see 60-70% failure rates. Getting disapprove 2-3 times, and with that rate we will not be able to finish all the CMDN applications. It should be simpler in requirements and review since this is not considered a product approval. We will get comments from the members that we can submit to the Ma'am Cecile.	
We would like to request to stop the selling of dental products to unlicensed dentist or traders and online sellers. Can we request for a memorandum from FDA?	We will have to clarify with the legal office if that will be a mandate of the FDA. Customized are not subject for registration. May we request for an official communication from your organization so we can answer your concerns. Ma'am Cecile: Regulation of FDA issues two authorizations, LTO and product registration. On dispensing to non-dentist, if that is covered by law, we can implement. However, if there is no existing law like the 9711, we cannot compel the selling by the unlicensed dentist. With the online selling, we cannot control especially under this pandemic. As long as the seller has the appropriate LTO, we cannot control them. For Rx medical devices, we can do something about it. All sellers must have LTO except for the retailer.
From CMDN (Class B, C & D) to CMDR, what will be the transition period? Can we still import while waiting approval of the CMDR? What if the 90 days application to CMDR is not enough?	By that time, we hope that it will be an online submission. Processing would be faster.
Suggestion by Rhoel: Can we apply 6 months prior to expiry of CMDN?	We can do amendment of the transition.
Right now, is there a possibility that we apply direct to CMDR than CMDN?	None.
Given the process registration of CMDN to CMDR, are you going to repeat the evaluation on the legal documents. (doc 1-7 common to all)?	Need to prepare requirements under CMDR. Submit the same legal requirements as submitted before.

CMDN is only a notification (low risk) but with what the industry is experiencing, we are giving a hard time by the evaluators unlike other ASEAN countries. Can you be more considerate to this application?	Our notification is not a simple notification considering the safety of the product. We have a continuous risk. Notification of MD is not a listing which also looks on the safety and quality of the product.
Regarding categorization, the 3 products have the same documents. The 2 passed and the other was denied and has clarification. How are going to do about it?	This is not covered by the agenda. We will take note of that.
Regarding the denials on CMDN, is there a possibility to extend the acceptance of CMDN from Mar 30, 2022?	We will consult Ma'am Cecile with the deadline.
Just wanted to clarify the timelines. In item 1, the deadline to secure/apply for CMDN is Mar 31, 2022. But in item 2, deadline is mentioned until Mar 31, 2023.	On April 1, 2023, apply direct to CMDR and not CMDN anymore.
If possible, can we add the statement that March 31, 2022 are only for products that are already being marketed but not on the list of 2014-005?	Noted. We will consider.
If by Mar. 31, 2022, can we still import products with pending CMDN applications?	Yes
I have a CPR on exam gloves, with the new guidelines, when can I apply for CMDN? Shall I wait for the CPR to expire?	Class A with the existing CPR will be renewed via the normal process. Check FDA Circular 2020-001. The registration number will be changed to CMDN.
The way I understand, the date 31 Mar 2022 is the date that we are allowed to import, distribute, manufacture Class B, C & D (not listed in Annex A) without CMDN. However, starting March 31, 2023, only those with CMDN & with pending applications will be allowed to import, distribute, manufacturer Class B, C & D (not listed in Annex A). Just wanted to confirm if my understanding is correct.	Item 1, the April 1, 2022 covers the existing the products in the market. Mar 31, 2023 will cover the new product to be imported and distributed in the market.
As early as May 2021, BoC no longer honors the CoE or LTO. Their reason is CMDN is now existing and implemented. We hope that this issuance will clear the understanding of the BoC.	That is why we need to issue this as soon as possible.

For Item no 6, may we request to extend the validity of CoE for Classes B, C, and D?	For deliberation.
Does it mean on No. 6 the validity of COE under Class A is extended from November 3, 2021 to March 31, 2022?	Extended until mar 31, 2022.
For Item No.6 - How about the CLASS B,C,D without the COE ?	You can apply until mar 31, 2022.
When is the target implementation date of this circular?	We cannot tell for now. It will still be revised. For review by FDA.
We understand that it is the manufacturer's responsibility to classify the product and as mentioned in the guidelines CDRRHR shall verify the classification and shall reclassify the device if another classification is deemed to be more appropriate. However, this will delay or prolong the process in the event that FDA will disapprove the application due to incorrect Risk Class. Is there a way to shorten the process, like a request or application with FDA for product classification?	No. There will be no application for product classification since the manufacturer should know their product's risk class. It will be another work for us to accept request or application for the classification of your product. This is the reason why we come up with this numerous reference list of Class A Devices.

Additional Statement added to Addendum of FDA Circular No. 2021-002

5. All Class B, C and D medical devices that are not included in the list of registrable products per FC No. 2020-001 as amended by FC No. 2020-001-A but were issued with a registration certificate prior to the implementation of the aforementioned FCs shall be required to secure a CMDR instead of a CMDN.

Reply: correction "secure" to "shall continue to apply for renewal"

***All extensions will come later if there is a need. – Director Cecile Matienzo**

B. DRAFT CLASS A LIST

Questions	Answers
Is there a transition period once the circular is implemented?	No transition periods.
Can we consider the medical device as Class A if there is a declaration from the legal manufacturer and were under Class A in Singapore and Malaysia?	Check the list first. For validation of FDA.
Can the manufacturer's classification enough?	It can still be changed depending on the ASEAN listing.
We just want to clarify if software is already included?	Yes. Study the list. Learn your devices.
Since there are new products under the list not mentioned with the previous listing would there be extension for the CMDN class A application which is only until November 3, 2021?	If there is a need.
I think it would be of great help to all stakeholders if CDRRHR will be more specific with the types of medical devices listed in Annex A of this Circular. For example, face mask. There are several types of masks - KN95, KF94, N95, etc. Instead of declaring surgical masks, it would be clear if specific types of mask are mentioned for proper guidance of the industry.	For medical application – it will fall under the face mask Class A. For general use not regulated.
Is there a separate classification for IVD?	A separate list will be issued.
Does it mean a software under Class A, B, C, or D will be part of Notification?	For now, it is under notification since it is not included in the list.
What about those classified under class A and not included in the list?	Provide the list of the product and we will review. Take note that other countries are not

	following the classification rule especially if it made in the US. We based it from AMDD.
Electric toothbrush – personal use	For deliberation.
Is this list based in the AMDD?	Some are under deliberation. Give us your comments.
In FDA Cir. 2021-001-A it was stated #69 Nasal Spray (without claims) is Class A, in this draft we cannot find the Nasal spray anymore. There's a list of Medical Device Borderline with Medicine from 8th AMDC, based on it, it stated disinfectant/antiseptic for dental is medical device. Can I inquire if Nasal Spray with Iodine as active ingredient a medical device since its mode of action is physical mode?	This will fall under drug. If saline solution, it is medical device. It will depend on the active ingredient and indication.
Regarding Annex A, item 95. For Silicon based cream, I have previous application with CCRR. It was denied and was informed that it is a medical device. Is it really under medical device?	If silicon based intended for lightening of scars it is under medical device.
Regarding batteries on the drafted list, can we delete them from the list? In the ASEAN Region, they don't require batteries to be registered as stand-alone. They include the batteries if included or part of one system. If we will include batteries, BoC might misinterpret the list of medical devices.	For deliberation. Give us the category and number of batteries.
To delete wire/power cable is part of active medical device equipment. Usually it is being imported separately.	For deliberation.
Personal lubricants classified under cosmetics from other countries – we will provide the list in a position paper. What if the intended use is for pleasure – we check the intended use?	Those intended for dryness. To mimic the natural vaginal fluid to prevent the dryness and itchiness. If not for medical use no need to register. We can add lubricant under borderline products.
If we don't have any CoE, for non-registrable products, what are we going to provide as proof?	Our reply to an inquiry is what you can provide as proof.
Can we request Dialysis Chair to be removed from the list since it does not fall as a medical device? Category E, page 13, item 25.	Noted

Philippine Association of Medical Device
PAMDRAP
Regulatory Affairs Professionals

Upon evaluating the Class A list that was emailed to us, under orthopedic, can we consider to adding the Reusable Guide Wires.	You can email us regarding that.
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***Powdered exam gloves will be removed from the draft list.**

*** Comments and suggestions will be deliberated. Please submit your comments within 7 days to cdrhr-prsdd@fda.gov.ph**

Minutes taker: Charmaine Roson – Documentation Committee