PAMDRAP GMM 2021

MEDICAL DEVICE REGULATORY UPDATE

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Food and Drug Administration

February 19, 2021
9:00 am – 12:00 am
Via Zoom

TOPICS:

- Update on Implementation of 2018-002
  FDA Circular 2021-002
- Update on Covid-Related Products
- Update on Medical Device Regulation
- What is it for better regulation…

Implementation of 2018-002

TIMELINE OF IMPLEMENTATION							
Activity	Validity	Timeline					
		2020	**2021**	2022	2023	2024	2025 and beyond
GENERAL MEDICAL DEVICE							
Preparation and approval of Issuance of the Phase implementation (FDA Circular)		September	**FDA Circular 2021-002 is issued on**				
Registration of MD in the List as Per FDA Circular 2020-001	5years	On-going Activity					
Notification of Class A Medical Devices	5years	On-going Activity					
Notification of Other Class B, C, D Medical Devices	2 years		**March**				
Registration of Other Class B, C, D Medical Devices	5years				**March**		

TIMELINE OF IMPLEMENTATION							
Activity	Validity	Timeline					
		2020	2021	2022	2023	2024	2025 and beyond
IVD Medical Devices							
Update of List of Registrable IVDs (FDA Circular)		September	Notes: To issue the new list of IVD that will be required to be registered (listed in FDA MC 2014-005 plus those that will be identified by the DOH programs) *** did not receive any new list to date				
Registration of IVD in the List	5years	On-going Activity					
Approval of New AO for IVD			1st Sem				
Notification of Class A IVD	5years			January			
Notification of Other Class B, C, D IVD	2 years			January			
Registration of Other Class B, C, D IVD Medical Devices	5years					January	

FDA CIRCULAR 2021-002

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"

Phases of implementation
Based on AO 2018-002

1. **Phase I**: Notification of Class B (low-moderate risk), C (moderate-high risk)- and D (high risk) that are non-registrable medical devices based- on FDA Memorandum Circular (MC) No. 2014-005. FDA MC 2014-005 was superseded by the list of medical devices in Annex A of FDA Circular No. 2020-001 entitled "Initial Implementation of Administrative Order no. 2018-0002 "Guidelines Governing the Issuance of an Authorization for a Medical Device Ba sed on the ASEAN Harmonized Technical Requirements"

2. **Phase 2**: Registration of Class D (Notification of Class D shall cease during this phase)

3. **Phase 3**: Registration of Class Band Class C (Notification of Class Band C shall cease during this phase)

Full implementation of AO 2018-002
FDA Circular 2021-002

1. The Center for Device Regulation, Radiation Health, and Research shall be accepting applications for CMDN for Class B, C and D medical devices that are not included in the list of medical devices in Annex A of FDA Circular No. 2020-001 and its subsequent amendment(s) upon the effectivity of this Circular.

2. 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.

3. The CMDN for Class B, C, and D medical devices shall be valid for two (2) years

4. Three (3) months prior to the expiration of the CMDN, the company shall apply for a CMDR for the product. Application for CMDR for Class B, C and D medical devices covered in this Circular shall follow the existing CMDR policies and procedures.

5. 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 as stated in item 2, Section V. General Guidelines of AO 2018-0002.

6. 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.

7. The fee for CMDN shall be ₱3,000.00 and an additional 1% thereof for the Legal Research Fee (LRF). This LRF imposition is pursuant to FDA Circular No. 2011-003 or the "Collection of Legal Research Fee Imposed by Republic Act No. 3870, as amended by PD 200 and further Amended by PD 1856".

8. The fee for the CMDR shall be in accordance with the existing fees during the time of the application.

DRAFT Transition Period for FDA Circular 2021-002

- CLASS B, C, and D medical devices that are not included in the list of medical devices in Annex A and its subsequent amendment(s) of FDA Circular 2020-001 are given until **March 2022 (can still be changed depending on the approval)** to apply for Certificate of Medical Device Notification.

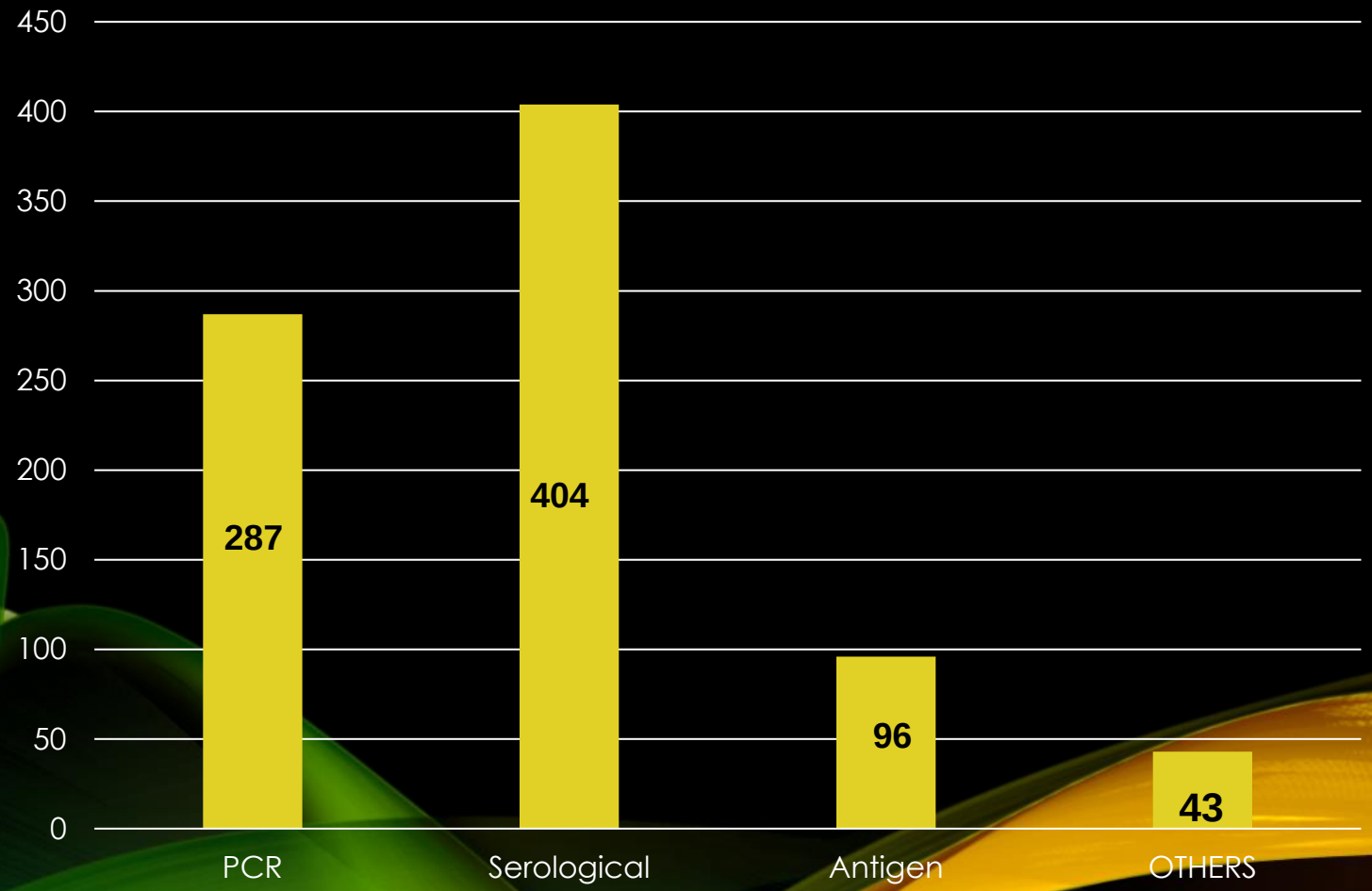
- During this period, the company may continue the importation and distribution of their products. However, on **01 April 2022 (this will follow after the date above)** only those with CMDN **or with pending applications** for CMDN are allowed to import and distribute their products.

How to apply for notification for classes B, C and D

- Thru the e-portal (e-notification)
- There are drop down choices for the classification
- If class A, automatic validity of 5 years and the order of payment is electronically generated for 5 years
- If Class B, C, D: Automatic validity of 2 years and the order of payment is electronically generated for 2 years
- Requirements for notification of classes B, C, and D are exactly the same as the notification for class A

Update on covid applications related to medical device regulation as of 22 January 2021

Distribution of Approved COVID Test Kits per Category



	2020	2021
Total Applications	2153	53
Approved	762	25
Disapproved	1363	31

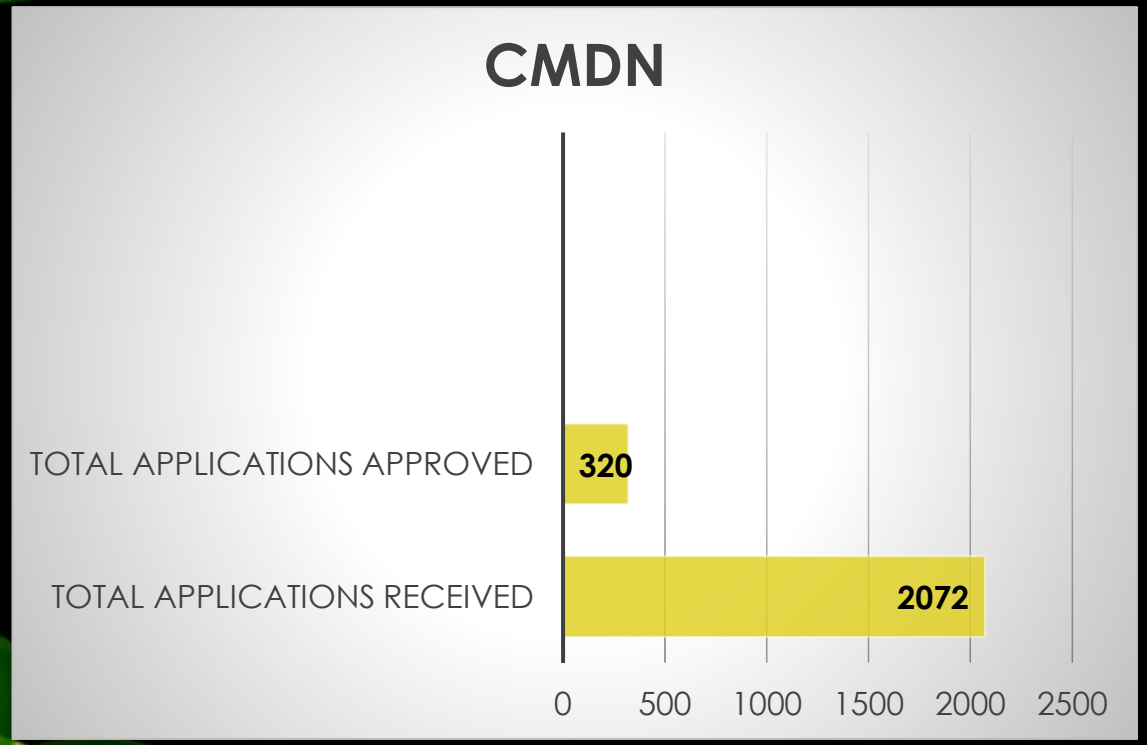
PPE LOCAL Manufacturers and Approved PPE's

As of 18 February 2021:

TYPE OF PPE	No. of Local Manufacturer
Face Mask	26
Gloves	2
Coverall	2

TYPE OF PPE	No. of Registered Products
Face Mask	22
Coverall	11
Gloves	1

Medical Device Regulatory update



Percentage of approved applications against total received applications is 15%

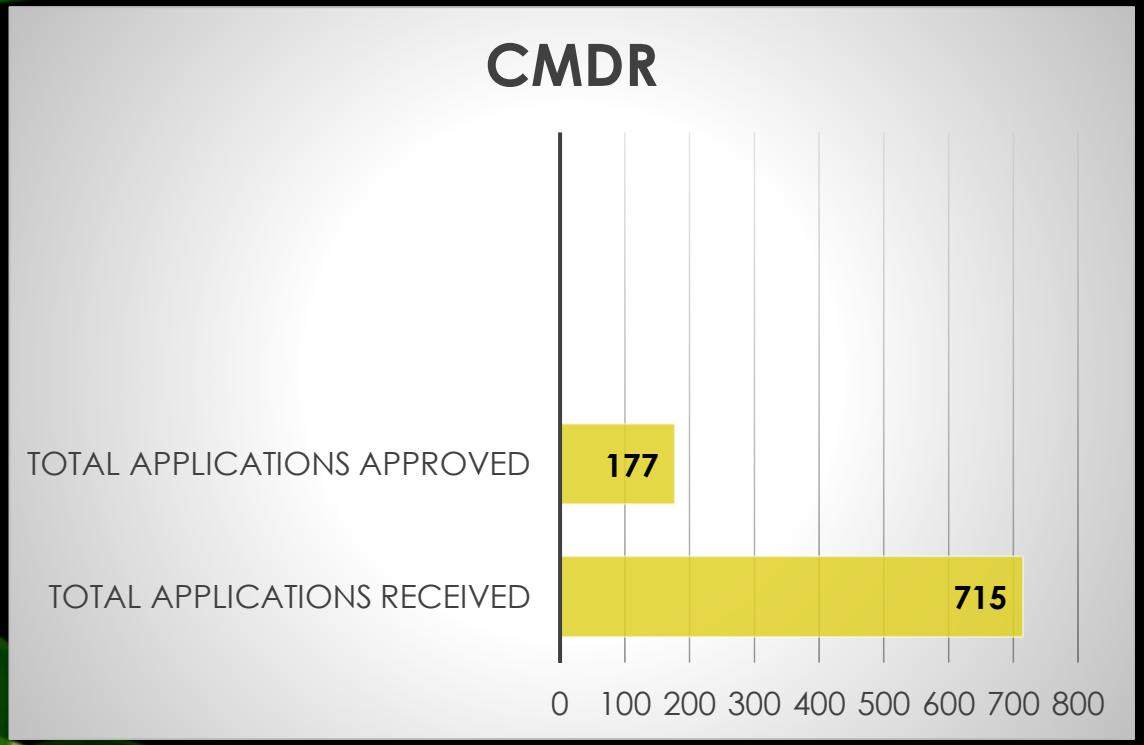
2,072 = 15,540,000.00

320 = 2,400,000.00

Loss: 13,140,000.00

STATISTICS OF APPLICATION OF CMDN
As of 18 February 2021

Medical Device Regulatory update



Percentage of approved applications against total received applications is 25%

715 = 5,632,500.00

177 = 1,327,500.00

Loss: 4,305,000.00

Statistics of application of CMDR
As of 31 December 2020

Application Procedure for Initial Registration

Procedures in Filing for Initial Application

1. The client shall prepare a folder in google drive or other online storage provider.

2. The prescribed format of the Folder Name shall be:
   2.1 CMDR_COMPANY NAME_PRODUCT NAME (Medical Device)
   2.2 CIVDMDR_COMPANY NAME_PRODUCT NAME (In-Vitro Medical Device)
   2.3 CHRDRWATER_COMPANY NAME_PRODUCT NAME (Water Purification Device System)
   2.4 CHRDRHCW_COMPANY NAME_PRODUCT NAME (Healthcare Waste Device System)

3. The folder name may not include the whole company name as long as it is distinguishable.

4. The product registration application file in PDF format shall be placed in the folder. There shall be one folder per application.

5. The client shall send one (1) email per application to cdrrhr-productregistration@fda.gov.ph with the following details and information.
Subject syntax: CMDR_COMPANY NAME_PRODUCT NAME
Body of Message:
Name of authorized person:
Contact number/ email address:
Company name:
File folder link:

THE FILE SHOULD NOT BE ATTACHED IN THE EMAIL. Doing so will invalidate the client's submission. Submissions with the wrong syntax will invalidate the application as well.

6. If submission is accepted, the client shall print-out the email reply containing the Document Tracking Number (DTN) and pay the appropriate fee through the accepted channels. The fee shall be in accordance with Administrative Order No. 50 s. 2001.

7. The client shall send an email with the attached proof of payment/bank-validated On-Coll Slip.
The subject shall be in this syntax: PROOF OF PAYMENT_COMPANY NAME_DTN

THIS EMAIL SHALL BE DIFFERENT AND DISTINCT FROM THE E-MAIL SENT DURING THE INITIAL APPLICATION. Failure to comply would invalidate the client's submission.

8. The email address cdrrhr-productregistration@fda.gov.ph is strictly for submission of INITIAL applications only. Follow-ups, inquiries, and the like shall be sent to cdrrhr.lrd@fda.gov.ph.

9. The application shall be submitted only on the schedule stated in FDA Circular No 2020-026, from 8:00 a.m. to 5:00 p.m. No applications shall be considered after 5:00 p.m.

Reminders:

- Send only applications to the **assigned email address**
- One (1) application : one (1) email
- Do not send compliance to cdrrhr@fda.gov.ph
- There are delays in sending the soft copy as compared to the LTO auto-notification or as indicated in the doctrack. This activity is an accommodated activity during this pandemic.

  - Always follow the procedures in sending applications or submission of documents based on FDA Circular 2020-026

SAMPLE CHECKLIST FOR PRE-ASSESSMENT
Class B:

1) **Notarized Application Form.**

- **Must be complete; product name on label must be consistent with that stated on the NAF;**
- **IFU, manufacturer's information must be consistent on all technical documentation and NAF;**
- **official form (unedited) must be used;**
- **e-signature accompanied by a copy of the company ID of the signatory is acceptable DURING THIS TIME;**
- **brand name and medical device name must be correct; for MD's that are classified incorrectly – evaluate LEGAL DOCUMENTS ONLY. "Technical documents WILL NOT BE EVALUATED**
- **Date of notary – September 2020. Notary dated before the issuance of 2020-026 is acceptable.**
- **Codes must be arranged accordingly. Include an annex for the codes, especially for multiple CPR applications. For applications with NO OTHER deficiencies, apart from the codes – "Submit an annex containing codes, along with the NAF."**

SAMPLE CHECKLIST FOR PRE-ASSESSMENT
Class B:

2. **Copy of Notarized Agreement/Letter of Authorization**
   - Must be valid
   - The product being applied must be indicated.
   - For imported medical devices, with notarized declaration from the legal manufacturer or product owner attesting that the authorization/agreement is true and correct.
   - For imported medical devices but the agreements are signed in the Philippines, it must be notarized locally, with passport ID page and record of arrival and departure of the principal to and from the Philippines of the signatory/ies, and must be signed by both parties.
   - For open-dated agreements/authorizations, if the certificate is beyond the 5-year period, a re-issued agreement/authorization must be submitted or a notarized attestation by the Principal that the agreement/authorization is still in effect.
   - For locally manufactured medical devices with exclusive distributors, the agreement should be duly notarized.
   - For locally manufactured medical devices with toll manufacturer, agreement between the trader and the manufacturer should be duly notarized.

SAMPLE CHECKLIST FOR PRE-ASSESSMENT
Class B:

3. **For imported Medical Devices – copy of 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.**

. Must be valid
. Accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.
. For products that are manufactured in multiple sites or toll manufacturers, identify or highlight product source.
. The product being applied must be indicated in the scope.
. For locally manufactured products, valid LTO of the manufacturer.

SAMPLE CHECKLIST FOR PRE-ASSESSMENT
Class B:

4. **For imported medical devices, 1 copy of Certificate of Product Registration, CE Certificate or any equivalent document attesting to the safety and effectiveness of the device issued by regulatory agency or accredited notified body in the country of origin.**

   - Must be valid
   - Accompanied by a notarized declaration from the legal manufacturer or product owner attesting that the certificate is true and correct.

SAMPLE CHECKLIST FOR PRE-ASSESSMENT Class B:

5. **Clear colored picture of the actual commercial product sample of the device for all sides without its packing, for all codes included in the application.**

- Pictures should not be pixelated when the view is increase in size/zoomed in.

SAMPLE CHECKLIST FOR PRE-ASSESSMENT
Class B:

6. Executive Summary.

The executive summary shall include the following information:

. an overview, e.g., introductory descriptive information on the medical device, the intended uses and indications for use of the medical device, any novel features and a synopsis of the content of the CSDT; (brief summary)

. the commercial marketing history;

. the list of regulatory approvals or marketing clearances obtained;

. the status of any pending request for market clearance; and

. the important safety/performance related information. (post market activities, ie. History of product recall, adverse events, etc.)

SAMPLE CHECKLIST FOR PRE-ASSESSMENT Class B:

7. **Relevant essential principles and method/s used to demonstrate conformity. (with a template) This Is a mandatory requirement with the new regulations. If the product has no documentation for this requirement then it is disapproved**

SAMPLE CHECKLIST FOR PRE-ASSESSMENT
Class B:

8. **Device description with the following information:**
    a. Intended use
        - If the product is part of the system, the specific use of the product as part of the system should be indicated and not the intended use of the system.
    b. Indications for use
    c. Instructions for use
    d. Contraindications
    e. Warnings
    f. Precautions
    g. Potential adverse effects
    h. Alternative therapy – practices and procedures (if applicable)
    i. Raw materials or formulation
        - List of all raw materials used as a component of the product (specify for which product part or component the raw material is used)
        - Must include quantity (for solutions) and technical specifications or detailed information on physical and chemical properties of each component.
        - If the device contains PVC, identify the PVC plasticizer used.
        - For kits/sets submit all raw materials and specifications used.

SAMPLE CHECKLIST FOR PRE-ASSESSMENT
Class B:

j. Other Relevant Specifications to include the ff:

. The functional characteristics and technical performance specifications of the device including, as relevant: accuracy, sensitivity, specificity of measuring and diagnostic medical devices, reliability, and other factors

. Other specifications including chemical, physical, electrical, mechanical, biological, software, sterility, stability, storage and transport, and packaging.

- Certificate of Analysis or Test Certificate with finished product specification
- For Stability, submit functionality and packaging/integrity test study of the product duly signed by the person who conducted the studies to justify the claimed expiration date
- For accelerated study, submit computation to justify the storage conditions used
- If no expiration, submit justification from the manufacturer why the device has no expiration
- Submit in-use stability study, as applicable. (e.g. contact lens solution, disinfectant)
- Storage condition
- For products with special storage conditions, submit transport stability study
- For packaging, clarify the type of packaging used. i.e. blister pack, carton box, etc.
- For medical devices with animal tissue origin, submit Certificate of Compliance with ISO 22442 – Medical devices utilizing animal tissues and their derivatives issued by Government Authority or notified body.

k. Other descriptive information to demonstrate conformity with the relevant Essential Principles (e.g. biocompatibility category for the finished medical device)

SAMPLE CHECKLIST FOR PRE-ASSESSMENT
Class B:

9. **Summary of Design Verification and Validation documents:**
    a. Declaration/Certificates of Conformity to the product standards issued by the manufacturer
    b. Summaries or reports of tests and evaluation based on other standards, manufacturer methods and tests, or alternative ways of demonstrating compliance covering the following appropriate tests reports and evaluations, whichever is applicable:
        - A listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the medical device with reference to the Essential Principles
        - Engineering test
        - Laboratory test
        - Biocompatibility test
        - Animal test
        - Simulated use
        - Software validation
        - Pre-clinical studies

***PNS, international standards (ISO, IEC) and other equivalent national standards

NOTE: Products that are not designed, manufactures, tested based on any international standard it is disapproved. For those that follow national standards – indicate equivalency

SAMPLE CHECKLIST FOR PRE-ASSESSMENT
Class B:

10. **Clear and complete colored pictures of label from all sides of the packaging (loose label ort artworks of all layers of packaging)**
    - Immediate label, secondary packaging, box label and package insert/brochure, whichever is applicable
    - For any additional product claims on the label, submit studies or tests supporting the claims
    - For imported products, if the brand name is the product's local brand, declaration from the manufacturer allowing use of the brand name and IPO approval of the said brand name; clarify if the brand name is the importer's own brand – if own brand – require IPO
    - For local manufactured products, IPO approval of the said brand name
    - If the CE marking is reflected on the label, submit a valid certificate supporting the placement of the CE mark
    - Pictures and text of the label should be clear and not be pixelated when the view is increased in size
    - Lot No., Batch No., Serial No., whichever is applicable should be reflected
    - Expiration date, reference codes/sizes/variants/model whichever is applicable should be reflected
    - Storage condition, sterilization method should be reflected if applicable
    - Importer and distributor's name and address should be reflected in the label of the product together with the provision of the Registration Number
    - Suggested Retail Price (SRP) in Philippine Peso

SAMPLE CHECKLIST FOR PRE-ASSESSMENT Class B:

11. Risk analysis and result

- Identify the risk
- Failure Mode Effect Analysis (FMEA)/Risk Benefit Analysis

SAMPLE CHECKLIST FOR PRE-ASSESSMENT
Class B:

12. Physical manufacturer information

a. Complete manufacturing process, from receipt of raw material to finished product, including quality assurance procedures.
   - **"Flowchart is not acceptable. It should be supported by a narrative that includes quality and assurance tests…"**

b. Brief summary of sterilization method
   - Standard parameters, sterilization procedures, validation protocol and result of latest sterilization revalidation
   - Valid ISO Certificate of the contracted sterilizing company if the sterilization is contracted out

c. For non-sterile devices:
   - Non-sterile declaration from the manufacturer
   - Sterilization guidelines prior to use (from the manufacturer), if applicable

SAMPLE CHECKLIST FOR PRE-ASSESSMENT Class B:

REMINDERS:

- **Documentary requirements must be arranged according to the CSDT format. If not arranged based on the CSDT/checklist it will be disapproved.**
- All documents must be submitted in English language. Documents submitted in any other foreign language not accompanied by English Translation will be disapproved.
- Documents to be uploaded should be in PDF searchable format of at least 150 dpi.
- The file name to be uploaded should consist of the name of the requirements.

TIMELINE BASED ON THE REVISED CITIZEN'S CHARTER

TYPE OF CERTIFICATION	TIMELINE
CMDN – Initial	20 working days
CMDL	7 working days
Initial – CMDR Class B	60 working days
Initial – CMDR Class C & D	90 working days
Renewal – All Classifications	20 working days
CFS	10 working days
Application for Compassionate Permit	7 working days
IVD CPR - Initial	90 working days (LRD process only, not counting Performance Testing timeline c/o NRL)
IVD CPR - Renewal	24 working days (LRD process only, not counting Performance Testing timeline c/o NRL)
Sales Promo Permit - Initial	7 working days
Sales Promo Permit - Amendment	7 working days
Healthcare Waste CPR - Initial	40 working days
Healthcare Waste CPR - Renewal	20 working days
Healthcare Waste CPR – Turned Initial	40 working days
Water Purification Devices/System CPR - Initial	40 working days
Water Purification Devices/System CPR - Renewal	20 working days
Water Purification Devices/System CPR – Turned Initial	40 working days
CPR Variation – MD and IVD	30 working days

SPECIAL ANNOUNCEMENT
For initial application only

PRE-ASSESSMENT
(NOT INCLUDED IN THE TIMELINE)
CDRRHR

PAYMENT
CASHIER

EVALUATION
(TIME LINE)
CDRRHR

EVALUATION PROCESS:
APPROVED/DISAPPROVED
(AS INDICATED IN THE FDA CHARTER)

RELEASING
RECORDS/FDAC

Issues and Concerns:

For the installed base/devices prior to this Circular, do we still need to apply for CMDN even if already reach end of life/end of production life/end of service life?

Or we will only apply for the accessories that will be imported as standalone as part of service/repair/parts replacement?

Issues and Concerns:

1. For the application of equipment as a system, are the accessories/spare parts will be reflected/listed in the CMDN as List of Configurations will be submitted during the application?

2. Do we need to apply for a separate accessories registration for those that will be shipped as standalone? Or do we declare it during application of the equipment? For example for ultrasounds, do we need to apply a separate CMDN application for probes, transducers? Or for ECG cables/ECG cable adapters/ECG electrodes/temperature probes? These are examples of accessories that can be shipped as standalone as replacement during service.

3. as a system, the accessories/consumables will be declared and charged separately. For standalone, are we required to have the part/component (non-registrable) registered, especially those for replacement? How do we import them?

a. Products such as X-ray, MRI, CT-Scan, Imaging and Ultrasound devices are different from Class A in terms of their configuration or components. Please clarify whether accessories/consumables which is part of the system can be submitted in ONE application and ONE Certificate. Or should we submit each of these accessories separately from the main device. SEPARATE

Issues and Concerns:

Is the entire FDA Circular applying to IVD products?

Annex A has its limited type of IVD product classification. What about other products like chemistry, hematology, ELISA and control reagents?

For verification to the one who raised this question.

Issues and Concerns:

Will FDA issue a certification for the non-regulated products to present to our stakeholders or tenders and BOC to avoid presenting all types of FDA circulars every time we transact with them? NO

In case you paid 3K a fess for 2 years and we decided to give up the product less than 2 years, can we refund the fee? No.

OFFICIAL DAY OF SUBMISSION – I am aware that this Memo needs to take effect 15 days after its publication in general circulation before they start accepting the CMDN application of Classes B, C & D devices. But my question is what is their estimated timeline to implement? And will FDA send arrange a virtual "Kapihan" regarding this. Just what they did last year (February 2020) before FDA Circular 2020-001 take effect.

Issues and Concerns:

validity of the CMDN for Classes B,C,D is provided but the COE for Classes B,C,D validity is not identified,- For clarification; For radiation emitting devices, do we still follow the current guidelines CFCR for every shipment?

When we apply for CMDR 3 mos prior expiration of the CMDN, will the timeline be shorten? Or will it still follow the timeline of a regular initial registration? Initial time-line

Does this already include the machines & softwares? For clarification. YES

Provided that COEs of Classes B,C,D validity is clearly identified, if ever, can company submit/apply COEs under classes B,C,D - directly as CMDR? This will lessen the redundancy of submission and request of documentation?

Issues and Concerns:

Will the registration number change from CMDN to CMDR if Classes B, C and D will be renewed or CMDR is implemented? The change will be costly especially to importers because the manufacturers will change their template on the labels. All costs will be handled by the importer. Suggestion: Yes. Suggestion: to request for longer transition period and to exhaust the labels. For ex. 1 year on manufacturing level

Regarding the CMDR, are small products with small labelings exempted from the printing or label sticker of the national requirements? For example, needle. No enough space to put the national requirements.

Who are allowed to put label stickers on machines? By parts are being delivered for assembling to the hospitals. Suggestion: To have a TWG on labelings of the machines

Issues and Concerns:

What is the impact of the standards in hierarchy. This will be included in the letter. Is there an impact in the Declaration of Conformity?

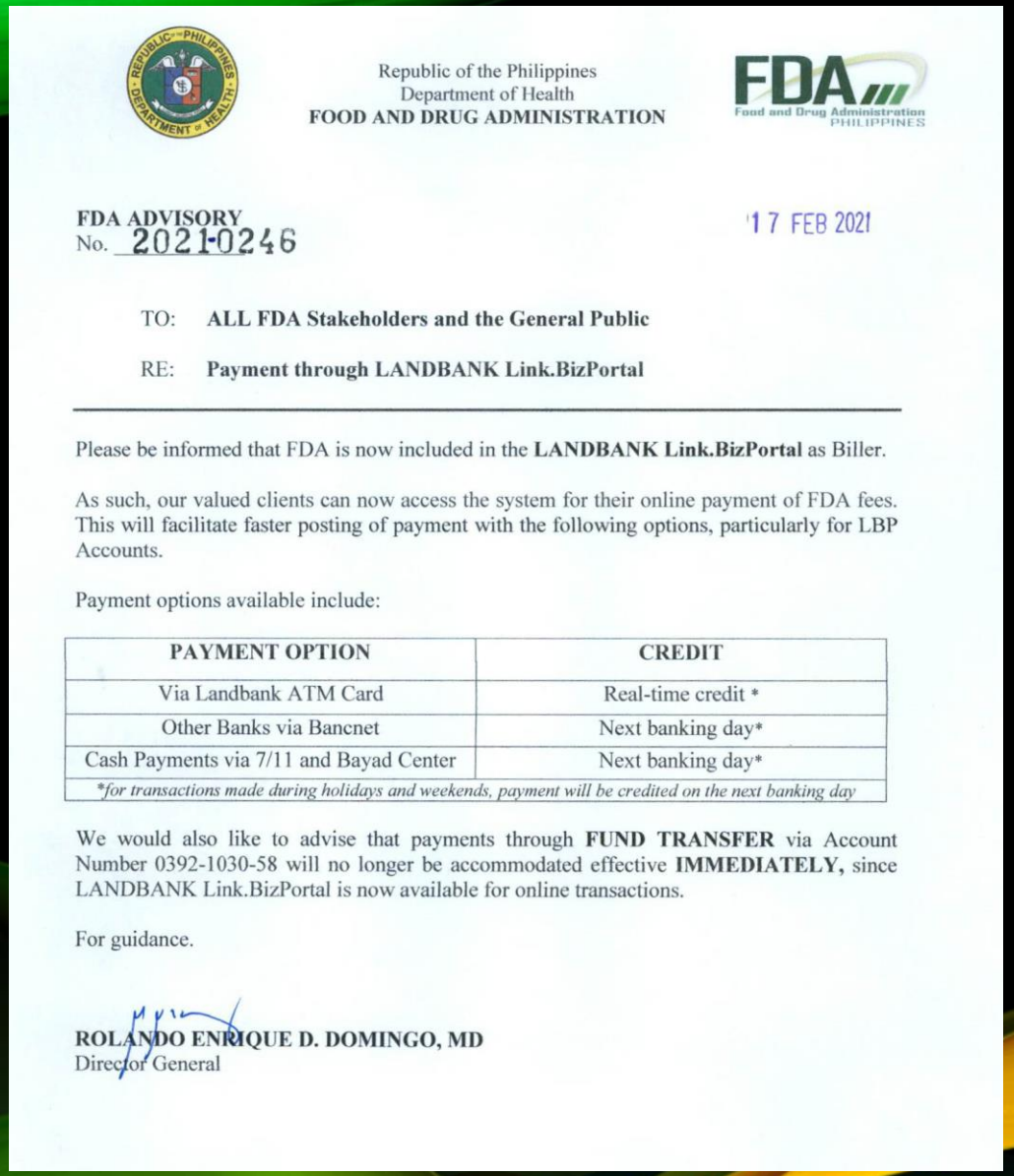
Can we use brochures or drawings instead of actual picture of the product since we usually deliver the machines/medical device directly to our customer and we also do the assembly on the site?

Issues and Concerns:

1. CDRR Automatic Renewal as announced by ARTA – automatically approved
   - Will this also take effect on CDRRHR's Automatic renewal?

2. Comment: Some members received a summons from FDA for not subjecting COVID products to RITM evaluation. RITM is still in backlog for testing.
   Request: Improve communication between FDA & RITM so that products that are in queue with RITM will not receive such FDA summons communication

Issues and Concerns:



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-0246

17 FEB 2021

TO: **ALL FDA Stakeholders and the General Public**

RE: **Payment through LANDBANK Link.BizPortal**

Please be informed that FDA is now included in the **LANDBANK Link.BizPortal** as Biller.

As such, our valued clients can now access the system for their online payment of FDA fees. This will facilitate faster posting of payment with the following options, particularly for LBP Accounts.

Payment options available include:

PAYMENT OPTION	CREDIT
Via Landbank ATM Card	Real-time credit *
Other Banks via Bancnet	Next banking day*
Cash Payments via 7/11 and Bayad Center	Next banking day*

**for transactions made during holidays and weekends, payment will be credited on the next banking day*

We would also like to advise that payments through **FUND TRANSFER** via Account Number 0392-1030-58 will no longer be accommodated effective **IMMEDIATELY,** since LANDBANK Link.BizPortal is now available for online transactions.

For guidance.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

New Payment portal

- **CMDN online submission: no option for Landbank LinkBiz portal.**

OPEN DISCUSSION

QNA

Strictly follow rules, regulations, processes

Keep updated

Read, Study

Do it the right way

THANK YOU!