Philippine Association of Medical Device
PAMDRAP
Regulatory Affairs Professionals

MINUTES OF THE MEETING

Meeting Title:	**21st GMM**		
Date:	30 July 2021	**Time:**	8:00 AM - 1:00 PM
Minutes Taker:	Documentation Committee	**Location:**	Online zoom meeting
Attendees:	Engr. Ma. Cecilia Matienzo, Engr. Helen Ocampo, Member Companies		

I. QUESTIONS AND ANSWERS

Topic: Updates of Draft Regulatory Issuances on Medical Device

- Since March 2020, the FDA-CDRRHR approved nine (9) regulatory issuances on medical device:
  - 1 – FDA Memorandum
  - 7 – FDA Circular
  - 1 – FDA Advisory
- The FDA-CDRRHR drafted twelve (12) regulatory issuances on medical device:
  - 5 – Administrative Order
  - 7 – FDA Circular
- The FDA-CDRRHR already conducted consultative workshop and public hearing for seven (7) proposed policies.
  - 3 – Administrative Order
  - 4 – FDA Circular

Please refer to the appending table for the summary of all the issuances presented.

Table 1: Summary of all the issuances presented by Engr. Helen N. Ocampo

Title	Brief Description	Issuance Type	Effectivity Date/ Current Status	Approved or Draft/ Proposed
Minimum Performance Requirements for COVID-19 Test Kits Used for SARS-CoV-2 Infection	This Circular aims to set the minimum performance requirement for COVID-19 test kits used for screening of SARS-CoV-2 infection. In addition, it aims to provide specific guidelines on the post-marketing surveillance of COVID-19 test kits issued with Special Certification by FDA.	FDA Memorandum No. 2021-009	23-Mar-2021	Approved
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 issuance aims to provide information regarding the acceptance of applications based on AO 2018-0002, validity of issued Certificate of Exemption (COE), and application fees for identified marketing authorizations. This shall guide establishments engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, and where applicable, the use, testing, promotion, advertising, or sponsorship of medical devices.	FDA Circular No. 2020-001	15-Mar-2020	Approved
Prohibition on the Online Selling of Essential Emergency Medical Supplies Beyond the Price Ceiling/Range set by Department Memorandum No. 2020-0058 and Department Memorandum No. 2020-0058-A	The said issuance is based on Department Memorandum No. 2020-0058 dated 31 January 2020 and Department Memorandum No. 2020-0058-A dated 11 February 2020 issued by the DOH declaring the price freeze of essential emergency medicines and supplies in the entire country due to COVID. The issuance prohibits the online selling of emergency medical supplies that are beyond the price ceiling/range set in the said Department Memorandum.	FDA Circular No. 2020-005	12-Mar-2020	Approved
Amendment to FDA Circular No, 2020-005 re: Prohibition on the Online Selling of Essential Emergency Medical Supplies Beyond the Price Ceiling/Range set by Department Memorandum No. 2020-0058 and Department Memorandum No. 2020-0058-A	Further amendment to include sterile gloves per pair (Size 6.5, 7, 7.5, 8) and safety goggles in the list of essential medical devices/supplies with prescribed price ceiling/range.	FDA Circular No. 2020-005-A	20-Mar-2020	Approved

Title	Brief Description	Issuance Type	Effectivity Date/ Current Status	Approved or Draft/ Proposed
Prohibition of Online Selling of Unregistered/Unnotified Medical Devices	This issuance is in line with the implementation of Joint DTI-DOH-DA AO No. 011 series of 2008 issued on 20 October 2008 and FDA Circular No. 2020-0012 dated 23 January 2020 wherein all retailers, sellers, distributors, suppliers or manufacturers engaged in electronic commerce with consumers are directed to ensure compliance with the requirements for safe and quality health products by placing in the market only FDA-authorized medical devices and supplies. Furthermore, this issuance prohibits the online selling of medical devices and supplies without the corresponding authorization (i.e. CMDN or CMDR / CPR).	FDA Circular No. 2020-010	20-Mar-2020	Approved
Interim Guidelines on the Manufacture of Personal Protective Equipment (PPE), Ventilators, and Respirators in Light of COVID-19 Situation	The Circular was issued to provide guidance to the companies and institutions signifying their interest to manufacture PPE, ventilators and respirators to address the COVID-19 public health emergency situation.	FDA Circular No. 2020-014	08-Apr-2020	Approved
Prohibition of Online Selling of FDA Certified COVID-19 Antibody Test Kits	This Circular prohibits the online selling of antibody test kits to ensure that the said products will be used by medical professionals only.	FDA Circular No. 2020-016	08-May-2020	Approved
Regulation of Face Shield	The FDA Advisory was issued to inform all concerned stakeholders and the public that face shield for community/public use is not regulated by the FDA; thus, no authorization or certification is required for the importation and distribution of face shield.	FDA Advisory No. 2020-1546	24-Aug-2020	Approved
Hierarchy of Product Standards for Medical Devices to be Complied with for Notification/Registration Purposes	The Circular aims to guide the local manufacturer, importer and/or distributor of the product standards to refer to and comply with prior to applying for a CMDN or CMDR for their medical device product.	FDA Circular No. 2021-001	04-Jan-2021	Approved

Title	Brief Description	Issuance Type	Effectivity Date/ Current Status	Approved or Draft/ Proposed
Guidelines on the Labelling Requirements for Medical Devices in the Philippines	The draft guidelines on labeling requirements for medical devices, serves to communicate safety instructions related to information to user and/ or patients, as well as to standardize the required policy, and to assure the safety, highest quality and performance of medical devices in the country. Moreover, it will strengthen the FDA mandate in regulation of medical devices.	Administrative Order (AO)	Already underwent consultative workshop. The draft AO was already posted at the FDA website for public comments.	Draft/Proposed
Rules and Regulations Governing the Issuance of an Authorization for an In-Vitro Diagnostic (IVD) Medical Device Based on the ASEAN Harmonized Technical Requirements	The proposed policy will ensure the quality, efficiency and safety of all IVD medical device marketed in the Philippines. This policy will strengthen the enforcement regulatory functions of the FDA in terms of regulating IVD medical device as stipulated in the three marching orders of the current administration.	Administrative Order (AO)	Already underwent consultative workshop and public hearing. For re-posting at the FDA website for public comments.	Draft/Proposed
Guidelines on the Conduct of Clinical Investigation of Medical Devices for Human Subjects in the Philippines	The proposed policy will ensure the safety and well-being of subjects participating in the clinical investigation of medical devices and ensure that the medical device is suitable for the population for which it is intended. It will also serve as the technical regulation implementing the international standard making it a mandatory requirement for sponsors, clinical research organizations and other entities engaged in the conduct of clinical investigation of medical devices.	Administrative Order (AO)	Already underwent consultative workshop and public hearing. For updating of the draft policy.	Draft/Proposed
Adoption of the Post Marketing Alert System (PMAS) Requirements, Annex 5 of the ASEAN Medical Device Directive (AMDD)	To establish guidelines on medical device post-marketing alerting system requirements on 1) importation and/or distribution records, 2) complaint records, 3) adverse event reporting criteria and reporting format, and 4) field safety corrective action reporting format.	Administrative Order (AO)	Already underwent consultative workshop and public hearing. The draft AO was already posted at the FDA website for public comments.	Draft/Proposed

Title	Brief Description	Issuance Type	Effectivity Date/ Current Status	Approved or Draft/ Proposed
Guidelines on the Licensing of Retailer of Medical Devices in the Philippines	This proposed issuance will provide specific guidelines supplementing the provisions of AO 2020-0017 on the licensing of retailers of medical devices. It aims to specify the establishments classified as retailers of medical devices; clarify the licensing of drug outlets which are also retailers of medical devices; provide specific requirements for and responsibilities of qualified persons of retailers of medical devices; and provide specific requirements for post-licensing inspection of retailers of medical devices.	FDA Circular	Licensing of retailers of medical devices is included in AO 2020-0017 entitled "Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing Administrative Order No. 2016-0003". Underwent public hearing, for decision on the comments received prior to posting on FDA website.	Draft/Proposed
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"	The proposed policy provides additional provisions to FDA Circular No. 2021-002. It aims to ensure the continuous supply of the above medical devices in the local market and to provide the manufacturers, importers and/or distributors of medical devices ample time to apply for CMDN.	FDA Circular	Posted on FDA website for public comments. For endorsement to FDA – Policy and Planning Service (PPS) for clearance	Draft/Proposed
Reference List of Class A Medical Devices	This issuance aims to provide guidance to concerned stakeholders about the list of medical devices classified as Class A (low risk medical devices) and help the industry to apply for the appropriate authorization such as CMDN for their products that fall under Class A classification.	FDA Circular	Endorsed to FDA – Policy and Planning Service (PPS) for clearance.	Draft/Proposed
Banning of all Mercury-Containing Thermometers, Sphygmomanometers, Dental Amalgam Capsules and Liquid Mercury for Use in Dental Restorative Purposes	This Circular aims to totally phase out the manufacture, distribution, importation, exportation, sale, offer for sale, donation, transfer, and where applicable, the use, promotion, advertising, or sponsorship of mercury-containing thermometers and sphygmomanometers along with liquid mercury and dental amalgam capsules.	FDA Circular	For preparation of summary of comments based on the conducted public hearing as per FDA Memo No. 2021-012.	Draft/Proposed

Title	Brief Description	Issuance Type	Effectivity Date/ Current Status	Approved or Draft/ Proposed
Licensing of manufacturers and distributors (importers, exporters, and/or wholesalers) of equipment or devices used for treating sharps, pathological and infectious wastes	This Circular aims to supplement the provisions of AO 2020-0017 providing for the announcement on the receiving of application for LTOs of the covered establishment and other relevant information regarding the implementation of the AO.	FDA Circular	For preparation of draft FDA Circular.	Draft/Proposed
Licensing of manufacturers and distributors (importers, exporters, and/or wholesalers) of water treatment devices/systems including installer of water treatment system providing installation, repair and maintenance services to operators of water refilling stations and other users of water treatment systems	This Circular aims to supplement the provisions of AO 2020-0017 providing for the announcement on the receiving of application for LTOs of the covered establishment and other relevant information regarding the implementation of the AO.	FDA Circular	For review of draft FDA Circular.	Draft/Proposed
Amendment of Administrative Order 2018-0002 “Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements”	There are some provisions on the AO that need to be revised and updated.	Administrative Order (AO)	For preparation of draft amendment of AO.	Draft/Proposed
Posting of the List of VAT-Exempt Products Pursuant to Republic Act No. 11534, Otherwise Known as the “Corporate Recovery and Tax Incentives for Enterprises (CREATE) Act”	This Circular intends to provide the guidelines in the posting of the List of VAT-Exempt Products in the place of business of establishments engaged in the manufacture, trade, distribution, and sale of VAT-Exempt health products.	FDA Circular	For clarification with FDA – Legal Services Support Center (LSSC) if medical devices should be covered by the proposed issuance.	Draft/Proposed

Table 2: Q&A with Engr. Cecile Matienzo

Question:	Answer:
Since the draft addendum to FDA Circular 2021-002 is not yet released, can we still import medical devices (Class B, C and D) not listed in Annex A using our LTO?	Yes, however, please take note that the basis is the FDA Circular 2021-0002 and not its addendum hence, we should already start applying.
Is it still required to submit notarized application form in CMDN?	Since submission of CMDN is now electronic, the application form is also now online. Upon submitting the form, you are already affirming that all information provided is true and correct. Whatever is indicated on the online form will automatically be reflected on the CMDN. Therefore, any errors on the issued certificate will be considered as a variation and not a correction.
Will there be extension for COVID-19 certificates?	If ever there will be an extension, it will be announced a day before.
We have an existing IPO certificate under Class 9 and 11. The product that we want to apply is under Class 9. Are we required to apply again for the brand name considering it is already our property?	IPO gives authority to use the brand name based on the goods that you applied for. CDRRHR checks whether the goods being applied with that specific brand name is covered in the issuance provided by IPO. When submitting to CDRRHR, it is better to submit the IPO certificate and the attachment listing down the goods.
Error in e-Services LTO renewal	FDA is currently migrating from e-portal to e-services. If there is an error, just email CDRRHR.
File size limitation of 2MB in uploading	Multiple file uploads with 2MB per file can be accepted. Eventually, FDA will migrate to e-Services which will have bigger capacity.
To whom should letter of intent for CDRRHR be addressed?	Can be addressed either to FDA CDRRHR Director or FDA Director General
For equipment, can we apply 1 CMDN application for the whole system? If yes, can all codes be reflected in CMDN?	For system applications, under the reference code/size/reference number/colors field, you may input the following: **Model** 1,2,3 <enter or space> **Component:** Component 1 (description), Component 2 (description), Component 3 (description), etc. **Accessories:** Accessories 1 (description), Accessories 2 (description), etc. **Consumable:** Consumable 1 (description), Consumable 2 (description), etc. **Optional accessories** should be applied separately.
For deficiency questions of systems, we are asked to clarify whether it will be distributed or imported separately or together with the system.	That question will no longer ensue. However, make sure that the CMDN number or CMDR number will be sticked/placed on the individual component. PHP 7,575 will be the registration fee for 5 years.

Can the CCTIT document be used as additional to make the legal documents such as FAA, ISO certificate, DOC valid?	CDRRHR to further check document verification process in China. CDRRHR does not require authentication of documents rather, they only require a declaration from the manufacturer that documents submitted are true and correct. Note that the declaration should be to a specific document (for example, with the ISO cert. number, expiry date must be stated in the declaration).
Estimate date in when IVD guidelines will be released	Approval will come from DOH since it will be an Administrative Order. Hopefully before the end of the year, it will be approved.
Declaration of shelf-life (equipment has service life)	CDRRHR is working on an instructional video. For shelf-life for equipment, there will be a specific format.
Is software included in CMDN?	Yes, for standalone software. For installed software, once the equipment is applied/registered, the software is also included.
Are we required to apply for variation for upgrades of software?	Yes, it will be under variation application as long as it is minor upgrade. Variation Guidelines will also be amended to capture software upgrades.
List of Class A Medical Devices - Electric toothbrush, batteries, rechargeable, lithium, replacement	They will be removed from the list. Electronic toothbrush will be removed until it is declared in ASEAN whether to regulate or not. Standalone batteries are considered as spare part.
Do we need to submit labels of peripherals or non-medical device (printers, monitors, etc.) when applying for system?	Yes. They become part of the system.
Specific position of country-specific labels	Mock up labels can be accepted
Schedule of QPIRA	For LTO applications, licensing seminar is mandatory not QPIRA. By last quarter of the year, FDA might conduct one licensing seminar (online)
Training for new regulations of medical device	CDRRHR will not provide lectures until all regulation loopholes/issues are addressed.
Labeling of software	For software not sold physically (i.e. available thru online only), the screenshot of the interface should be submitted for post-marketing surveillance.
Classification of Medical Device	Provide justification (indicate the rule, intended use, special feature, and the supporting classification, etc.) and CDRRHR will further check. Refer also to FDA Circular 2020-001 for the reference Classification of some devices.
Patient circuits – there are many configurations (adult, pedia) – how should this be registered/payment?	• CMDN – no single application, multiple CMDN; the system is not capable to produce multiple CMDNs. • CMDR – there is single application, multiple CMDR

	Single application for multiple CPR for CMDR is only a horizontal condition. Examples: Scenario 1 - Patient circuit for Pedia, Neonate, Adult (Changes in size) - This can be single application, multiple CMDRs Scenario 2 - Pedia has other configurations (Model A, Model B, Model C) - Neonate has other configurations (Model A, Model B) - Adult has other configurations (Model A, Model B, Model C) Note that these cannot be under single application, multiple CPR. However, you can file for one application for "Pedia" and CDRRHR will issue multiple CPRs for the different configurations.
Regarding the high flow nasal cannula, it is not yet included in the ISO certificate since TUV has not yet audited. Can IEC be accepted instead?	IEC is not accepted because it is a standard and not a certification body. ISO certificate should be submitted. If the cannula is intended as support of oxygen and connected to a ventilator, it is registrable and under the ventilator. If the function is to humidify the oxygen, it is non-registrable.
Tubing – when is it considered as Class A or Class B?	Refer to FDA Circular 2020-001-A
With the upcoming ECQ, will the agency consider accepting commitment letter for notarized documents?	FDA will issue advisory.
Medical device cleaner – detergent	Detergent is not a medical device Disinfectant is a medical device
With regards to orthopedic implants - one product family and all variety of plates but implanted in different anatomy, can it be submitted under single application?	It should be separate applications since they have different intended use (different anatomy). Different configurations for a single indication (one anatomy) can be under single application.
Is CSDT synopsis required for CMDR?	CSDT synopsis is the summary content and it is required.
Can we change position of the label sticker bearing the registration number with no change of information?	Person who raised the question was asked to email CDRRHR.

Mock-up sticker is placed in front while, the actual sticker is placed at the side. CPR is already approved.	
Is Test Report (Calibration test, overall performance test) issued by Philippine National Metrology Laboratory is equivalent for Certificate of Conformity on the aspect of manufacturer relating to metrology for devices with measuring functions accepted?	Yes.
Are accessories sold individually required to be registered separately?	Can follow the format explained previously. Optional accessories should be applied separately.
Some countries do not notarize the attestation letter or letter of authenticity. However, on the actual document being notarized, it is already indicated that this is already attested to be true and correct. Is this acceptable?	Send MCCM a copy
On PMAS, will we be required to report to FDA all Adverse Events or Field Safety Corrective Action (FSCA) outside the Philippines?	If the product is registered in Philippines but the AE did not happen here locally, it can be submitted to CDRRHR as FYI. In ASEAN, the platform for information sharing among Health Authorities is not yet in place.
For PMS, can we submit summary reporting of AE or FSCA or do we need to report each time	Wait for the guidelines to be released.

Minutes taker: Giselle Regio

*Disclaimer: Minutes of the meeting, the questions and answers are based on what the minutes-takers have heard and captured. Those written shall not deemed as final.