Center for Device Regulation, Radiation Health and Research (CDRRHR)

Updates of Draft Regulatory Issuances on Medical Device

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CDRRHR latest approved issuances

Title: **Minimum Performance Requirements for COVID-19 Test Kits Used for SARS-CoV-2 Infection**

Brief Description:

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.

CDRRHR latest approved issuances

Title: **Minimum Performance Requirements for COVID-19 Test Kits Used for SARS-CoV-2 Infection**

Issuance Type: Issued as **FDA Memorandum No. 2021-009**

Effectivity Date: **23 March 2021**

CDRRHR latest approved issuances

Title: **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"**

Brief Description:

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.

CDRRHR latest approved issuances

Title: **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"**

Issuance Type: Issued as **FDA Circular No. 2020-001**

Effectivity Date: **15 March 2020**

CDRRHR latest approved issuances

Title: **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**

Brief Description:

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.

CDRRHR latest approved issuances

Title: **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**

Issuance Type: Issued as **FDA Circular No. 2020-005**

Effectivity Date: **12 March 2020**

Food and Drug Administration PHILIPPINES

CDRRHR latest approved issuances

Title: **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**

Brief Description:

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.

CDRRHR latest approved issuances

Title: **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**

Issuance Type: Issued as **FDA Circular No. 2020-005-A**

Effectivity Date: **20 March 2020**

FDA Food and Drug Administration PHILIPPINES

CDRRHR latest approved issuances

Title: **Prohibition of Online Selling of Unregistered/Unnotified Medical Devices**

Brief Description:

This issuance is in line with the implemention 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).

CDRRHR latest approved issuances

Title: **Prohibition of Online Selling of Unregistered/Unnotified Medical Devices**

Issuance Type: Issued as **FDA Circular No. 2020-010**

Effectivity Date: **20 March 2020**

CDRRHR latest approved issuances

Title: **Interim Guidelines on the Manufacture of Personal Protective Equipment (PPE), Ventilators, and Respirators in Light of COVID-19 Situation**

Brief Description:

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.

CDRRHR latest approved issuances

Title: **Interim Guidelines on the Manufacture of Personal Protective Equipment (PPE), Ventilators, and Respirators in Light of COVID-19 Situation**

Issuance Type: Issued as **FDA Circular No. 2020-014**

Effectivity Date: **8 April 2020**

CDRRHR latest approved issuances

Title: **Prohibition of Online Selling of FDA Certified COVID-19 Antibody Test Kits**

Brief Description:

This Circular prohibits the online selling of antibody test kits to ensure that the said products will be used by medical professionals only.

CDRRHR latest approved issuances

Title: **Prohibition of Online Selling of FDA Certified COVID-19 Antibody Test Kits**

Issuance Type: Issued as **FDA Circular No. 2020-016**

Effectivity Date: **8 May 2020**

CDRRHR latest approved issuances

Title: **Regulation of Face Shield**

Brief Description:

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.

CDRRHR latest approved issuances

Title: **Regulation of Face Shield**

Issuance Type: Issued as **FDA Advisory No. 2020-1546**

Dated: **24 August 2020**

CDRRHR latest approved issuances

Title: **Hierarchy of Product Standards for Medical Devices to be Complied with for Notification/Registration Purposes**

Brief Description:

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.

CDRRHR latest approved issuances

Title: **Hierarchy of Product Standards for Medical Devices to be Complied with for Notification/Registration Purposes**

Issuance Type: Issued as **FDA Circular No. 2021-001**

Dated: **4 January 2021**

Draft/Proposed Policies by CDRRHR

Title: **Guidelines on the Labelling Requirements for Medical Devices in the Philippines**

Brief Description:

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.

Draft/Proposed Policies by CDRRHR

Title: **Guidelines on the Labelling Requirements for Medical Devices in the Philippines**

Issuance Type: Administrative Order (AO)

Current Status: Already underwent consultative workshop. The draft AO was already posted at the FDA website for public comments.

Draft/Proposed Policies by CDRRHR

Title: **Rules and Regulations Governing the Issuance of an Authorization for an In-Vitro Diagnostic (IVD) Medical Device Based on the ASEAN Harmonized Technical Requirements**

Brief Description:

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.

Draft/Proposed Policies by CDRRHR

Title: **Rules and Regulations Governing the Issuance of an Authorization for an In-Vitro Diagnostic (IVD) Medical Device Based on the ASEAN Harmonized Technical Requirements**

Issuance Type: Administrative Order (AO)

Current Status: Already underwent consultative workshop and public hearing. For re-posting at the FDA website for public comments.

Draft/Proposed Policies by CDRRHR

Title: **Guidelines on the Conduct of Clinical Investigation of Medical Devices for Human Subjects in the Philippines**

Brief Description:

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.

Draft/Proposed Policies by CDRRHR

Title: **Guidelines on the Conduct of Clinical Investigation of Medical Devices for Human Subjects in the Philippines**

Issuance Type: Administrative Order (AO)

Current Status: Already underwent consultative workshop and public hearing. For updating of the draft policy.

Draft/Proposed Policies by CDRRHR

Title: **Adoption of the Post Marketing Alert System (PMAS) Requirements, Annex 5 of the ASEAN Medical Device Directive (AMDD)**

Brief Description:

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.

Draft/Proposed Policies by CDRRHR

Title: **Adoption of the Post Marketing Alert System (PMAS) Requirements, Annex 5 of the ASEAN Medical Device Directive (AMDD)**

Issuance Type: Administrative Order (AO)

Current Status: Already underwent consultative workshop and public hearing. The draft AO was already posted at the FDA website for public comments.

Draft/Proposed Policies by CDRRHR

Title: **Guidelines on the Licensing of Retailer of Medical Devices in the Philippines**

Brief Description:

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.

Draft/Proposed Policies by CDRRHR

Title: **Guidelines on the Licensing of Retailer of Medical Devices in the Philippines**

Issuance Type: FDA Circular

Current Status: 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 Policies by CDRRHR

Title: **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"**

Brief Description:

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.

Draft/Proposed Policies by CDRRHR

Title: **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"**

Issuance Type: FDA Circular

Current Status: Posted on FDA website for public comments. For endorsement to FDA – Policy and Planning Service (PPS) for clearance

Draft/Proposed Policies by CDRRHR

Title: **Reference List of Class A Medical Devices**

Brief Description:

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.

Draft/Proposed Policies by CDRRHR

Title: **Reference List of Class A Medical Devices**

Issuance Type: FDA Circular

Current Status: Endorsed to FDA – Policy and Planning Service (PPS) for clearance.

Draft/Proposed Policies by CDRRHR

Title: **Banning of all Mercury-Containing Thermometers, Sphygmomanometers, Dental Amalgam Capsules and Liquid Mercury for Use in Dental Restorative Purposes**

Brief Description:

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.

Draft/Proposed Policies by CDRRHR

Title: **Banning of all Mercury-Containing Thermometers, Sphygmomanometers, Dental Amalgam Capsules and Liquid Mercury for Use in Dental Restorative Purposes**

Issuance Type: FDA Circular

Current Status: For preparation of summary of comments based on the conducted public hearing as per FDA Memo No. 2021-012.

Draft/Proposed Policies by CDRRHR

Title: **Licensing of manufacturers and distributors (importers, exporters, and/or wholesalers) of equipment or devices used for treating sharps, pathological and infectious wastes**

Brief Description:

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.

Draft/Proposed Policies by CDRRHR

Title: **Licensing of manufacturers and distributors (importers, exporters, and/or wholesalers) of equipment or devices used for treating sharps, pathological and infectious wastes**

Issuance Type: FDA Circular

Current Status: For preparation of draft FDA Circular.

Draft/Proposed Policies by CDRRHR

Title: **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**

Brief Description:

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.

Draft/Proposed Policies by CDRRHR

Title: **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**

Issuance Type: FDA Circular

Current Status: For review of draft FDA Circular.

Draft/Proposed Policies by CDRRHR

Title: **Amendment of Administrative Order 2018-0002 "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements"**

Brief Description:

There are some provisions on the AO that need to be revised and updated.

Draft/Proposed Policies by CDRRHR

Title: **Amendment of Administrative Order 2018-0002 "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements"**

Issuance Type: Administrative Order (AO)

Current Status: For preparation of draft amendment of AO.

Draft/Proposed Policies by CDRRHR

Title: **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"**

Brief Description:

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.

Draft/Proposed Policies by CDRRHR

Title: **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"**

Issuance Type: FDA Circular

Current Status: For clarification with FDA – Legal Services Support Center (LSSC) if medical devices should be covered by the proposed issuance.

Summary

Since March 2020, the FDA-CDRRHR approved nine (9) regulatory issuances on medical device:

- **1 – FDA Memorandum**
- **7 – FDA Circular**
- **1 – FDA Advisory**

Summary

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**

THANK YOU!

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Food and Drug Administration
PHILIPPINES