FDA
Food and Drug Administration
PHILIPPINES

• PAMDRAP 24th GMM 2022

MEDICAL DEVICE REGULATORY UPDATE

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December 2, 2022

TOPICS:

- What's new?
- What's up?
- What's your Question?

What's new?

• Establishment License

License to Operate as Retailer already mandatory based on FDA Circular 2022-007: Use of e-Services for Retailers (September 9, 2022)

Reference Guidelines on Retailers:
FDA Circular No. 2021-021 – Guidelines (October 7, 2021)
FDA Advisory 2021-2634 – Pilot Implementation (Nov 2, 2021)

• Product Registration

Abridged Approval
FDA Circular 2022-002: (September 27, 2022)

• General Guidelines

A. All applications for registration of medical devices approved by the NRA of any ASEAN member country under the AMDD-CSDT requirements shall have an abridged processing by the FDA through the Center for Device Regulation, Radiation Health, and Research (CDRRHR) provided that the medical device being applied to the FDA is the same medical device that has been approved by the said reference NRA.

B. The FDA abridged processing of application for registration shall only be applicable to Class B, C and D medical devices.

C. In compliance with AO No. 2018-0002, the applicant shall submit complete legal and applicable technical requirements when applying for registration of medical devices. The technical requirements to be submitted shall be the latest and the same as those submitted to the reference NRA where the CPR was issued.

D. FDA reserves the right to forego abridged processing, as may be warranted, in case of any of following circumstances:
   1. Receipt of any negative report on the medical device from other countries;
   2. When there are conflicting views or assessments from NRAs of other ASEAN countries on the same medical device; and
   3. Other circumstances that may entail the FDA's careful evaluation of medical device applications for authorization.

• Procedural Guidelines

A. Applicant shall submit all the legal and technical requirements pursuant to the provisions of AO No. 2018-0002. The Notarized Application Form (see Annex A) shall indicate the following statements:
   1. Attestation from the applicant that the product details including the CSDT technical documentation submitted to FDA are exactly the same as the product details and that the CSDT technical documentation are the latest filed /approved dossier by the reference NRA; and
   2. Acknowledgement and concurrence that in the event that there is an unauthorized change in the product details and CSDT documentation:
      a. The FDA shall automatically suspend the License to Operate and/or Certificate of Medical Device Registration of the product;
      b. The applicant shall voluntarily recall the product from the market in accordance with the FDA guidelines on product recall; and
      c. The applicant shall indemnify and/or hold FDA free and harmless against any and all third party claims and/or actions pertaining to the above unauthorized change(s).

B. The application shall still be subjected to pre-assessment during which the FDA through the CDRRHR shall check on the completeness of the legal and technical requirements. Only those applications that complied with the pre-assessment shall be issued an Order of Payment.

C. The legal requirements shall undergo compliance evaluation while the technical requirements shall not be subjected to technical review by the CDRRHR except for the labeling requirements.

D. The CDRRHR shall verify the submitted CPR from the reference NRA.

E. The labelling requirements shall be evaluated based on those prescribed in AO No. 2018-0002 and any subsequent future labeling issuances.

F. The turnaround time for the abridged process shall be thirty (30) working days which shall start upon receipt of the proof of payment by the CDRRHR.

Variation:

- **Center Memorandum 2015-001 dated January 14, 2015**

- **FDA Circular 2017-014 dated 15 December 2017**

Will be amended into minor and major variation:

Updates on In-vitro Diagnostic AO

This is already forwarded to DOH for final review and approval of the Secretary of Health or the OIC

What's up?

Type of Issuance	TITLE	STATUS
AO	Adoption of the Post Marketing Alert System (PMAS) Requirements, Annex 5 of the ASEAN Medical Device Directive (AMDD)	Reendorsed to DOH for review/approva
FDA Circular	Banning of all Mercury-Containing Thermometers, Sphygmomanometers, Dental Amalgam Capsules and Liquid Mercury for Use in Dental Restorative Purposes	Approved as FDA Circular
AO	Rules and Regulations Governing the Issuance of an Authorization for an In-Vitro Diagnostic Medical Device (IVD)	Endorsed to DOH for review/approval

Type of Issuance	TITLE	STATUS
FDA Circular	Specific List of Registrable In Vitro Diagnostic Medical Devices (IVDs) and Revised Technical Requirements for Registration of COVID-19 Test Kits	The title was revised to "List of In Vitro Diagnostic Medical Devices (IVDs) that are Required to Undergo Performance Validation or Technical Review by FDA-Common Services Laboratory/National Reference Laboratory Prior to FDA Registration This is for release for endorsement to LSCC and PPS for clearance once the proposed AO on IVD is approved
FDA Circular	Requirements for the Issuance of a Special Certification for Emerging New In Vitro Diagnostic Medical Devices Used for Detection and Diagnosis of SARS-CoV-2 Infection	For finalization of the draft policy
FDA Circular	Good Storage and Distribution Practices for Medical Devices	Proposed policy has been finalized; documents are being prepared for clearance of PPS and LSSC
AO	Revised Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements	For revision of Draft AO to align the provisions with the AO on IVD; Undergoing RIA

Type of Issuance	TITLE	STATUS
FDA Circular	Guidelines on the Labelling Requirements for Medical Devices in the Philippines	To be released as FDA Circular. Will await the approval of the Revised Guidelines Governing the Issuance of an Authorization for a Medical device based on the ASEAN Harmonized Technical Requirements Repealing AO No. 2018-0002
AO	Guidelines on the Conduct of Clinical Investigation of Medical Devices for Human Subjects in the Philippines	Final draft is for review within CDRRHR

What's your Question?

THANK YOU