Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2022-008

27 SEP 2022

SUBJECT : **Abridged Processing of Application for Registration of Medical Devices Approved by the National Regulatory Authority of Any ASEAN Member Country**

I. RATIONALE

Republic Act (RA) No. 9711 otherwise known as the "Food and Drug Administration (FDA) Act of 2009" states that it is a policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed, directed and designed to: (a) protect and promote the right to health of the Filipino people; and (b) help establish and maintain an effective health products regulatory system.

Further, RA No. 11032 or the "Ease of Doing Business and Efficient Government Service Delivery Act of 2018" mandates all offices and agencies that provide government services to evaluate and improve their transaction systems and procedures and reengineer the same if deemed necessary to reduce bureaucratic red tape and processing time.

In pursuit of providing better and efficient government service delivery system, the Food and Drug Administration (FDA) supports the implementation of good reliance practices (GRelP) in the regulation of medical device products.

Annex 10 entitled "Good reliance practices in the regulation of medical products: high level principles" of the World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations: Fifty fifth report emphasized that reliance allows national regulatory authorities (NRAs) to make the best use of resources, build expertise and capacity, increase the quality of their regulatory decisions, reduce duplication of effort and, ultimately, promote timely access to safe, effective and quality assured medical products.

On 26 January 2018, Department of Health Administrative Order (AO) No. 2018-0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements" was issued to provide guidelines on the documentary requirements for the registration of medical devices and to align the registration requirements to the ASEAN Common Submission Dossier Template (CSDT). This is in line with the implementation of the CSDT among the ASEAN member countries pursuant to the provisions of the ASEAN Medical Device Directive (AMDD).

To carry out GRelP in the regulatory processes of medical device products consistent with the provisions of the above-mentioned laws and AO, this FDA Circular is hereby issued.

II. OBJECTIVE

This Circular aims to provide guidelines on the abridged processing of application for registration of medical devices with product approval issued by the NRA of any ASEAN member country under the AMDD-CSDT requirements.

III. SCOPE

This Circular shall apply to Class B, C and D medical devices that are covered under AO No. 2018-0002, with product approval issued by the NRA of any ASEAN member country under the AMDD-CSDT requirements, and which are to be imported, distributed and sold in the Philippines. This issuance shall not cover medical devices with issued Certificate of Product Registration (CPR) based on abridged approval in other countries outside the ASEAN. Furthermore, in consonance with AO No. 2018-0002, this Circular shall not cover in vitro diagnostic and refurbished medical devices.

IV. DEFINITION OF TERMS

The terms used in this Circular shall have the meaning as defined in R.A. 9711 and its Implementing Rules and Regulations, and related laws and regulations. However, for clarity and for purposes of these guidelines, the following terms are defined as follows:

A. **Abridged processing** refers to the expedited evaluation process of the FDA for registration of medical devices approved by the NRA of any ASEAN member country under the AMDD-CSDT requirements. This shortened evaluation process is based on application of reliance.

B. **ASEAN** refers to the Association of Southeast Asian Nations.

C. **Reliance** refers to the act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.

D. **Same medical device** means that the medical device submitted to the FDA is exactly and consistently the same as in all its brand/model/manufacturer and/or technical documentations (such as but not limited to design; raw materials and composition; intended use; instruction for use; finished product specification; manufacturing including sterilization process; and supporting studies of safety, performance and quality) as the medical device approved by the reference NRA.

E. **Reference national regulatory authority (NRA)** refers to the FDA counterpart regulatory authority of any ASEAN member country which approves medical devices based on the AMDD-CSDT requirements.

V. 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.

VI. 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.

VII. SEPARABILITY CLAUSE

In the event that any provision or part of this Circular is declared invalid, the other provisions hereof shall not be affected.

VIII. EFFECTIVITY

This Circular shall take effect fifteen (15) days after its publication in the Official Gazette or in any newspaper of general circulation and upon filing with the University of the Philippines Law Center – Office of the National Administrative Register.

DR. SAMUEL A. ZACATE
Director General

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