Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

**FDA CIRCULAR**
No. _____

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

## I. RATIONALE

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.

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.

Furthermore, RA No. 11032 or the "Ease of Doing Business and Efficient Government Service Delivery Act of 2018" mandated 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.

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 and notification of medical devices with product approval issued by the NRA of any ASEAN member country under the AMDD-CSDT requirements.

## III. SCOPE

This issuance shall apply to medical devices covered under AO No. 2018-0002 that are to be imported, distributed and sold in the Philippines. In consonance with the said AO, 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/notification 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 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 or the counterpart regulatory authority of the ASEAN member country.

## V. GUIDELINES

A. All applications for registration and notification 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 reference NRA of the ASEAN member country.

B. In compliance with AO No. 2018-0002, the applicant shall submit complete legal and applicable technical requirements when applying for registration/notification of medical devices. The technical requirements to be submitted shall be the same as those submitted to the reference NRA of the ASEAN member country where the Certificate of Product Registration (CPR) was issued.

C. CPRs issued based on abridged approval in other countries outside the ASEAN are not qualified in the FDA abridged processing set forth in this Circular.

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

E. 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. All applicants shall submit all the legal and technical requirements pursuant to the provisions of AO No. 2018-0002. The Notarized Application Form shall indicate the following statements:
   1. Attestation from the applicant the product details including the CSDT technical documentation are exactly the same as the product details and CSDT technical documentation submitted in the ASEAN counterpart; 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 may automatically suspend the LTO and/or CMDR or CMDN of the product;
      b. The applicant shall voluntarily recall the product from the market; 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. All applications shall still be subjected to pre-assessment. During the pre-assessment, 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 of the ASEAN member country.

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

## 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 an Official Gazette or in a newspaper of general circulation and upon filing three (3) certified true copies with the University of the Philippines Law Center – Office of the National Administrative Register.

**FRANCISCO T. DUQUE III, MD, MSc**
Secretary of Health

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