Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

18 NOV 2021

FDA ADVISORY
No. 2021-3084

TO: **IMPORTERS, DISTRIBUTORS AND TRADERS OF MEDICAL DEVICES AND OTHERS CONCERNED**

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

The Food and Drug Administration (FDA) supports the implementation of good regulatory reliance practices for increased efficiency of regulatory systems which will result to faster access to safe, quality and effective medical devices.

In line with this and in consideration of the harmonized ASEAN Common Submission Dossier Template (CSDT) under the ASEAN Medical Device Directive (AMDD), the FDA shall have an abridged processing of application for registration/notification of medical devices approved by the Regulatory Authority of any ASEAN member country under the AMDD-CSDT requirements. However, the company still needs to submit all the legal and applicable technical requirements pursuant to 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 expedited review process shall take effect on 25 November 2021.

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN: 20211118081000