



22 JUL 2019

**FDA MEMORANDUM CIRCULAR**  
No. 2019-005

**TO: ALL PARTICIPATING LICENSED IMPORTERS AND DISTRIBUTORS OF MEDICAL DEVICES**

**SUBJECT: Pilot Study on the Implementation of Department of Health Administrative Order (AO) No. 2018-0002 re: Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements**

## **I. BACKGROUND AND OBJECTIVE**

Section IX. Phases of Implementation of AO 2018-0002 entitled “Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements” provides that the requirement of registration for all medical devices not indicated in the list of registrable medical devices (FDA Memorandum Circular No. 2014-0005) shall be implemented in phases. These phases of implementation include:

Phase 2: Registration of Class D medical devices

Phase 3: Registration of Class B and Class C medical devices

To assess the capability of the medical device companies in complying with the technical requirements for initial registration of Class B, Class C and Class D medical devices based on the ASEAN Harmonized Technical Requirements in preparation for the above-mentioned phases of implementation of AO 2018-0002, the Food and Drug Administration (FDA) – Center for Device Regulation, Radiation Health and Research – Licensing and Registration Division (CDRRHR-LRD) shall conduct a Pilot Study. The Pilot Study shall be participated by medical device marketing authorization holders (MAH) selected by CDRRHR-LRD based on the following criteria: 1) licensed importer and/or distributor of randomly selected Class B, C and D medical device and 2) willingness to participate in the said study.

In line with this, the commencement of filing of application for the Pilot Study is hereby promulgated.

## **II. SUBMISSION PROCESS**

1. Filing of application shall be based on the existing policy under FDA Circular No. 2016-010 re: New Procedure for Filing of Application for Medical Device Product Registration and Medical Device Establishment License and its amendment.

2. Participating company shall be allowed to submit only one application for the assigned product under the Pilot Study. However, in the event that the medical devices are not well represented, the CDRRHR-LRD shall enjoin the participating companies to submit another application.
3. The application form to be used shall be the form indicated in Annex I of AO 2018-0002.
4. Registration fee shall follow the existing guidelines on fees and charges at the time of the submission of the application.
5. The checklist of requirements shall be in accordance with AO 2018-0002.
6. The participating company shall attach the letter of invitation to participate in the Pilot Study.


### **III. REVIEW AND APPROVAL OF APPLICATION**

1. The period for the technical review of the submitted documents shall be six (6) to nine (9) months.
2. In case there are technical verification required, dialogue between the CDRRHR-LRD and representative of the company shall be allowed for mutual comprehension.
3. A Certificate of Product Registration (CPR) shall be issued by CDRRHR after complying with the requirements with AO 2018-0002; otherwise, the application shall be disapproved.
4. All approved CPRs shall be issued with corresponding new series of Medical Device Registration numbers.

### **IV. IMPLEMENTATION OF THE PILOT STUDY**

All participating companies can submit their application relative to the Pilot Study starting 19 August 2019 following the existing schedule of filing of application.

This Memorandum Circular shall take effect immediately upon approval and upon posting at the FDA website.

  
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Undersecretary of Health  
Officer-in-Charge, Director General



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