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NEW PROCEDURE IN THE APPLICATION OF THE VARIATION OF CERTIFICATE OF PRODUCT REGISTRATION FOR MEDICAL DEVICES

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I. BACKGROUND

Republic Act (RA) No. 3720 (Food, Drugs and Devices and Cosmetics Act), as amended by RA No. 9711 (Food and Drug Administration Act of 2009) were all enacted to establish an effective regulatory system for the authorization, registration and monitoring of health products.

Section 5 (e) of RA No. 9711 mandated the FDA to issue certificates of compliance with technical requirements to serve as basis for the issuance of appropriate authorization and spot-check for compliance with regulations regarding operation of manufacturers, importers, exporters, distributors, wholesalers, drug outlets, and other establishments and facilities of health products.

FDA issues Certificate of Product Registration (CPR) to health products prior to importation and distribution. If there are amendments, changes or variation in the issued CPR, the companies are required to file a variation application.

In the light of increased volume of variation applications, FDA recognizes the importance to improve its effectiveness and efficiency. To address volume of variation applications, there is a need to improve the procedure in this application.

II. SCOPE

This circular shall cover all medical device industry which has variation, amendment or changes in the CPR issued by the Center for Device Regulation, Radiation Health, and Research (CDRRHR).

III. DETAILS

The filing of application shall be guided by FDA Circular No. 2016-010. However, the new procedures in the application for variation of medical device product registration to be implemented by the Licensing and Registration Division of CDRRHR shall be as follows:

1. The applicant can file for only one (1) variation application in single transaction, regardless of the number of issued Certificate of