



15 DEC 2017

FDA CIRCULAR
No. 2017-014

TO: ALL MEDICAL DEVICE COMPANIES

SUBJECT: New Procedure in the Application of the Variation of Certificate of Product Registration for Medical Devices

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 Product Registration (CPR). The nature of changes that shall be considered are as follows:
 - change of legal manufacturer, exporter and manufacturer provided that the name and address of legal manufacturer, exporter and manufacturer are the same for all CPRs to be amended
 - change of importer and distributor
 - change of location and/or address of importer and distributor
 - change of address of manufacturer
 - change and/or addition of sterilization site
 - change of label design
 - change of Instruction for Use (IFU)
 - all other changes which are the same or uniform with the issued CPRs.
2. The fees and charges shall be computed based on the number of CPRs to be amended.
3. The list of all CPRs to be amended shall be submitted using the following format (both in pdf and word format):

Product Description (exactly the same as stated in the CPR)	Product Registration Number

4. The applicant shall be informed of the approved changes in the form of letter. This shall be applied to all variation applications received from 22 July 2016 onwards.
5. All approved changes shall be reflected in the CPR during the renewal of the product registration.
6. The company may request for the re-issuance of the CPR to reflect all the changes in the CPR upon payment of the re-issuance fee.

IV. REPEALING CLAUSE

Previous issuances which are inconsistent with those provided in this Circular are hereby rescinded/repealed and/or modified accordingly.

V. SEPARABILITY CLAUSE

If any provision in this Circular, or application of such provision is held invalid, the remainder of the provisions of this Circular shall not be affected.

VI. EFFECTIVITY

This Circular shall take effect fifteen (15) days upon approval.


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