

[FDA CIRCULAR NO. 2013-025, October 15, 2013]

AMENDMENT OF THE CERTIFICATE/S OF PRODUCT REGISTRATION (CPRS) OF DRUG PRODUCTS

To effectively improve the efficiency of the Center for Drug Regulation and Research (CDRR) specifically in processing request for amendments of the Certificate of Product Registration (CPR), the Center shall institute changes in processing amendments for:

- a. Change of Ownership
- b. Change of Business Name
- c. Change of Business Address
- d. Change of Importer/Distributor

For applications involving the aforementioned administrative changes, the individual CPR shall no longer be amended. Instead, the CDRR shall issue a Certification listing the product/s amended. The Certification shall be binding until the validity of the individual CPRs. The company applicant is directed to attach the Certification or copy of the Certification to the CPR affected by changes.

For products with pending renewal applications, the change will be automatically reflected in the CPR to be issued by CDRR.

This Memorandum Circular shall take effect 15 October 2013.

For your information, guidance and strict compliance.

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