[FDA Circular No. 2015-012, July 30, 2015]

ADDITIONAL REQUIREMENTS FOR THE EFFECTIVE IMPLEMENTATION OF FDA CIRCULAR NO. 2013-014, LIST OF PRODUCTS REQUIRING BIOEQUIVALENCE (BE) STUDIES AS PART OF THE APPLICATION FOR MARKETING AUTHORIZATION IN ADDITION TO RIFAMPICIN AND THE 11 PRODUCTS LISTED IN BUREAU CIRCULAR NO. 2006-008

Adopted: 30 July 2015
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To further safeguard the public and ensure that all applicable generic products in the market have passed the requirements for interchangeability [e.g. bioequivalence (BE) study or biowaiver], the following additional requirements are hereby instituted:

- Marketing authorization of drug products given conditional approval of two (2) years during renewal registration shall not be revalidated without submission of satisfactory BE study report, or biowaiver, whichever is applicable.
- Starting 01 July 2016, the marketing authorization of drug products covered shall no longer be renewed unless a satisfactory BE study or biowaiver, whichever is applicable, is submitted at the time of filing of the application for renewal registration.
- Submission of schedule for in vivo or in vitro equivalence testing in lieu of actual BE study report or biowaiver, as well as any requests for extension shall not be accepted.

Failure to comply with the abovementioned additional requirements shall mean revocation of the marketing authorization and the subsequent recall of the products from the market.

(SGD) JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Acting Director General