Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

21 January 2015

FDA CIRCULAR
No. 2015-001

TO: **ALL DRUG MANUFACTURERS AND DISTRIBUTORS (IMPORTERS AND WHOLESALERS)**

SUBJECT: **Clarifications on the Regulations Governing Principal and Identical Drug Products as defined under Administrative Order No. 2005-0031**

Administrative Order No. 2005-0031, "Guidelines and Procedure for the Issuance of the Principal Certificate of Product Registration and the Listing of Identical Drug Products based on the Identity of Manufacturer and Pharmaceutical Formulation", was issued to address concerns of unnecessary duplication of technical dossier evaluation in relation to the registration of identical drug products, defined as having **identical drug formulation** and **manufacturer/source of finished product** with that of the principal product. This led to the opening of an alternative pathway for registration of these products via listing with significantly reduced requirements based on the assumption that the safety, efficacy, and quality aspects of principal products have been thoroughly assured. Thus, the concepts of Principal Certificate of Product Registration (PCPR) and Certificate of Listing of Identical Drug Product (CLIDP) were established.

Identical drug formulation is defined as having the same name(s) and amount(s) of active medicinal ingredients per dosage unit, excipients, components, and manufacturing process as that of the principal product.

During the implementation of the abovementioned regulation, technical issues with regard to the "similarity" of the principal and the identical drug products were identified. It is in this context that this regulation is issued.

For the clarification of all marketing authorization holders (MAHs) and applicants of principal and identical drug products, FDA hereby reiterates that an **identical drug formulation** as defined above must be complied with for all principal and identical drug products (e.g. color, scoring, imprints, embossed/debossed, among others should be uniform for both principal and identical drug products; branded principal products cannot reflect the brand name or any markings identifiable/synonymous to the brand name on the tablet/capsule surface to avoid misbranding of identical drug products).

Incoming applications for CLIDP starting 16 February 2015 must ensure compliance with the abovementioned provisions; otherwise, these applications shall be denied outright and shall be advised to apply for full registration (i.e. a regular

Certificate of Product Registration [CPR] in accordance with existing rules and regulations).

Any previously approved CLIDPs are required to apply for the appropriate variation (e.g. change of capsule color) to be identical with the principal product prior to or during the renewal of their respective authorizations. Likewise, principal products bearing the brand name or any markings identifiable/synonymous to the brand name on the tablet/capsule surface are required to apply for appropriate variation. Application for variation shall be until **30 March 2015**; failure to comply shall mean disapproval of renewal applications and subsequent withdrawal from the market.

For your information and strict compliance.

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