Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

24 June 2015

FDA CIRCULAR
No. 2015-011

TO: ALL APPLICANTS AND HOLDERS OF CERTIFICATE OF PRODUCT REGISTRATION OR MARKET AUTHORIZATION FOR DRUG PRODUCTS

SUBJECT: Guidelines on Implementing FDA Circular No. 2014-011 on Adoption of Unique Global Product Identification Number for Drug Products

The following guidelines are hereby provided for compliance to FDA Circular No. 2014-011, "*Adoption of Unique Global Product Identification Number*" of applicants and holders of marketing authorization of drug products:

1. All drug product applicants and holders shall have the following:

    a) a unique establishment identification number, and
    b) a unique global product identification number.

    1.1. Both a) and b) shall be obtained by joining a global standards organization.

    1.2. When a local drug establishment joins a global standards organization, a unique establishment identification number is assigned to it and is provided with a series of unique global product identification numbers that can be used to identify their products.

    1.3. Imported products may have a unique global product identification number obtained by the overseas manufacturer after joining a global standards organization in another country or region of origin. In this case, the local distributor-importer shall only apply for a unique establishment identification number since the unique global product identification number accompanying the imported product is already acceptable.

    1.4. The unique global product identification number shall be as per stock keeping units (SKUs).

2. By 31 December 2015, both a) and b) shall be required to be indicated in the integrated application form or other systems of application in the future. No application shall be accepted by FDA without the said numbers.

3. Both numbers shall be stored in the FDA database together with the pertinent information about the establishment and products and shall be shared with the relevant government agencies.

4. By 30 June 2016, the unique global product identification number in barcode or QR Code shall be required to be reflected on the labeling materials of the product. Both (1) the batch and, if applicable the lot number, and (2) expiry date shall be part of the barcode.

Consistent with Good Distribution Practices (GDPs) that are implemented by FDA to all drug establishments, the unique establishment identification number and the unique global product identification number shall be used in ensuring the integrity of the drug supply chain, both domestically and globally.

For information and strict compliance.

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[1] Pursuant to DPO 2015-1845

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