Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

25 JUL 2016

FDA CIRCULAR
No. 2016-011

TO : **ALL APPLICANTS AND MARKETING AUTHORIZATION HOLDERS OF DRUG PRODUCTS**

SUBJECT : **Moratorium on the Implementation of FDA Circular No. 2015-011 entitled "Guidelines on Implementing FDA Circular No. 2014-011 on Adoption of Unique Global Product Identification Number for Drug Products"**

On 24 June 2015, the Food and Drug Administration (FDA) issued Circular No. 2015-011 entitled "Guidelines on Implementing FDA Circular No. 2014-011 on Adoption of Unique Global Product Identification Number for Drug Products". This policy requires the use of the Global Product Identification Number (GPIN) for drug products, which is a unique 14-digit code specific for a product presentation of a specific company that is secured from a global standards organization. The GPIN serves as a track and trace system that counteracts supply chain security risks such as counterfeiting. The policy requires that by 30 June 2016, the GPIN shall be required to be reflected on the labeling materials of products, which include both the batch and if applicable the lot number, and expiry date as part of the GPIN.

In light of the discussions made during the Asia-Pacific Economic Cooperation meeting in Peru last 23-25 February 2016, and in consideration of the readiness of concerned establishments to comply with the requirements and guidelines issued by FDA, **a moratorium on the directives mentioned in the abovementioned policies is hereby issued** until further notice.

Despite this moratorium, voluntary compliance is still encouraged by FDA through:

- submission of GPIN through existing application forms
- reflecting on the labels of drug products, whether in 1D or 2D, provided proper variation applications are submitted

This FDA Circular is effective immediately.

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