




29 April 2014

FDA CIRCULAR
No. 2014-011

TO: All Establishments Seeking to, or Currently Engaged in the Manufacture, Import, Export, Distribution and Retail of Health Products in the Philippines

FROM: 
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SUBJECT: Adoption of Unique Global Product Identification Number

I. Rationale

On 5 October 2013, the 25th APEC Ministers Meeting issued a joint ministerial statement where the adoption of global data standards is recognized in addressing chokepoints in the Supply Chain Framework Action Plan. Specific chokepoints include the documentation for border clearance, security and data reporting for export, documentation for regulatory clearance as part of importation, and inspections.¹

Section 5 of Republic Act no. 9711, the Food and Drug Administration Act of 2009, has declared as a function of the agency “to develop and issue standards and appropriate authorizations that would cover establishments, facilities and health products”. Further, the same section allows the agency to “after due process, to order the ban, recall, and/or withdrawal of any health product found to have caused the death, serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, dangerous, or grossly deceptive, and to require all concerned to implement the risk management plan which is a requirement for the issuance of the appropriate authorization”

A unique global product identification number is issued by international organizations and implemented in more than 100 countries. The identification numbers are part of widely used supply chain standards system recognized by the World Customs Organization and the World Health Organization. A global product identification system strengthens enforcement against counterfeit products, facilitates execution of risk management plans including recalls and bans, and enables global identification of products manufactured in the Philippines by local companies. Each product is given a unique identification code that can be adapted into a barcode, a Quick Response code, or other similar electronic identification marks. The adoption of such a system is expected to reduce the time entailed in clearing products through borders, facilitating trade and improving traceability.

¹ Bayhaqi, A, Yuhua, BZ, Outcome Report: Symposium on Supply-Chain Connectivity Measurement Framework, Asia-Pacific Economic Cooperation Policy Support Unit, August 2012.





II. Objectives

For the promotion of accountability of regulated establishments over registered products, a Global Trade Item Number or an equivalent unique global product identification number is adopted as a requirement for all products seeking registration with the Food and Drug Administration.

III. Scope

This issuance shall cover all FDA-regulated products and establishments.

IV. Guidelines

A. Principles

1. The Food and Drug Administration (the 'Agency') does not issue the unique global product identification number.
2. Establishments are to obtain through a process independent from the Agency, the unique global identification numbers;
 - i. Each establishment is assigned a unique establishment identification number;
 - ii. Each product is assigned a unique product identification number (Global Trade Item Number or GTIN);
 - iii. Each product identification number can be accounted to the proprietary establishment;
 - iv. The assigned identification numbers do not expire and are permanently associated with the establishment and the product.
3. Each manufacturing batch or lot of a product may be assigned a unique identification number as determined by the establishment;
 - i. A product identification number is not equivalent to a manufacturing batch or lot number.
4. The unique global product identification number can be adapted without loss of information into a barcode, a Quick Response code, or any equivalent identification graphic.
5. The exterior of the product (i.e. packaging, labels, and/or containers) as presented to consumers must bear the product identification number and/or its equivalent identification graphic;
 - i. Appropriate identification numbers must be displayed on the product exterior in a manner that allows unaided visual verification by a majority of consumers;
 - ii. Appropriate identification graphics must be displayed on the product exterior in a manner that allows interpretation and/or verification by readily available electronic scanners.

B. Requirement for Application

1. Each application for authorization of an establishment must indicate in the application form the unique establishment identification number.
2. Each application for authorization of a product must indicate in the application form the Global Trade Item Number.
3. No documents are required to be provided in support of the identification number as part of the authorization process.



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4. The Agency can verify the identification numbers provided through a network that can synchronize global data.
5. Failure to provide a verifiable Global Trade Item Number by itself is sufficient ground for denial of application.

V. Repealing Clause

Any regulation or provision inconsistent with the terms of this Circular is repealed or modified accordingly.

VI. Saving Clause

If any provision or term of this Circular is declared invalid by any court or tribunal, such declaration shall not affect the remaining provisions of this Circular.

VII. Effective Date

This Circular takes effect on 30 June 2015