[FDA CIRCULAR NO. 2014-011, April 29, 2014]

ADOPTION OF UNIQUE GLOBAL PRODUCT IDENTIFICATION NUMBER

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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 he 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.

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