

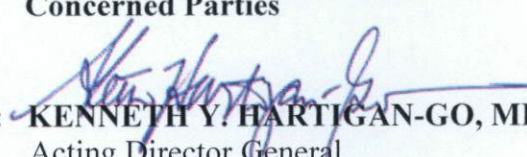


28 August 2013

**FDA MEMORANDUM CIRCULAR**

No. 2013-032

**TO : All FDA-Licensed Establishments, FDA Personnel, and Other Concerned Parties**

**FROM :  KENNETH Y. HARTIGAN-GO, MD  
Acting Director General**

**SUBJECT : REQUIREMENTS FOR THE IMMEDIATE RELEASE OF PRODUCTS COVERED BY THE FDA AT THE BUREAU OF CUSTOMS**

Effective **September 15, 2013**, the Food and Drug Administration (FDA) will no longer issue letters of clearance or certifications for the Bureau of Customs (BOC) in order to release imported products and raw materials under the jurisdiction of the FDA.

The FDA letter of clearance or certification will no longer be a requirement or condition for the immediate release of finished products for as long as the importer is able to present or submit valid FDA License to Operate and valid Certificate of Product Registration or Notification. However, for raw materials, including ingredients and additives that are used for producing or processing finished products, the following shall be presented or submitted to the Bureau of Customs for immediate release:

a) Food

- i. Raw materials, such as food ingredients and food additives, that are imported by FDA-licensed food establishments for their own use, the License to Operate shall be presented or submitted to the Bureau of Customs.
- ii. Food ingredients and food additives, among other raw materials, that are intended for distribution or for sale, the License to Operate and the Certificate of Product Registration shall be presented or submitted to the Bureau of Customs.

b) Drugs

For raw materials used for drug manufacturing, only the License to Operate shall be presented or submitted to the Bureau of Customs.





Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



c) Cosmetics, and Household and Urban Hazardous Substances

For raw materials used in the manufacture of cosmetics and household and urban hazardous substances both the License to Operate and the Certificate of Notification/Registration are no longer required to be presented or submitted to the Bureau of Customs.

The BOC may verify or validate all establishments and products with FDA authorization using the FDA website ([www.fda.gov.ph](http://www.fda.gov.ph)).

The following shall still require the FDA certification prior to release from the Bureau of Customs:

- a) All donated health products, which may need sampling and testing of products, or
- b) Products that have no market authorization yet, but will be used for exhibition, in trade promotion, or for clinical trial purposes, among others. Until such time that the FDA has not yet instituted an on-line application, payment, approval and release of certification, all applicants shall follow the existing procedure.

Application for import clearance or certification shall be received by FDA only until **September 14, 2013**.

For guidance and strict compliance.

