[FDA CIRCULAR NO. 2012-012, September 05, 2012]

GUIDELINES FOR HANDLING RAPID ALERTS ARISING FROM QUALITY DEFECTS

I. INTRODUCTION

Pursuant to Republic Act 9711 and its implementing Rules and Regulations, it may become necessary to implement urgent measures such as the recall of one or more defective batch(es) of a health product during its marketing period or an investigational product during clinical trials.

Also, pursuant to Bureau Circular 8 s. 2001, the guidelines for handling recall (voluntary and FDA-directed) is in place, however, the FDA shall notify the countries of destination of the defective product.

II. SCOPE

This Circular covers the transmission of information when urgent action is required to protect public or animal health by means of a rapid alert relating to the recall of health products, which have quality defects or which are falsified, between FDA, other government agencies responsible for human and veterinary health products. It may also be extended to authorities in countries with which the manufacturer has made appropriate arrangements on GMP. This Circular may be used also for transmission of other information such as cautions-in-use, product withdrawals for safety reasons or for follow-up messages to any of the above listed categories.

This Circular may also be used to notify quality defects, counterfeit or fraud in active pharmaceutical ingredients, investigational medicinal products, and other ingredients when deemed relevant by the FDA.

Health product vigilance alerts are not included within the scope of this procedure.

III. GUIDELINES

A. Issuance, Handling of Notifications of Defective Health Products

The FDA shall have a written procedure for the issue, receipt and handling of notifications of defective products, batch recalls and other rapid alerts during and outside normal working hours.

B. Criteria for Issuing a Rapid Alert

1. The aim of the Rapid Alert System is to transmit only those alerts whose urgency and seriousness cannot permit any delay in transmission. To ensure its effectiveness, the system must not be saturated by the transmission of less urgent information. In each case a professional assessment must be made of the

seriousness of the defect, its potential for causing harm to the patient or (in the case of a veterinary product) harm to animals, consumers, operators and the environment, and the likely distribution of the affected batch(es).

Annex 1 provides guidance on the classification of the urgency of the recall of defective health products.

<> Class I defects are potentially life threatening. A rapid alert notification must be sent to all contacts of the rapid alert notification list irrespective of whether or not the batch was exported to that country.
<> Class II defects could cause illness or mistreatment, but are not Class 1. A rapid alert notification should be sent to all contacts of the rapid alert notification list as it might be difficult to know where a batch has been distributed. If the product distribution is known, the notification should be only sent to the contacts concerned.
<> Class III defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons. These are not normally notified through the Rapid Alert System.

2. Where appropriate, the rapid alert system may be used for notification to authorities concerned of the recall of products or an embargo on the distribution of products following suspension or withdrawal of a manufacturing/importation/wholesale authorization.

C. Issuing a Rapid Alert Notification

1. Responsibility

1.1 The FDA Philippines shall issue the rapid alert if the defect in-the product was first identified in the Philippines. The FDA shall lead the investigation of the defect and issue the rapid alert. The alert should include a recommendation on proposed action for all affected authorities.

2. Format of the rapid alert and its transmission

> 2.1 A suitable format for the notification of quality defects by the Rapid Alert System is given in Annex 2. The form should be completed clearly in English. The notification and relevant documents should be sent to the rapid alert contact list by electronic mail. The contact list and any relevant documents should be attached to the notification.

The electronic mail message should use a unique subject line to identify the rapid alert and any follow-up messages.

The subject line should consist of the following:

RapidAlert; [Qdefect / Counterfeit / Fraud], Class [I/II]: Product [Name / INN], Action [Recall / No Recall / Follow-up], Rapid alert reference number. (For example Rapid/Alert; Qdefect; I, ProductX; FolIow-up,PH/I/07/01).

The rapid alert should be given a unique reference number with the following format:

For example, **PH/II/05/02** would indicate a class II rapid alert initiated by Philippines, being the 5th rapid alert initiated by Philippines and that it is the second correspondence regarding this rapid alert.