Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
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05 September 2012

FDA CIRCULAR
No. 2012-012

TO : **All Concerned**

SUBJECT : **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 I. 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.

5. 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.

B. 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 RapidAlert; Qdefect; I, ProductX; Follow-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.

2.2. Class I rapid alert must be disseminated within 24 hours of the national notification.

2.3. When an authority issues a further rapid alert for a batch, the field 18 in the form in Annex 2 "Detail of Defect/Reason for recall" should begin with the text: "Supplemental Rapid Alert following rapid alert #ref. no.#".

D. Rapid alert contact list

1. The FDA shall maintain the contact list for the rapid alert notifications.
2. There is normally one contact per authority nominated. Changes to contact names or details must be notified to the FDA and are circulated immediately to the entire list by electronic mail. Contact details include telephone and fax numbers, electronic mail address, which should be monitored at all times.

E. Fraud and Falsified Products

1. The Rapid Alert System should be used to notify authorities of the possible presence in the legal distribution network of falsified products or those resulting from fraud in manufacture, packaging, distribution or promotion and products containing falsified starting materials.

2. If the fraud or falsification was first detected in the Philippines, the FDA should issue the notification. The format for the rapid alert notification in Annex 2 may be used.

3. Notification should be sent to the entire contact list.

F. Follow-Up Action

1. The FDA shall have a written procedure to describe follow-up action to a rapid alert notification. The FDA shall monitor the conduct and effectiveness of any recall that it initiates as a result of the rapid alert notification.

2. All follow-up actions transmitted through the Rapid Alert System should use the form for Follow-up and Non-urgent Information for Quality Defects detailed in Annex 3 to separate it from Rapid Alerts. The reference number linking it to the original Rapid alert following the same format as described above.

G. Further Use of Rapid Alert Contact List

1. Although the contact list for rapid alert notifications shall be only used for the transmission of notification falling in the scope of this Circular, the list may be used for the communication of other important and urgent information related to health products. These messages should clearly identify the subject and whether they are for information or action.

H. Annex

Annex 1: Classification of Rapid Alerts
Annex 2: Format for Rapid Alert Notification of a Quality Defect
Annex 3: Format for Follow-up and Non-Urgent Information for Quality Defects

IV. Repealing Clause

All other issuances inconsistent with this Circular are hereby repealed.

V. Separability Clause

In case any provision of this Circular is declared contrary to law or unconstitutional, other provisions which are not affected hereby remain in force and in effect.

VI. Effectivity

This Circular shall take effect immediately.

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Annex 1
Rapid Alert System: Classification of Urgency of Defective Health Product Alerts

CLASS I
Class I defects are potentially life threatening or could cause a serious risk to health. These must be notified through the Rapid Alert System in all cases.
Examples:

- Wrong product (label and contents are different products)
- Correct product but wrong strength, with serious medical consequences
- Microbial contamination of sterile injectable or ophthalmic product
- Chemical contamination with serious medical consequences
- Mix-up of some products with more than one container involved
- Wrong active ingredient in a multi-component product, with serious medical consequences.

CLASS II
Class II defects could cause illness or mistreatment, but are not Class I. 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.
Examples:

- Mislabelling, e.g. wrong or missing text or figures
- Missing or incorrect information (leaflets or inserts)
- Microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences
- Chemical/physical contamination (e.g. significant impurities, cross-contamination, particulates)
- Mix up of products in containers
- Non-compliance with specification (e.g. assay, stability, fill/weight)
- Fautly closure with serious medical consequences (e.g. cytotoxics, child- resistant containers, potent products).

CLASS III
Class III defects may not pose a significant hazard to health, but withdrawal may have been initiated for other reasons. If deemed relevant by the issuing authority, the rapid alert system may be used.
Examples:

- Faulty packaging, e.g. wrong or missing batch number or expiry date
- Faulty closure
- Contamination, e.g. microbial spoilage, dirt or detritus, particulate matter

Annex 2

IMPORTANT – DELIVER IMMEDIATELY

FDA Food and Drug Administration PHILIPPINES	**Rapid Alert Notification of a Quality Defect / Recall**	
1. To: (See list attached if more than one)		
2. Product recall class of defect	(Circle one) I II	3. Counterfeit/Fraud (please specify)
4. Product:	5. Marketing Authorization Number:	
6. Brand/Trade Name	7. INN or Generic Name	
8. Dosage Form	9. Strength	
10. Batch Number (if bulk):	11. Expiry Date:	
12. Pack size and presentation	13. Date Manufactured:	
14. Marketing Authorization Holder		
15. Manufacturer Contact Person Telephone/Fax/Email	16. Recalling Firm Contact Person Telephone/Fax/Email	
17. Recall number assigned		
18. Details of the defect/Reason of Recall:		
19. Information on distribution including exports (type of customer, e.g. hospitals):		
20. Action taken by issuing Authority:		
21. Proposed Action:		
22. From (issuing Authority):	23. Contact Person: Telephone::	
24. Signed	25. Date	26. Time

*This is intended only for the use of the party to whom it is addressed and may contain information that is privileged, confidential, and protected from disclosure under applicable law. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us by telephone immediately and return it to us at the above address by mail. Thank you****************

Annex 3

FDA Food and Drug Administration PHILIPPINES	**Follow-up and Non-urgent Information for Quality Defects**	
1. To: (See list attached if more than one)		
2. Recall number assigned		
3. Product:		4. Marketing Authorization Number:
5. Brand/Trade Name		6. INN or Generic Name
7. Dosage Form:		8. Strength:
9. Batch Number (if bulk):		10. Expiry Date:
11. Marketing Authorization Holder:		
12. Manufacturer		13. Contact Person
14. Subject Title *Add message here*:		
15. Proposed Action:		
16. From (issuing Authority):		17. Contact Person
18. Signed	19. Date	20. Time