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

25 JUL 2016

**FDA CIRCULAR**
No. 2016-012

**TO** : **ALL LICENSED ESTABLISHMENTS OF HEALTH PRODUCTS AND OTHER CONCERNED STAKEHOLDERS**

**SUBJECT** : **Guidelines on Product Recall**

## 1. RATIONALE

Republic Act No. 3720, also known as the "Food, Drug and Cosmetic Act", as amended, and Republic Act No. 9711, also known as the "Food and Drug Administration (FDA) Act of 2009" and its Implementing Rules and Regulations were all enacted to establish an effective regulatory system for the authorization, registration, and monitoring of health products.

Section 5 (i) of Republic Act No. 9711 mandated the FDA to require all manufacturers, traders, distributors, importers, exporters, wholesalers, retailers, consumers and non-consumer users of health products to report to the FDA any incident that reasonably indicates that a product has caused or contributed to the death, serious illness or serious injury to a consumer, a patient, or any person. Moreover, Section 5 (k) of the same law empowers the FDA, 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.

Recall is the method of withdrawing or correcting unsafe or hazardous health products from the distribution chain that may present a health hazard to the consumer or user. It is an action taken by establishments involved in the supply chain (e.g., manufacturers, distributors, or retailers) as (1) part of their responsibility to protect the public health and well-being, (2) compliance to the appropriate good practices (e.g., good manufacturing, distribution, or storage practices), and (3) compliance to existing standards and regulations.

## 2. OBJECTIVE

The objective of this FDA Circular is to provide guidelines in the conduct of product recall.

## 3. SCOPE

This FDA Circular shall apply to all licensed manufacturers, traders, distributors (importers, exporters, and wholesalers), and retailers of health products.

## 4. GENERAL GUIDELINES

4.1. Triggers for recall may arise after review of a safety issue, efficacy concern, if applicable, and quality defect discovered by either FDA, the Market Authorization Holder (MAH), other regulatory agencies, healthcare professionals, or members of the general public.

4.2. A Product Recall Committee (PRC) for each Center shall oversee the recall system for health products under their respective jurisdiction. All PRCs report directly to the Office of the Director General (ODG).

4.3. Decision to recall shall be based on appropriate evaluation of available evidences and applicable laws, rules, and regulations.

4.4. The overall responsibility of conducting recall lies with the MAH, including the conduct of appropriate communication with stakeholders, healthcare professionals, and the public, following an effective and efficient recall strategy.

4.5. All other establishments involved in the supply chain shall coordinate and cooperate with the MAH.

4.6. The primary role of the FDA is to closely monitor and supervise the effectiveness of the conduct of the recall by the MAH. Nonetheless, the FDA is not precluded to intervene and enforce any regulatory action and to provide scientific, technical and operational advice.

4.7. Risk Management Plan (RMP) is a key component in the conduct of recall.

## 5. IMPLEMENTING MECHANISM

5.1. *Product Recall Committee*

5.1.1. A PRC shall be created in each Center, composed, at the minimum, of the following members:

5.1.1.1 Director
5.1.1.2 Division Chief, Licensing and Registration Division (LRD)
5.1.1.3 Division Chief, Product Research and Standards Development Division (PRSDD)
5.1.1.4 Senior Officer from the Common Services Laboratory (CSL)
5.1.1.5 Senior Officer from the Field Regulation Operations Office (FROO)
5.1.1.6 PRC Secretariat from PRSDD

5.1.2. The PRC shall perform the following functions:

5.1.2.1 Review the triggers for recall
5.1.2.2 Conduct appropriate communications
5.1.2.3 Oversee the recall system
5.1.2.4 Recommend the order of recall and/or the termination of recall of any unsafe and hazardous product to the FDA Director General.

5.2 *Triggers for Recall*

Triggers may come from the different post-marketing surveillance (PMS) activities conducted by the FDA which may include, but not limited to:

5.2.1 Health product quality/complaints processing;

5.2.2 Adverse Events (AEs) monitoring and Events-based Surveillance Response (ESR) reports;
5.2.3 Sampling, testing, and verifying of health products;
5.2.4 Post-licensing inspection, monitoring, and investigations;
5.2.5 Post-evaluation of acknowledged notifications;
5.2.6 Advertisements and promotional articles monitoring;
5.2.7 Coordination with regulatory agencies and international partners.

Triggers may also come from reports submitted by MAHs as a result of their own PMS activities.

5.3 *Product Recall Review*

5.3.1 Review of Trigger

Triggers that have been initially reviewed by the responsible offices are submitted to the PRC for health hazard evaluation.

5.3.2 Health Hazard Evaluation

Health hazard evaluation is conducted to determine whether a health product in question arising from a trigger should be recalled or not. The factors considered in the conduct of health hazard evaluation is attached as Annex A.

Any conclusion shall be supported by scientific documentation.

5.3.3 Decision

5.3.3.1 If a trigger is deemed for recall: Conference with the MAH

The PRC prepares a Product Recall Resolution (PRR) containing information on (1) the trigger and related evidences, (2) the result of the health hazard evaluation, and (3) the recall classification as categorized below:

5.3.3.1.1 Class I Recall – product defects/conditions that are potentially life threatening or could result to severe health risk, health impairment or effects such as permanent damage to health or death.
5.3.3.1.2 Class II Recall – product defects/conditions that could cause poisoning or temporary/medically reversible adverse health problem or mistreatment.
5.3.3.1.3 Class III Recall – product defects/conditions that may not pose a significant hazard to health, but withdrawal may have been initiated for other reasons.

The PRC shall call for a conference with the MAH, within forty eight (48) hours, to present the PRR. In the same event, MAH shall present their appropriate recall strategy. Agreement by both FDA and MAH on the recall strategy to be

implemented must ensue for the commencement of the recall. Otherwise, a Product Recall Order (PRO) shall be issued and recall shall be implemented by the FDA at the expense of the MAH.

5.3.3.2 If not deemed for recall

The trigger is returned to the endorsing office for consideration of other more appropriate regulatory action.

5.4 *Product Recall Process*

5.4.1 Recall Strategy

A recall strategy consistent with the RMP shall be developed by the MAH. The following elements shall be included:

5.4.1.1 Depth of Recall, specify the level in the distribution chain (e.g. consumer level, retail level or wholesale level)

5.4.1.2 Recall Communications containing the identified list of establishments as per distribution records to be contacted and contents of such communications

5.4.1.3 Recall operation instructions and corresponding timelines of completion

5.4.1.4 Recall status reporting of MAH to FDA, specifying the frequency of submission

5.4.1.5 Disposal strategy

5.4.2 Communication Activities

Appropriate communication activities shall be undertaken by FDA and the MAH to protect the public.

5.4.2.1 Issuance of FDA Advisory

An FDA Advisory shall be issued for Class I recalls, and as deemed necessary and appropriate by FDA. Such advisory shall be posted in the FDA website and/or other forms of media to alert the public.

5.4.2.2 Communication

The MAH shall promptly notify all concerned parties (e.g. establishments involved in the supply chain, hospitals, outlets and health facilities, healthcare professionals, and the general public) on the product recall, copy furnishing the FDA.

The minimum information required for any communication is attached as Annex B.

5.4.3 Recall Operations

The responsibility to conduct recall shall be assumed by the MAH, with proper coordination with all stakeholders involved. Throughout the operation, recall status reports shall be submitted according to the frequency specified in the recall strategy. For Class I, products are immediately pulled out of the selling area.

The content of recall status reports is attached as Annex C.

5.4.4 Completion of Product Recall

Completion of recall operation refers to the complete retrieval of all products ordered to be recalled nationwide (both rural and urban) as verified by FDA. Upon completion, the MAH is required to submit the Final Recall Status Report, including details on the final inventory and disposition of the recalled products for the termination of the recall.

5.4.5 Termination of Product Recall

The list of documents required to be submitted for termination of product recall, depending on the final disposition, is attached as Annex D. Upon receipt of the documents, the PRC shall verify if the product has been completely retrieved and has been properly disposed in accordance with the strategy:

5.4.5.1 If the PRC has determined that the product recall has been completed, a Termination Letter to that effect shall be issued to the MAH indicating such. An FDA Advisory concerning the termination of the recall shall be issued, whenever applicable.

5.4.5.2 If the PRC has determined that the product recall has not been satisfactorily completed, appropriate action shall be conducted by FDA.

5.5 *Effectiveness Checks of Recall Procedure*

5.5.1 FDA Effectiveness Checks

FDA, thru the FROO, shall monitor the effectiveness of the product recall conducted by an MAH through review of recall status reports, periodic inspection, disposal (if warranted), and monitoring of involved establishments.

5.5.2 MAH Effectiveness Checks

Effectiveness checks by MAH is conducted to ensure that all concerned, within the depth of the recall specified, have received the communication and their compliance to the recall operations. These checks shall be part of the recall status report.

5.6 *Responsibility of MAHs to Initiate Recall*

MAHs have the overall responsibility for continuously ensuring the safety, efficacy, and quality health products. This is consistent with the requirements of good practices and part of product stewardship.

Whenever triggers have been observed, MAHs are expected to review the risks involved and apply appropriate risk mitigation activities consistent with their RMPs. Should a recall be deemed necessary, the MAHs shall coordinate with the responsible Center for a conference, discussing the health hazard evaluation conducted by the MAH that prompted the decision to recall and the proposed recall strategy to be implemented. Media announcement from the MAH is required for Class I and II voluntary recalls.

5.7 *Product Recall Order*

A Product Recall Order (PRO) shall be issued by the FDA, signed and approved by the Director General, when (1) the MAH refuses to conduct a recall after the PRC has

established the need for recall, or (2) the MAH fails to effectively conduct the recall as agreed.

The PRO shall specify the violation, the product recall classification, depth of recall and the recommended duration of recall to be undertaken by the MAH from receipt up to the complete removal of the concerned health product from the market. Any other instructions appropriate to the conduct of the recall may also be included.

## 6. VIOLATIONS

Violations of any provision of this FDA Circular, in line with the provisions of Republic Act No. 3720 and Republic Act No. 9711 and its implementing rules and regulations shall be a ground for the filing of appropriate administrative charges that could lead to the imposition of administrative sanctions such as, but not limited to, imposition of fines, suspension, cancellation or revocation of any market authorization issued by FDA.

## 7. REPEALING CLAUSE

Bureau Circular No. 8 s. 2001, as well as provisions on previous circulars and memoranda that are inconsistent with this issuance are hereby withdrawn, repealed, and/or revoked accordingly.

## 8. SEPARABILITY CLAUSE

If any provision in this Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions of this Circular shall not be affected.

## 9. EFFECTIVITY

This Circular shall take effect 15 days following its publication in two (2) newspapers of general circulation and submission to the University of the Philippines Office of the National Administrative Register (ONAR).

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# Annex A
# Factors Considered in Health Hazard Evaluation

The following are factors to be considered in the decision to recall:

A. Disease, injury, illness, or poisoning has already occurred from the use of the health product;
B. Any existing condition(s) that may lead to exposure of the population;
C. Hazard to various segments of the population (e.g. pregnant women, children, surgical patients, geriatric, pets, livestock, etc.), who are expected to be exposed to the health product. Particular attention is given to more vulnerable population;
D. Severity of the hazard to which the population at risk may be exposed;
E. Likelihood of occurrence of the risk of exposure to which the population may be exposed;
F. Short- and long-term consequences of the health effects;
G. Risk of gross deception to the general public;
H. Non-compliance to FDA standards;
I. Misdeclaration of hazardous substance/content;
J. Materials that contaminated the product whether accidental or intentional; and
K. Other factors that an attending circumstance may warrant.

# Annex B
# Minimum Information Required for Communications

Communications must convey, at the minimum, the following information:

A. Details of the product to be recalled (product name, percent active ingredient, pack size, registration/notification number, lot/batch number, any other pertinent descriptive information of the health product), and use of the health product, where applicable;
B. Reason for recall and associated health risk;
C. Urgency of action;
D. Warning that further distribution, dispensing, selling and immediate cessation of use of any remaining health product; and
E. Instructions on what to do with the health product.
F. Instructions to notify the MAH of compliance
G. Initial preventive measures to reduce health risks

# Annex C
# Content of Recall Status Reports

At the minimum, recall status reports shall contain the following information:

A. Number of establishments, date and method of notification;
B. Number of establishments responding to the recall communication and quantity of health products on hand at the time it was received;
C. Number of establishments that did not respond (if needed, the identity of the non-responding consignees may be requested by the FDA);
D. Number of health products returned/accounted by each establishment communicated;
E. Results of effectiveness checks by MAH;
F. Estimated time of completion of the recall
G. How the health product is being quarantined

In addition to the abovementioned information, (1) the initial status report shall contain details on the media announcement (for Class I and II MAH-initiated recalls) and (2) the final status report shall contain (a) details on the final disposition of the recalled health products including destruction if warranted and the (b) final inventory.

# Annex D
# Documents Required for the Termination of Product Recall

A. Where destruction is deemed necessary, whether actual health products or labeling materials, the following must be complied with:
   1) Presence of an FDA authorized representative is required and notice must be given not later than one (1) week prior to the actual destruction activity;
   2) Performed only in a duly accredited Department of Environment and Natural Resources (DENR) waste treatment facility;
   3) The following documents shall be submitted after the destruction:
      (a) Certificate of Destruction issued by the DENR accredited third party waste treatment facility
      (b) Photographs of the whole destruction activity covering even the transport of stocks meant for destruction
      (c) Copy of the signed FDA inspection report of destruction, signed by all relevant officers during the actual destruction

B. Where the health product is to be redressed, PRC approval is necessary. The health product should comply with its registered specifications and applicable GMP requirements. The following documents must be submitted:
   1) Copy of the signed FDA inspection report of redressing
   2) Submission of actual labeling material

C. Where the MAH intends to return the affected health products to the source country, the MAH shall secure approval from the PRC. If granted, the following must be complied with:
   1) Notice must be given no later than one (1) week prior to the actual activity
   2) Presence of an FDA authorized representative is required during inventory, sealing and packing of the recalled products at the appropriate warehouse of the MAH
   3) Copy of the signed FDA inspection report
   4) Returned shipment documents must be provided within fifteen (15) calendar days upon receipt of concession