



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

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BUREAU CIRCULAR

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Subject: GUIDELINES TO BE OBSERVED ON THE IMPLEMENTATION OF PRODUCT RECALL SYSTEM

Chapter II of R.A. 3720 as amended by E.O.175, otherwise known as the "Foods, Drugs, Devices and Cosmetics Act" declares it the policy of the state, "to insure safe and good quality supply of food, drug and cosmetics and to regulate the production, sale and traffic of the same to protect the health of the people".

For the proper implementation of the above policy and in accordance with Chapter II, Section 3 (b) of this same Act and Section 12.1 of A.O.43-A, s. 1999 with subject "Current Good Manufacturing Practice Guidelines for Drugs", the following guidelines to be observed on the recall of all types of regulated products from the market are hereby promulgated.

1. General Information

Recalls are actions taken to remove a product from the market. Recalls maybe initiated by BFAD or are voluntary actions on the part of manufacturers and distributors to carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise deceptive.

Recalls are an appropriate alternative method for removing or correcting marketed products, including their labeling and/or promotional literature, that violate the laws administered by the Bureau of Food and Drugs (BFAD). They are generally more efficient and afford equal and more timely consumer protection than formal administrative or civil actions, especially when the product has been widely distributed.

2. Scope

This Guidelines shall apply to the recall of all types of products regulated by the Bureau of Food and Drugs.

3. BFAD Committee for Product Recall

A BFAD Committee for Product Recall is hereby created to evaluate the health risks presented by a violative product. It shall be composed of the following members:

- Chief of Product Services Division (PSD), Laboratory Services Division (LSD) and Legal Information and Compliance Division (LICD)

- Chief of Regulation Division I (RD I) or Chief of Regulation Division II (RD II)
- Medical Consultant / Deputy Director

In case a product recall is agreed upon, a written concurrence shall be submitted to the BFAD Director for approval and proper issuance of recall order.

4. Health Hazard Evaluation

An evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by the BFAD Committee for Product Recall and will take into account, but not be limited to, the following factors:

- 4.1. Whether any disease or injury has already occurred from the use of the violative product.
- 4.2. Whether any existing condition(s) could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.
- 4.3. Assessment of hazard to various segments of the population, e.g. pregnant women, children, surgical patients, pets, livestock, etc. who are expected to be exposed to the product being considered. Particular attention should be given to the hazard to those individuals or groups who may be at greater risk.
- 4.4. Assessment of the degree of seriousness of the health hazard to which the population at risk would be exposed.
- 4.5. Assessment of the likelihood of occurrence of the hazard.
- 4.6. Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

A product will also be considered for recall if it presents a risk of gross deception to the general public.

5. Recall Classification

- 5.1. Class I Recall – is a situation in which there is a reasonable probability that the use or exposure to a violative product will cause serious adverse health consequences or death.
- 5.2. Class II Recall – is a situation in which use or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- 5.3. Class III Recall – is a situation in which the use or exposure to a violative product is not likely to cause adverse health consequences.

Some examples of product defects that are subject to recall are listed according to classification in Appendix 1.

6. Who Will Initiate Recall

Recalls may be undertaken by the manufacturers and distributors of a violative product 1) at any time on their own initiative or 2) in response to a recall order by BFAD.

6.1. Firm Initiated Recall

A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. A firm that does so because it believes the product to be violative (i.e., the product presents a risk of injury or does not conform to registered specifications) is mandated to notify immediately the BFAD.

The firm should provide the following information:

- 6.1.1 Identity of the product involved.
- 6.1.2 Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.
- 6.1.3 Evaluation of the risk associated with the deficiency or possible deficiency
- 6.1.4 Total amount of such products produced and/or the time span of the production
- 6.1.5 Total amount of such products estimated to be in distribution channels
- 6.1.6 Distribution information, including the number of distribution outlets and where necessary, the names and addresses of the distribution outlets
- 6.1.7 A copy of the firm's recall communication if any has been issued or a proposed communication if none has been issued yet.
- 6.1.8 Proposed strategy for conducting the recall
- 6.1.9 Name and telephone number of the official who should be contacted concerning the recall

6.2. BFAD Ordered Recall

The Director of the BFAD may order a firm to initiate a recall upon the recommendation of the BFAD Committee for Product Recall when the following determinations have been made:

- 6.2.1. That a product that has been distributed presents a risk of illness or injury or gross consumer deception
- 6.2.2. That the firm has not initiated a recall of the product
- 6.2.3. That an agency action is necessary or advisable to protect the public health and welfare

The firm shall be notified of decision to order recall, and of the need to begin immediately a recall of the product. The notification will specify the violation, the health hazard classification, the recommended recall strategy to be undertaken by the firm and any other instructions appropriate to the conduct of the recall.

7. General Procedure for Product Recall

- 7.1 The BFAD Committee for Product Recall, upon receipt of a case report, will assess the hazard presented by a product being recalled or considered for recall. Such case report may come from the responsible company (company initiated), BFAD technical divisions, DOH or other government offices, or consumer complaints.
- 7.2 The Committee will submit a written recommendation to the BFAD Director for the issuance of a recall order or to confirm a company initiated recall
- 7.3 The concerned DOH Offices will be informed of the decision to order product recall
- 7.4. A Public Health Alert will be issued within twenty-four (24) hours for cases that have been determined as Class I or Class II Recall.
- 7.5 If recall is not firm-initiated, a notification will be issued to the firm regarding the recall recommendation together with a request for the submission of recall plan/procedure and other information listed in section 6.2.
- 7.6. An in-depth inspection of responsible establishment/ production facilities where the violation occurred will be conducted by the concerned inspection division of the BFAD (RD I or RD II)
- 7.7 If necessary, other DOH units and government agencies will be utilized in implementing the recall
- 7.8 The concerned BFAD inspection division will audit the recall operation by developing and implementing a recall audit program.
- 7.9. In case the concerned firm refuses to conduct a product recall, regulatory action and/or other measures will be pursued by BFAD
- 7.10. The BFAD will determine when a recall will be terminated and upon such determination, provide written notification of the termination to the recalling firm.

8. Public Health Alert

Within twenty-four (24) hours after the BFAD Director issues an Order for Product Recall, the BFAD will issue Public Health Alert for the purpose of alerting concerned populations to either serious health hazards or other situations deemed to be in the public interest.

Class I Recall - Notices and warnings shall be issued, by tri-media, to the general public, health professionals, health institutions, industry associations, distribution outlets for such products and all other concerned parties.

Class II Recall – Notices and warnings shall be issued to 1) groups and institutions that are identified as those who generally use or are exposed to the product and 2) those who could help remove such violative products from the market or prevent such products from being used

Class III Recall - Notices and warnings shall be issued to concerned parties and distribution outlets.

9. Recall Strategy

A recall strategy suitable for individual recall circumstances shall be developed by the BFAD and/or the recalling firm. The following elements shall be included in a recall strategy:

- 9.1 Depth of Recall – depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain which the recall is to extend. Ex. consumer level, retail level or wholesale level
- 9.2 Public Alert /Warning to be issued by the recalling firm – the purpose is to alert the public that a product being recalled presents a serious hazard to health
- 9.3 Effectiveness checks – the purpose is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action.

In developing a recall strategy the duration to complete the recall operation should also be considered. Completion of a recall operation should be within the following recommended period:

- Class I Recall - seven (7) days
- Class II Recall - fifteen (15) days
- Class III Recall - thirty (30) days

10. Recall Status Report

10.1. The recalling firm is mandated to submit periodic recall status reports to the BFAD so that the agency may assess the progress of the recall. The frequency of such reports will be determined by the relative urgency of the recall and will be specified by the BFAD in each recall case; generally the reporting interval will be between 2 and 4 weeks.

10.2. Unless otherwise specified, the recall status report should contain the following information:

- 10.2.1 Number of consignees notified of the recall, and date and method of notification
- 10.2.2 Number of consignees responding to the recall communication and quantity of products on hand at the time it was received
- 10.2.3 Number of consignees that did not respond (if needed, the identity of non-responding consignees may be requested by the BFAD)
- 10.2.4 Number of products returned or corrected by each consignee contacted and the quantity of products accounted for
- 10.2.5 Number and results of effectiveness checks that were made
- 10.2.6 Estimated time for completion of recall

10.3 Recall status reports are to be discontinued when the recall is terminated by BFAD

11. Refusal By or Failure of Firm to Conduct Effective Product Recall

Seizure, multiple seizure or other court action shall be undertaken by the BFAD when a firm refuses to conduct a recall ordered by BFAD, or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing.

12. Disposition of Recalled Products

Products which have been subject of a recall must immediately be removed from the market and must not be allowed for distribution and sale. Upon completion of the recall procedure, the concerned company shall notify the BFAD of the final disposition of the product.

- a. If the product is to be destroyed, the destruction should be witnessed by a BFAD representative.
- b. If the product has been reprocessed to comply with registered specifications, distribution and sale of the reprocessed product shall only be allowed following a written recommendation from the BFAD to do so.

This Circular shall take effect immediately.

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Director