


**PRODUCT RECALL SYSTEM
In the Philippines**


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LEGAL BASES

Republic Act 3720
Foods, Drugs, Cosmetics, and
Devices Act
Bureau Circular No. 8 series 2001
Product Recall System




Bureau Circular No. 8 s. 2001

**Guidelines To Be Observed On The
Implementation Of Product Recall
System**




SCOPE:

**This guideline shall apply to the
recall of all types of products
regulated by BFAD.**




BFAD Committee for Product Recall:

- Chief of Product Services Division
- Chief of Laboratory Services Division
- Chief of Legal Information
Compliance Division
- Chief of Regulation Division I and II
- Medical Consultant / Deputy Director



BFAD Committee for Product Recall:

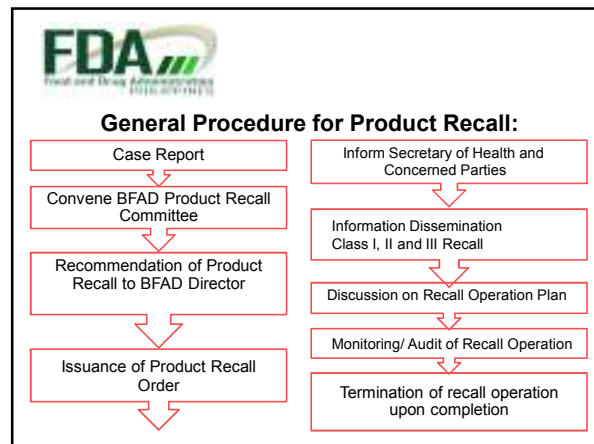

- *Created to evaluate the health risk presented by a violative product*
- *In case a product recall is agreed upon, a written concurrence shall be submitted to the BFAD Director for approval and proper issuance of recall order.*



Who will initiate Recall?

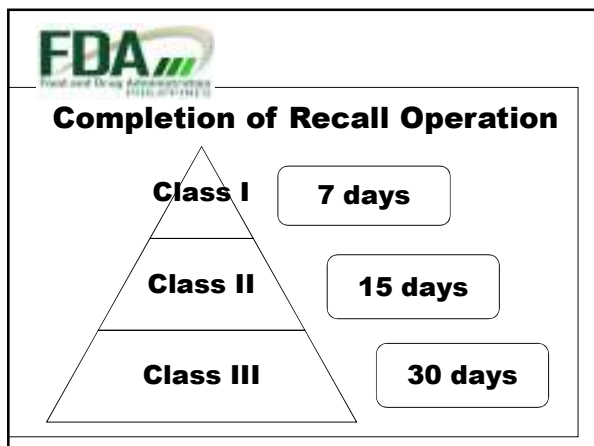
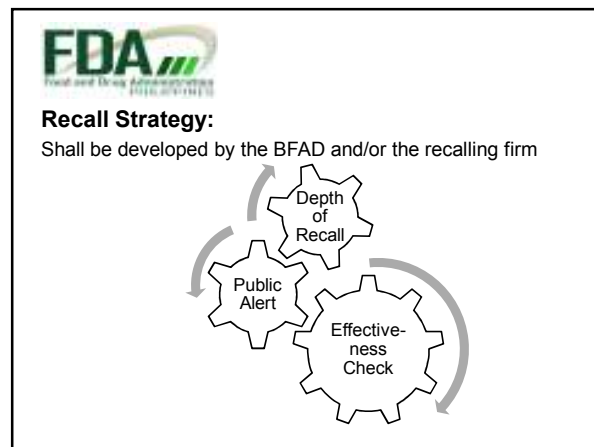

Manufacturers and Distributors of a violative product:

1. at any time on their own initiative
- Firm Initiated Recall
2. in response to a recall order by BFAD
- BFAD Ordered Recall

Public Health Alert:
To be issued by BFAD within 24-hours after issuance of Order for Product Recall.

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

Recall Status Report:

- The recalling firm is mandated to submit Periodic Recall Status Reports to BFAD so that the agency may assess the progress of the recall.
- Frequency of such reports will be determined and specified by BFAD in each recall case relative to the urgency of the recall.



Content of the Recall Status Report:

- Number of consignees notified of the recall, and date and method of notification;
- Number of consignees responding to the recall communication and quantity of products on hand at the time it was received;
- Number of consignees that did not respond (if needed, the identity of non-responding consignees may be requested by the BFAD)



- Number of products returned or corrected by each consignee contacted and the quantity of products accounted for;
- Number and results of effectiveness checks that were made;
- Estimated time for completion of recall.



Disposition of Recalled Products:

- The recalling firm will notify BFAD of the final disposition:
 1. For destruction.
 - Submit Procedure for the disposal of recalled products
 - Destruction should be witnessed by BFAD representatives
 2. For reprocessing
 - Reprocessed products shall be allowed for distribution and sale only upon recommendation by BFAD



Thank you !