INTRODUCTION TO TOBACCO PRODUCT RECALLS

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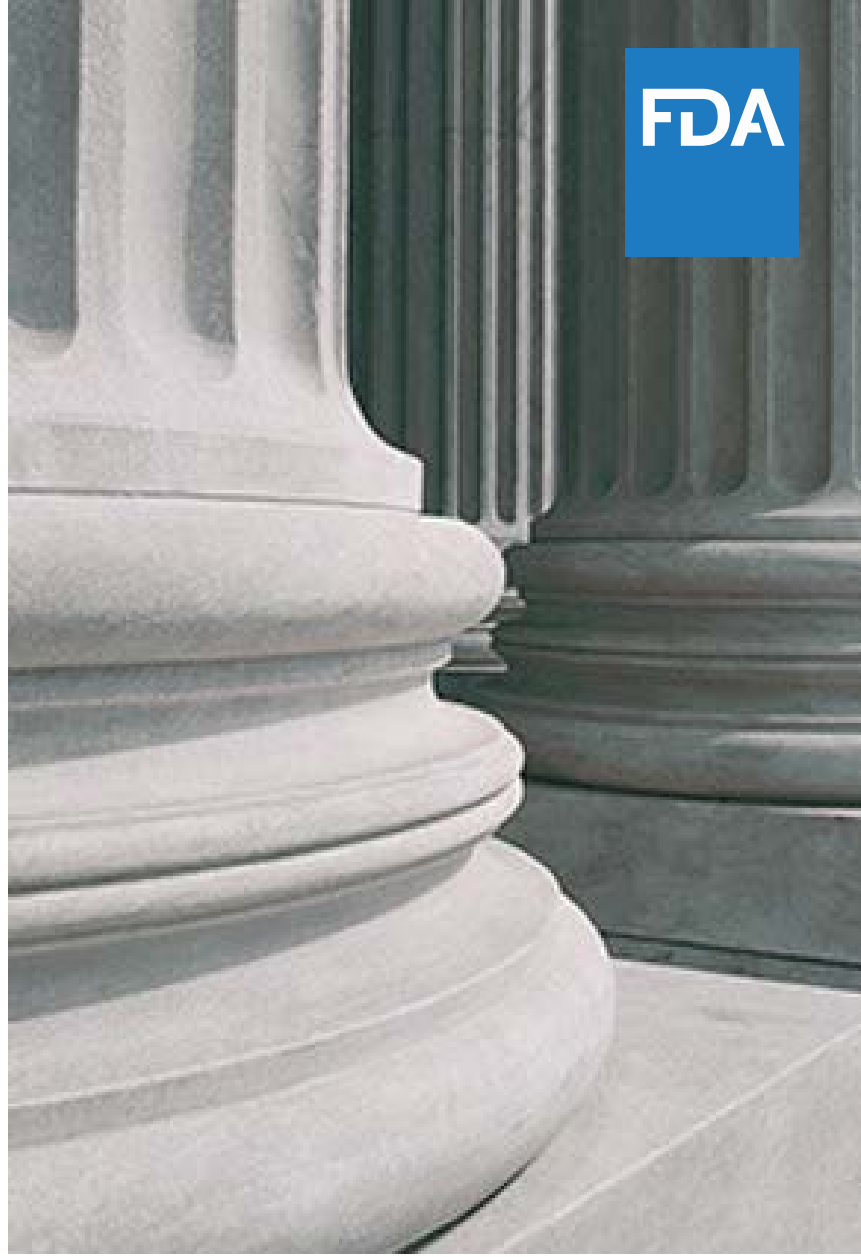

- FDA's recall authority
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- Recall readiness
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FDA'S RECALL AUTHORITY

Mandatory Recall

Under Section 908(c) of the FD&C Act, if the FDA finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the FDA shall issue an order requiring the appropriate person to immediately cease distribution of such tobacco product

Voluntary Recall

Under 21 C.F.R. § 7.40(b) recalls may also be undertaken voluntarily by manufacturers and distributors at any time, or at the request of the FDA

RECALL DEFINITION

Under 21 C.F.R. § 7.3, a recall is a firm's removal or correction of a marketed product that FDA considers to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), and against which FDA would initiate legal action

Recalls are generally voluntary actions taken by a firm when it determines that a tobacco product is misbranded or adulterated

FDA may make a request for a recall under 21 C.F.R. § 7.45 when it appears:

- The distributed product presents a risk of illness or injury or gross consumer deception
- Agency action is necessary to protect the public health and welfare
- The firm has not initiated a recall

ACTIVITIES THAT ARE NOT RECALLS

Removals and corrections may not meet the definition of a recall

- With other products, FDA has considered a removal to mean moving a product from where it is used or sold to another location
- 21 C.F.R. § 7.3(h): “Correction means the repair, modification, adjustment, relabeling, destruction, or inspection . . . of a product without its physical removal to some other location.”

Stock Recovery

- 21 C.F.R. § 7.3(k): A firm’s removal or correction of a product that has not been marketed or that has not left the direct control of a firm

Market Withdrawal

- 21 C.F.R. § 7.3(j): A firm’s removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration or which involves no violation

RECALL CLASSIFICATION

Under 21 C.F.R. § 7.3(m), FDA assigns a numerical designation to product recalls:

Class I Recall – A situation in which there is a reasonably probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death

Class II Recall – A situation in which use of, 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

Class III Recall – A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences

RECALL READINESS

General steps that can be taken to be prepared for a recall before an incident occurs:

- Identify appropriate personnel
- Train personnel on their recall responsibilities
- Establish a recall communications plan
- Use adequate product coding
- Maintain distribution records

PROBLEM WITH DISTRIBUTED PRODUCT

What can a firm do if there is a problem with a distributed product?

- Identify the problem
- Investigate the problem
- Make decisions and take action
- Consult with FDA about the problem

RECALL PROCESS

Generally, there are five major steps in the recall process:

1. Initiation of a recall including notifying FDA
2. Determination by FDA that the action is a recall and subsequent classification
3. Information dissemination: recall communications and potential public warning
4. Monitoring and auditing the recall
5. Termination of a recall

RECALL INITIATION: PROCEDURES

Possible actions for initiating a recall:

- Develop a recall strategy
- Notify direct accounts about the product being recalled, including what should be done with respect to the recalled product
- Notify the public about a potentially violative product that presents a serious hazard to health
- If firm initiated, notify FDA that firm is undertaking a recall and submit requested information
  - The appropriate contact for tobacco product recalls can be identified at: *https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm*

RECALL INITIATION: INFORMATION TO SUBMIT TO FDA

FDA may request the following information from firms during a recall:

1. Identity of the product involved
2. The reason for the recall and the date and circumstances of discovery
3. Evaluation of the risk associated with the deficiency or possible deficiency
4. Injuries or adverse events either reported to the firm or known to the firm
5. Total amount of such products produced and/or the timespan of production
6. Total amount of such products estimated to be in distribution channels
7. Distribution information, including the number and identity of direct accounts
8. A copy of the firm's public notification or recall communication or a proposed communication if none has issued
9. A proposed recall strategy
10. Name and telephone number of firm official to contact concerning the recall

RECALL INITIATION: RECALL STRATEGY

A firm's recall strategy is a planned, specific course of action to be taken in conducting a recall

An effective recall strategy often takes into account:

- Communication through entire distribution chain
- Results of a health hazard evaluation
- Ease in identifying the affected product(s)
- Degree to which the product's deficiency is obvious to the consumer
- Degree to which the product remains unused in the marketplace

FDA DETERMINATION OF RECALL AND CLASSIFICATION

FDA will review the information submitted by the firm to:

- Determine whether the removal or correction constitutes a recall
- Determine the appropriate recall classification
- Recommend any appropriate changes in the firm's strategy for the recall

Firms do not need to delay initiation of a recall pending FDA review of the firms submitted information

INFO DISSEMINATION: RECALL COMMUNICATIONS

A firm's recall communications generally:

- Are brief and to the point
- Identify the product, size, lot number(s), code(s) or serial number(s) and any other information needed to identify the product
- Explain the reason for the recall and the hazard involved
- Provide instructions on what should be done with the recalled product
- Provide a means for the recipient of the communication to report to the recalling firm whether it has any of the product

INFO DISSEMINATION: PUBLIC WARNINGS

Used to alert the public that a product being recalled presents a serious health hazard

- Public warnings can be disseminated through general or specialized news media
- FDA generally gives firms the first opportunity to draft and issue public warnings
- FDA may issue public warnings in a variety of forms, including, but not limited to, press releases, emails, and web and social media postings

INFO DISSEMINATION: FDA ISSUED PUBLIC WARNINGS

FDA may prepare and issue public warnings on its own initiative

- If a firm issues a public warning that is deficient in any respect, FDA may supplement or correct that warning with its own public warning
- If a firm's public warning is not reasonably likely to be adequately received by the target audience, FDA may ask the firm to reissue its public warning and/or FDA may issue its own public warning
- Additionally, FDA may publicly issue information that may address outstanding questions about the nature of the incident and/or the Agency's actions

INFO DISSEMINATION: PUBLIC WARNING CONTENTS

Elements that can be included in a public warning are:

- Information to help identify the recalled product
- The geographic areas and dates of distribution of the product
- A thorough description of the product defect, health hazard involved, and reason(s) for the recall
- The name and contact information for the recalling firm
- Instructions to consumers or users
- The number and nature of any illnesses/injuries/complaints associated with the product
- A description of common symptoms of any illness of concern

INFO DISSEMINATION: PUBLIC WARNING CONTENTS

Generally, public warnings do not include:

- Content that detracts from or defeats the purpose of the warning
- Content that promotes the qualities of the product being recalled, other products sold by the firm, or the firm in general

MONITORING & AUDITING: RECALL STATUS REPORTS

Recall status reports are requested by FDA to assess the progress of the recall

The reports generally contain the:

- Date and method of notification of recall to consignees
- Number of consignees that were notified of the recall
- Number of consignees that responded to the recall
- Number of consignees that did not respond to the recall
- Amount of product returned by each consignee or products accounted for
- Number and results of effectiveness checks that were conducted
- Estimated time frame for completion of the recall

MONITORING & AUDITING: EFFECTIVENESS CHECKS

It is generally the recalling firm's responsibility to ensure that the recall is effective

The effectiveness check is used to verify that the recall notification letter was received by the customer, that the customer read and understood the letter, and followed the recall instructions

A guide on conducting recall effectiveness checks can be found in *FDA's Regulatory Procedures Manual (August 2018), Chapter 7 – Recall Procedures – Attachment H – Methods for Conducting Recall Effectiveness Checks*

TERMINATION OF A RECALL

A recall will be terminated when FDA determines, in accordance with the recall strategy, that all reasonable efforts have been made to remove or correct the product, and when it is reasonable to assume that the product has been removed and proper disposition has been made

- FDA will provide written notification to the firm
- Firms may also request termination of their recall by submitting a written request

REFERENCES

21 CFR Part 7, Subpart C: Recalls (Including Product Corrections)--Guidance on Policy, Procedures, and Industry Responsibilities

Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C: Guidance for Industry and FDA Staff

Regulatory Procedures Manual (RPM) (Chapter 7) – Recall Procedures

Investigations Operations Manual (Chapter 7) – Recall Activities