

Regulatory Procedures Manual

Chapter 7: RECALL PROCEDURES

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7-1 PURPOSE

This chapter provides definitions, responsibilities, and procedures for agency components to initiate, review, classify, publish, audit and terminate recall actions. It implements 21 CFR Part 7 Subpart C – Recalls (Including Product Corrections) – Guidelines on Policy, Procedures, and Industry Responsibilities. See also [Investigations Operations Manual](#) Chapter 7 - Recall Activities. It also discusses FDA non-voluntary recalls and includes a reference to the procedures for implementing each of these authorities, including recalls of Medical Devices, Radiation Emitting Electronic Products, Biological Products, Human Tissue Intended for Transplantation, Infant Formula, Tobacco Products, and Food Products.

7-2 BACKGROUND

Recalls are an effective method for removing or correcting marketed products, their labeling, and/or promotional literature that violate the laws administered by the Food and Drug Administration (FDA). Recalls afford equal consumer protection but generally

are more efficient and timely than formal administrative or judicial actions, especially when the product has been widely distributed.

FDA regulated firms may initiate a recall at any time to fulfill their responsibility to protect the public health from products that present a risk of injury or gross deception, or are otherwise defective. Firms may also initiate a recall following notification of a problem by FDA or a state agency, in response to a formal request by FDA, as statutorily mandated or as ordered by FDA.

All agency components are expected to follow the requirements of this chapter. Although this chapter primarily implements 21 CFR Part 7 Subpart C, some deviation from the policy, definitions, responsibilities, and procedures under 21 CFR Part 7 Subpart C may occur with statutorily mandated and ordered recalls. See [Section 7-5-3](#). These deviations are noted throughout this chapter.

Guidelines delineating the responsibilities of industry in conducting recalls are in 21 CFR 7.40-7.59. Industry Guidance is available on the Internet at the FDA web site. It is designed for all FDA regulated industry and provides guidance both in the conduct of recalls and in the information needed by FDA to classify, monitor, and assess the effectiveness of a recall.

7-3 SUMMARY OF FDA RESPONSIBILITIES AND PROCEDURES

FDA responsibilities are summarized below. This chapter is arranged according to the following outline:

1. Initiation of a Recall. Includes voluntary, and non-voluntary recalls.
2. Determination that the Action is a Recall; Strategy; Classification. FDA formalizes the recall action by determining that the action meets the definition of a recall under 21 CFR 7.3(g)¹ or the applicable definitions for recalls conducted under different regulatory or statutory authorities. FDA reviews the information, including the recall strategy provided by the firm, assesses the health hazard presented by the recalled product, and classifies the recall in accordance with 21 CFR 7.41.
3. Notification and Public Announcement. FDA reviews a firm's recall strategy and suggests changes, including the issuance of a public announcement. FDA notifies the firm of the classification of the recall. The agency may issue its own public announcement of a firm's recall. FDA posts information about recalls at various locations on the FDA's Internet site: www.fda.gov/. FDA provides recall

¹ As defined in 21 CFR 7.3(g), "Recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or stock recovery." As defined in 21 CFR 7.3(j), "Market withdrawal means 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, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc."

information to other federal and state government agencies and to foreign governments.

4. Monitoring and Auditing the Recall. FDA develops and implements a recall audit strategy to ensure that the recall action has been effective.
5. Termination of a Recall. FDA determines when a recall should be terminated.

FDA may take appropriate regulatory action or other measures when the firm fails to recall violative product or when a recall action fails. Regulatory actions will be taken in consultation and coordination with the appropriate compliance branch, the appropriate center recall and compliance staffs, OSPOP/DE/ROB, and when indicated, the Office of Chief Counsel, when:

a firm refuses to recall or sub-recall after being requested or ordered to do so by the FDA;

or

the agency has reason to believe that the firm's recall strategy is not effective, or is not being **implemented** effectively

7-3-1 Responsibilities of the Office of Strategic Planning and Operational Policy/Division of Enforcement/Recall Operations Branch (OSPOP/DE/ROB)

OSPOP/DE/ROB responsibilities are detailed in [SMG 1121.81](#). OSPOP/DE/ROB serves as the agency focal point for guidance on recall plans and recall procedures; directs and coordinates field activities in support of all product recalls; and maintains communication with other agency components, industry, and domestic and foreign government agencies to ensure proper implementation and completion of recall plans and activities.

7-3-2 Responsibilities and Procedures – ORA/Office of Partnerships and Operational Policy (OPOP)

The responsibilities of Office of Strategic Planning and Operational Policy (OSPOP), in Office of Partnerships and Operational Policy (OPOP), are detailed in [SMG 1121.70](#). OSPOP develops, coordinates, and reviews compliance policies and regulatory procedures that can relate to recalls.

7-3-3 Responsibilities and Procedures – Office of Information Systems Management/ Division of System Solutions (DSS) /Enforcement Systems Branch

OISM/DSS/ESB responsibilities are detailed in [SMG 1121.812](#). DSS/ESB supplies recall information to internal FDA entities, in response to Freedom of Information Act (FOIA) requests, and, as appropriate, to applicable government agencies under the Government-Wide Quality Assurance Program (GWQAP). DSS/ESB is the business owner for the Enforcement Report application.

7-4 RECALL ENTERPRISE SYSTEM

The Recall Enterprise System (RES) is an electronic data system used by FDA recall personnel to submit, update, classify, and terminate recalls. Market withdrawals, stock recoveries, and safety alerts are not normally entered into RES. However, divisions may, consistent with agency policy, be directed by the Center Recall Unit (CRU) or OSPOP/DE/ROB to enter a specific market withdrawal or safety alert into RES and to monitor and audit the action in the same manner as a recall.

There may also be some instances where a division enters an action into RES and the CRU determines that the action does not meet the definition of a recall. The CRU will designate the action in RES as a market withdrawal, stock recovery, or safety alert. The CRU may also non-concur with the recall recommendation, for example in instances where a product is not under FDA jurisdiction and the recall is referred to another agency.

RES User Guides contain the detailed information needed for the use of RES. Electronic copies of the guides have been provided to field and center recall coordinators. The RES application currently has help information available for each screen. The RES increases efficiency in processing recall information by:

1. allowing field and center recall coordinators to input recall information via an on-line, Intranet system that captures all stages of the recall;
2. increasing communication of recall information between the field, headquarters, and the appropriate center(s) offices and reducing duplication of efforts;
3. providing a central, searchable database to more efficiently track information and generate and disseminate reports of recall activities.

The information entered in RES is gathered from various sources, including, the firm, ORA and the CRU. ORA is the business owner for the RES database. A RES account can be obtained by providing a FACTS User ID and completing the RES Account Request Form available on Inside.FDA. Submit the form via the preferred method of electronic mail to ORA Recall OE and indicate "RES Account Request" on the subject line. A Recall Operations Branch member will contact the requestor for the type of account or access that is requested and needed. Issues with RES (e.g. data entry, inability to access a record, failure of auto-generated emails delivered or sent) should be directed to the ORA Apps Desk.

Requests for deletion of RES events (such as duplicate events) should be directed to the OSPOP/DE recall staff, except for CBER events contact the CBER CRU.

7-4-1 Enforcement Report

The Enforcement Report is an online weekly publication of all recalls monitored by FDA once they are classified (21 CFR 7.50) and may be listed prior to classification when FDA determines the firm's removal or correction of a marketed product(s) meets the definition of a recall. Those records published prior to classification are referred to as "not yet classified" records. Recalls and "not yet classified" records are directly sourced

from RES and are compiled into weekly reports based on the classification date or the date the record is determined to meet the definition of a recall. Recalls and "not yet classified" records are posted to the Enforcement Report when Centers set the recall to be posted in RES. More information can be found on the [Enforcement Report home page](#).

Note: Change requests to the Enforcement Report should be directed to the CRU.

7-5 INITIATION OF A RECALL

A manufacturer or distributor may voluntarily initiate a recall at any time. Initiation of a recall means a recalling firm's first communication about a voluntary recall, to its direct accounts or to the public. FDA may conduct informal discussions with a manufacturer or distributor that include voluntary recall as an option. FDA may also request a recall, as provided for under 21 CFR 7.45. Under certain authorities, FDA may mandate a recall.

7-5-1 Firm Initiated Recalls

If a recall is firm-initiated under 21 CFR 7.46, the agency will review the information provided by the recalling firm under 21 CFR 7.46(a). This includes reviewing and suggesting changes to the firm's recall strategy, recall communication, and press release (if necessary).

FDA may inform a firm that a product violates the law and recommend they cease distribution and recall the product without specifically requesting a recall.

Evidence to support FDA's recommendation may be collected by FDA, a federal or state partner, or a third party.

If a firm decides to recall under these circumstances, the firm's action is considered a firm-initiated recall under 21 CFR 7.46(c). If a firm asks whether FDA is requesting a recall, FDA should explain that it is not requesting a recall, as a determination under 21 CFR 7.45 has not been made and that the agency has not exercised its authority under 21 CFR 7.45, or invoked its mandatory recall authority. This recommendation does not preclude FDA from considering other actions in the future.

When considering FDA's authority to request that a firm initiate a recall, see 21 CFR 7.45 and RPM Section 7-5-2, FDA Requested Recall.

When considering cease distribution and voluntary recalls under section 423(a) of the Act, see RPM Section 7-5-3, FDA Mandated Recalls.

Discussions with firms about firm-initiated recalls pursuant to a recommendation shall be conducted by: (1) the Program Director or designee, with the concurrence of the Center Director of the Office of Compliance or designee; or (2) the Center Director of

the Office of Compliance or designee, with the concurrence of the Program Director or designee.

- These discussions may occur during conversations with the firm(s), the firm's US agent (for a foreign firm), or the firm's legal representative. Such discussions should be documented in internal meeting minutes or notes, in accordance with agency's procedures.

If the firm does not agree to cease distribution and/or recall following FDA's recommendation, the agency may consider further action, as appropriate, including, but not limited to: public notification to consumers, healthcare practitioners, etc., an FDA-requested recall letter, an FDA-mandated recall (in the case of certain regulated products), seizure, administrative detention, or injunction. ORA and the Center(s) will consider taking appropriate follow-up action. ORA and the Center(s) will also determine whether the potential recall could cause a shortage of a regulated product and identify appropriate timeframes in which to accomplish these tasks based on the degree of risk associated with the recall. For firm initiated recalls, the agency will conduct a health hazard evaluation (HHE), (precedent HHEs or written classification policies may be used), will classify the recall, and will advise the firm in writing of the assigned recall classification. The letter to the firm will recommend any appropriate changes in the firm's recall strategy and advise the firm that its recall will be placed on the FDA web site. FDA will also assign audit checks as appropriate, will monitor the effectiveness of the recall communication, correction or removal, will verify appropriate product disposition, and will terminate the recall when appropriate.

The division:

- submits a Recall Alert;
- gathers information about the recall. It may conduct an establishment inspection and collect samples of the recalled or other suspect products;
- submits a Recall Recommendation and other information about the recalled product to the appropriate center;
- offers guidance to the recalling firm;
- monitors the recall; and,
- terminates Class II and III recalls and recommends termination for Class I recalls.

1. Recall Alert

The division, will submit a recall alert through RES within one working day, after the division recall staff has learned that a recall has been initiated and the firm has provided the necessary information. The purpose of the recall alert is to notify the appropriate CRU and OSPOP/DE/ROB of a firm's correction or removal is initiated or underway. Additionally, the recall alert will notify CRU and OSPOP/DE/ROB of the potential hazard or anticipated classification. The division should submit this Recall Alert through RES by completing, at a minimum, all the fields identified in

[Attachment A](#), and may submit any other information at the same time. In those instances where either the recalling firm has not submitted complete information or where entering the information will result in a delay of submitting the alert, enter a general description or “pending” in the mandatory fields identified in Attachment A. For recalls where the manufacturing site or responsible firm is located outside the monitoring division, copy the division recall staff where the manufacturing site or responsible firm is located. Alerts have not been required for device recalls under section 518(e), biologics recalls for which CBER issued an "alert to possible recall," and corrective action program (CAP) recalls involving radiation emitting medical devices and electronic products. These exemptions will continue under RES.

2. Recall Recommendation and Related Information

The purpose of a recall recommendation is to notify the CRU and OSPOP/DE/ROB Recall that the firm’s action is recommended as a recall and its anticipated classification. Additionally, it serves as a notification to the CRU that the necessary information is available and entered in RES for the CRU to review and classify the recall. The division must submit a complete Recall Recommendation (RR) through RES within five working days after the recalling firm has provided the information necessary for the RR. When the information is submitted through the RES system, it automatically alerts the appropriate CRU and OSPOP/DE/ROB via e-mail. See [Attachment B](#) for guidance on the information required by the CRU to review and classify the recall. The division may submit the Recall Alert and Recommendation up to 10 working days after the division learns of a “completed” recall. When sending recommendations where the manufacturing site or responsible firm is located outside the monitoring division, copy the division recall staff where the manufacturing site or responsible firm is located.

If there is insufficient information to submit an RR, the division recall coordinator should telephone or email the appropriate CRU and OSPOP/DE/ROB for advice on a course of action.

Notes:

1. When requested by OSPOP/DE/ROB or the CRU, submit an RR for a product removal as a result of actual or alleged tampering with individual unit(s) where there is no evidence of manufacturer or distributor responsibility. They should recommend the action be designated as a market withdrawal since, although the situation may present a health hazard, there is no one identified as responsible for the violation. This RR submission and market withdrawal recommendation will allow documentation and monitoring of the market withdrawal.
2. FDA does not ordinarily classify or audit interstate milk shippers (IMS) and Interstate Shellfish Shippers (ISS) product recalls where such actions have been, or are being, handled expeditiously and appropriately by the state(s). The FDA division office in which the recalling firm is located must be ensured that all state(s) involved in an IMS plant's recall are participating in ensuring removal of the product from commerce and that,

when appropriate, state(s) issue warnings to protect the public health. In the event that FDA determines that the states are unable to effect the recall actions necessary, the agency will classify, publish, and audit the recall, including issuance of a public warning when indicated.

3. Exported products may not be documented in RES when the following scenarios apply:
 - The product(s) are labeled for export only, and/or
 - The product(s) are labeled for foreign distribution only (e.g. all labeling in foreign language), and/or
 - The recall is already monitored by competent foreign authority (e.g. the U.S. firm contract manufactured for a foreign firm, no U.S. distribution, and the foreign firm assumes responsibility for recalling marketed product and has reported the recall to be monitored by the foreign authority, and/or
 - Foreign firm is the recalling firm and has no U.S. distribution.

3. Establishment Inspection

The division will contact the firm to obtain recall information and, in the case of recalls that have been classified as or appear to be class I or significant class II recall situations, an establishment inspection should, in addition to other activities, determine the root causes of the problem and document violations for possible regulatory action. See the [IOM Chapter 7 – Recall Activities](#) for information on conducting recall related inspections.

In many recall situations, the firm's production facility may differ from the recalling facility, typically a headquarters or corporate office. In these cases, the monitoring division will contact the division where the violation occurred and request an inspection of the responsible establishment. The investigating division, in turn, should keep the monitoring division informed of the inspectional progress and findings.

Usually during this initial contact, the center has neither evaluated the health hazard nor classified the recall. In that case, the division office should not urge the firm to expand its recall efforts.

If the recall has been completed before FDA's knowledge of it, division personnel should obtain documentation of actions taken to dispose of or recondition the recalled products. This documentation may include processing records or laboratory analysis, process validation protocols and reports, signed destruction receipts, salesperson's written receipts, corporate official's signed statement on firm's stationery, etc. The division should update RES with the recommendation and termination information within 10 days of learning of the recall.

If the responsible firm is out of business or is unable to conduct an effective recall for any reason, the division should notify the CRU and OSPOP/DE/ROB. The division

and the CRU should develop an appropriate course of action to recommend to the ACRA. In significant situations involving a serious health hazard, this could involve issuance of press to notify the public and/or FDA notifying consignees directly.

4. Official Samples

The division must determine the need for an official sample, either physical or documentary. Typically collect samples when they best demonstrate the defect and potential hazard. The decision to collect an official sample is a division management prerogative unless required by specific headquarters' initiated assignments, or the occasional direct request from the CRU or OSPOP/DE/ROB. Samples collected should document interstate movement as well as the violation.

5. Firm Recall Communication and Notification

The FDA Division Recall Coordinator (DRC) should offer guidance to the recalling firm and will offer to review the text of recall communications to consignees so that the product will be promptly removed or corrected. The CRU and OSPOP/DE/ROB staff are available, if necessary, to assist the DRC. Recall communications can be in multiple forms including press releases, telephone calls, telegrams, telefaxes, mailgrams, or first class letters. For tobacco products, the Center for Tobacco Products should be contacted for guidance on any recall communications and notifications submitted by the recalling firm.

The recalling firm should discuss any recall communications and notifications with the FDA DRC before issuance. The possible need for bilingual or multilingual communications should be explored between the FDA DRC and the firm.

All recall communications should be written in accordance with the following guidelines: be brief and to the point; clearly identify the product(s) such as the product name, size, brand name, serial numbers(s), potency, dosage, type, model, lot number(s), UPC codes, Unique Device Identifier (UDI) if applicable, and any other pertinent descriptive information to enable accurate and immediate identification of the product; contain a concise statement of the reason for the recall; state known or potential hazard(s), and instructions for consignees to follow in handling the recall. If possible, the recall letter may provide the initial shipping date and quantities shipped. See [Exhibit 7-4](#) Model Recall Letter.

If a firm has voluntarily initiated a recall of any product(s), then it is responsible for promptly notifying each of its direct accounts. If the depth of the recall is beyond the direct accounts, then the direct accounts should be instructed by the recalling firm to contact sub-accounts that may have received the product.

Sub-accounts, which further distributed the product, should continue the recall to the depth established in the recall strategy. A written recall communication to sub-accounts should be in addition to any other means of communication, such as monthly sales bulletins, manufacturer representative visits, or recorded phone messages. These actions may aid in a sub-recall effort, but they are an inadequate communication of the recall.

Ensure that the recalling firm conspicuously marks the outside (e.g. the envelope) and the enclosed information (e.g., the recall letter or other type of message) of the recall communication “DRUG (or FOOD, BIOLOGIC, MEDICAL DEVICE, TOBACCO PRODUCTS, etc.) RECALL (or CORRECTION).” Additionally, the outside and enclosed information should be marked “URGENT” for all Class I and Class II recalls, and, when appropriate, for Class III recalls.

Recall communications should be sent in the most expeditious manner and commensurate with the hazard of the product being recalled, and, where appropriate, sent with proof of receipt (e.g., by certified mail). All communication methods related to the firm’s recall should be documented accordingly.

Recall communication, particularly letters to direct accounts and sub-accounts should include a postage-paid, self-addressed post card, envelope, or other arrangement to enable the consignee to report the amount of the product available and its disposition. Recall communications should direct that the consignee submit a report regardless of whether or not any of the products are on hand. It should also stress prompt return of the post card or other report. (See Exhibits 7-4, 7-5, 7-6, [FDA Recall Industry Guidance](#) webpage for model letters, envelopes, and recall return response forms.) The guidelines referenced above and additional information on Recall Communications can be found in 21 CFR 7.49.

Note: A FDA Food Recall/Action Initiation Process Flow – Timeline for Class I Human Food Recalls (SAHCODH) is in Appendix A. It describes a timeline for FDA to follow in pursuing Class I food recalls and provides options to follow should a firm not initiate a recall.

7-5-2 FDA Requested Recall

This section only applies to FDA requested recalls in accordance with 21 CFR 7.45. FDA Requested Recalls are ordinarily reserved for urgent situations where mandatory recall authority does not exist or is not appropriate. Additionally, FDA Requested Recalls should only be pursued following informal recall discussions with a firm per the procedure in RPM 7-5-1.

FDA recall requests are directed to the firm that has primary responsibility for the manufacture or marketing of the product when the firm does not undertake a product recall on its own initiative. FDA requested recalls are most often classified as Class I. Generally, before FDA formally requests a recall action, the agency will have evidence capable of pursuing an action such as seizure, injunction, warning letter, etc. The completion of either a firm initiated or FDA requested recall does not preclude FDA from taking further regulatory action against a responsible firm. The Associate Commissioner for Regulatory Affairs (ACRA) approves all FDA requests for firms to conduct recalls.

FDA requested recalls may begin with various communications between the field and headquarters units but will be formally initiated when the division/center creates a compliance action in CMS “FDA Requested Voluntary Recall.” All data and documentation related to the problem, as indicated above under the Recall

Recommendation and the Establishment Inspection paragraphs, will be obtained and uploaded into CMS. The Division/Center which created the action will schedule a call between the division, center, OSPOP/DE/ROB, and OCC to discuss the merits of the action and make a decision whether or not to pursue FDA Requested Recall. If the decision is to pursue, the CRU will process the recommendation as outlined in the following paragraphs on Recall Classification and Strategy and submit an Action Memorandum and draft FDA Requested Recall Letter to the ACRA through OSPOP/DE/ROB. The draft letter will specify the violation(s), health hazard involved, recommended recall strategy, timeframe for the firm's response to FDA, and any other instructions appropriate to effectively conduct the recall (See Exhibit 7-7). The Center will upload the recommendation package into CMS and notify OSPOP/DE/ROB that the recommendation is ready for review.

OSPOP/DE/ROB will review the Action Memorandum and promptly prepare and forward to OCC a recommendation through CMS which includes the draft FDA Requested Recall Letter. After OCC review and approval, OSPOP/DE/ROB will forward the final package to the ACRA for final review and signature of the FDA Requested Recall Letter.

If the center's recommendation is approved by the ACRA and the letter to the recalling firm signed, OSPOP/DE/ROB will send the ACRA signed letter to the firm indicating FDA's determination of the need to immediately begin a recall.

When the division receives a copy of the letter sent to the responsible firm by the ACRA, division personnel should verify the firm's receipt of the letter and, where appropriate, make arrangements to visit and/or inspect the firm as soon as possible. Coordination with the CRU, Office of Criminal Investigations, or other offices may be necessary in special situations.

The division office will offer the same guidance to the recalling firm as outlined above in Firm Recall Communication and Notification and will assist the firm in arranging the text of recall communications to consignees so that the product will be promptly removed or corrected. Once the recall has been initiated, the DRC will enter the recall into RES and ensure the CMS Action includes the RES Event number for future data tracking.

All parties will work collectively with the Office of External Affairs to draft, clear, and promptly release, if warranted, a public statement regarding the FDA Requested Recall. Although only one statement will be used, two statements should be drafted and cleared, one which indicates the firm initiated a recall and one which indicates the firm refused to recall. If the product is related to an ongoing issue, i.e. outbreak, previously released public statements can be used and/or amended in lieu of creating a new statement.

Various sections of the law authorize FDA to order a firm to recall a product or mandate recall requirements. Additionally, recalls may be ordered by a consent decree. Below is a listing of mandated and ordered (via statute or consent decree) recall types as well as links existing statutes, regulations, procedures and guidance documents.

1) Ordered recalls

a. Commodity: Foods other than infant formula

Statute: [Section 423 of the FD&C Act \[21 U.S.C. § 350\]](#)

Implementing Regulations: N/A

Criteria: Gives the FDA the authority to order a responsible party to recall an article of food where the FDA determines that there is a reasonable probability that the article of food (other than infant formula) is adulterated under section 402 of the FD&C Act [21 U.S.C. § 342] or misbranded under section 403(w) of the FD&C Act [21 U.S.C. § 343(w)] and that the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals (SAHCODHA).

Procedures: Regulatory Procedures Manual, Chapter 7, Attachment J

Industry Guidance: [Guidance for Industry and FDA Staff: Questions and Answers Regarding Mandatory Food Recalls](#)

b. Commodity: Medical Devices for Human Use

Statute: [Section 518\(e\) of the FD&C Act \[21 U.S.C. § 360h\]](#)

Implementing Regulations: [21 CFR 810](#)

Criteria: Gives the FDA the authority to order a recall of a device where there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death.

Procedures: Regulatory Procedures Manual, Chapter 7, Attachment G

Industry Guidance: N/A

c. Commodity: Tobacco Products

Statute: [Section 908\(c\) of the FD&C Act \[21 U.S.C. § 387h\(c\)\]](#)

Implementing Regulations: N/A

Criteria: Where 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, gives FDA the authority to issue an order

requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the FDA determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

Procedures: Regulatory Procedures Manual, Chapter 7, Attachment I

Industry Guidance: N/A

d. Commodity: Controlled Substances

Statute: [Section 569D of the FD&C Act \[21 U.S.C. § 360bbb-8d\]](#)

Implementing Regulations: N/A

Criteria: Where there is a reasonable probability that a controlled substance would cause serious adverse health consequences or death, the FDA may, after providing the appropriate person with an opportunity to consult with the agency, issue an order requiring manufacturers, importers, distributors, or pharmacists, who distribute such controlled substance to immediately cease distribution of such controlled substance.

Procedures: Regulatory Procedures Manual, Chapter 7, Attachment K

Industry Guidance: N/A

e. Commodity: Biological Products

Statute: [Public Health Service Act \(PHS Act\) recall authority for biological products \(42 U.S.C. 262\)](#)

Implementing Regulations: N/A

Criteria: If a determination is made that a batch, lot, or other quantity of a product licensed under the PHS Act presents an imminent or substantial hazard to the public health, the FDA has the authority to issue an order for its immediate recall.

Procedures: N/A

Industry Guidance: N/A

f. Commodity: human cell, tissue, and cellular and tissue-based product (HCT/P)

Statute: [legal authority of section 361 of the Public Health Service Act \(PHS Act\) \(42 U.S.C. 264\)](#)

Implementing Regulations: [21 CFR Part 1271.440](#)

Criteria: Upon a FDA finding that there are reasonable grounds to believe that an HCT/P is a violative HCT/P because it was manufactured in violation of the regulations in 21 CFR part 1271 and, therefore, the conditions of manufacture of the HCT/P do not provide adequate protections against risks of communicable disease transmission; or the HCT/P is infected or contaminated so as to be a source of dangerous infection to humans; or an establishment is in violation of the regulations in this part and, therefore, does not provide adequate protections against the risks of communicable disease transmission

Procedures: Regulatory Procedures Manual Chapter 5 - Administrative Actions, Order of Retention, Recall, Destruction, and Cessation of Manufacturing Related to Human Cell, Tissue, Cellular and Tissue-Based Products (HCT/Ps)

Industry Guidance: N/A

2) Mandated Recall Requirements

a. Commodity: Infant Formula

Statute: [350a\(f\)](#)

Implementing Regulations: [21 CFR Part 107, Subpart E](#)

Criteria: When the Food and Drug Administration determines that an adulterated or misbranded infant formula presents a risk to human health, a manufacturer shall immediately take all actions necessary to recall that formula, extending to and including the retail level, consistent with the requirements of 21 CFR Part 7 Subpart E.

Procedures: Regulatory Procedures Manual, Chapter 7, Attachment F

Industry Guidance: N/A

b. Commodity: Recalls of Radiation Emitting Electronic Products Under Subchapter C - Electronic Product Radiation Control of Chapter V of The Federal Food, Drug, And Cosmetic Act (The Act), Formerly the Radiation Control For Health And Safety Act Of 1968 (RCHSA)

Statute: mandated recall provisions written into the Act [\(Sec. 535\(a\)\) \[21 U.S.C. 360III\]](#)

Implementing Regulations: [21 CFR 1000 – 1050](#)

Criteria: The law requires a manufacturer, when he learns that a product he manufactures is either defective or not in compliance with a published

performance standard, to notify the Secretary of Health and Human Services (delegated to CDRH Director), and to notify the first purchaser (and known subsequent transferees) of the defect(s) or noncompliance(s). Subchapter C is specific as to the method of notification and procedure, and contains "repair, replace or refund" provisions.

Procedures: Regulatory Procedures Manual, Chapter 7, Attachment E

Industry Guidance: See [FDA Homepage for Radiation-Emitting Products](#)

3) Recalls Ordered by Consent Decree

Recalls may be ordered by FDA in accordance with the terms of a consent decree when FDA determines, based on the results of an inspection, the analysis of a sample, data received from the defendants, an expert, an auditor, or any other method, that the defendants have failed to comply with the provisions of a consent decree, have violated the Act or applicable regulations, and/or additional corrective actions are necessary to achieve compliance with the consent decree. In such cases, the recall will be initiated and monitored within the timeframes and manner prescribed by the consent decree. Correspondence to the recalling firm should include the injunction number and/or other identification of the injunction (example: United States v. ABC Firm, Inc., et al, [Injunction number]). Consent decrees typically authorize FDA to bill defendants for expenses associated with recalls initiated under a consent decree including, as applicable: inspections, investigations, supervision, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses to implement and monitor recalls. Consequently, time spent reviewing and monitoring the recall should be recorded.

7-5-4 Removals and corrections involving products exported from the U.S. and products imported to the U.S.

In most instances, removals and corrections of violative products exported from the U.S. will be entered, processed, and classified in RES. For example, when a firm removes/corrects a violative product(s) manufactured in the U.S. where some or all of the products/lots were distributed outside of the U.S., the action should be documented as a recall in RES.

Similarly, removals and corrections of imported products should be documented in RES. Removals and corrections of imported products may be conducted by the foreign firm, the importer of the product, or by a US affiliate of the foreign firm.

OSPOP/DE/ROB may receive reports of removals and corrections from firms that export products into the U.S. or from foreign authorities that may need to be documented in RES. These include foreign food inspections resulting in firms removals, emails from foreign firms, foreign government.

In such cases, OSPOP/DE/ROB's responsibility is to:

1. Acknowledge receipt of the information from the foreign authority or firm.

2. If the information is received from a foreign authority, ascertain whether requests for additional information should be made to the authority or directly to the recalling firm. Request, if necessary, contact information for the firm official who will provide FDA with recall information.
3. If necessary, request additional information: reason for recall, product description and codes, product labeling, firm's U.S. consignee/distribution list, firm-owned or affiliated U.S. facilities, firm's U.S. affiliate, agent, or importer.
4. Upon receipt of the information from the firm or foreign regulator, forward to the appropriate CRU for their situational awareness and include the ORA Recall Coordinator for the appropriate division, once a division has been identified. OSPOP/DE/ROB may request the CRU to confirm a violation or potential for health hazard, as necessary.
5. Refer the recall to an ORA Recall Coordinator for the appropriate Program Division. OSPOP/DE/ROB will consider available information when determining which Program Division should handle the matter to assign the recall. Some factors for consideration may include the location of the foreign firm's U.S. facilities (U.S. corporate headquarters or sister company), location of importer(s), the U.S. firm listed on the product packaging, location of US agent or firm's affiliate and any existing contractual agreements with the foreign firm. In instances when there is more than one US Importer or more than one US firm affiliated with the recalling firm, OSPOP/DE/ROB will designate the Monitoring Division as the Division where the highest amount of distribution occurred.

However, some removals and corrections of imported/exported products may not be documented in RES. Divisions should consult the CRU and OSPOP/DE/ROB when confronted with the following scenarios:

- 1) The product(s) are labeled for export only, and/or
- 2) The products are labeled for foreign distribution only (e.g. all labeling in foreign language), and/or
- 3) The recall is already being monitored by a foreign authority (e.g. the US firm contract manufactured for a foreign firm and the foreign firm is taking responsibility for recalling marketed product and has reported the recall to be monitored by the foreign authority).

Pharmaceutical Inspection Co-operation Scheme (PIC/S)

FDA is a member of PIC/S, a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. Recall information is shared between PIC/S members who follow the PIC/S SOP "[Procedure for Handling Rapid Alerts and Recalls Arising from Quality Defects.](#)"

1) OSPOP/DE

- Manages FDA's PICS/RANS Outlook mailbox by forwarding incoming Rapid Alerts to appropriate centers, sending Rapid Alerts generated by FDA centers to PIC/S members, and facilitating responses to inquiries received from PIC/S members

2) CDER, CVM, and CBER Recall Units

- Review incoming Rapid Alerts from PIC/S members to determine whether FDA follow-up is necessary and direct the follow-up
- Review incoming FDA recalls to determine whether they fit the PIC/S SOP criteria for generating a Rapid Alert to other PIC/S members, generate the rapid alert and forward it to the PICS/RANS mailbox for OSPOP/DE to disseminate
- As needed, respond to additional inquiries from other PIC/S members

3) FDA Division Recall Coordinators

- For potential class I and II pharmaceutical recalls, list any foreign direct consignees in the RES Recall Recommendation

Rapid Alert System for Food and Feed (RASFF)

RASFF or the Rapid Alert System for Food and Feed is a platform that enables information sharing from the European Union regarding Food & Feed Safety Events.

RASFF sends notifications via email when a food or feed poses a serious health risk in the European market and a rapid action is warranted. The RASFF member that identifies the problem, takes the relevant actions (e.g. recalls) and triggers the rapid alert. FDA's Office of Crisis Management (OCM) receives these rapid alerts, including ones that list US consignees for products that have been recalled by foreign firms. OCM transmits recall related RASFF information in an email to the OSPOP/DE/ROB, the appropriate Center Recall Unit (CRU) and the respective HAF Divisions where consignees are located.

Subsequently the following steps take place:

- The CRU reviews the information to determine if expedited follow up will be needed based on the following two criteria: the recalled product is in violation of the FD&C Act

and may cause serious health consequences. If those criteria are met, the appropriate Center advises the respective HAF Division to monitor the event.

A domestic recall may not be necessary if, for example, the product is past its shelf life or has not been distributed by the initial importer.

There are other factors that may justify additional follow up outside of normal regulatory procedures. Examples of these factors may include the population affected by the problem and/or the possible public concern or other stakeholder attention to the problem.

-If there is more than one US consignee located under different HAF Divisions, OSPOP/DE/ROB designates the monitoring division. In this instance the foreign firm is considered the recalling firm.

-The respective HAF Division enters the event in Recall Enterprise System (RES) and monitors the recall. The appropriate Center classifies the event.

Note: For instances when a recall may warrant an import alert, please refer to RPM Ch 9.

7-6 RECALL CLASSIFICATION AND STRATEGY

The Center Recall Unit (CRU):

1. initiates a health hazard evaluation;
2. finalizes a recall strategy;
3. determines that the firm's action is a recall, classifies the recall, and, for Class I recalls, prepares an Action Memorandum for Center Director or his/her designee concurrence and,
4. updates RES with classification, audit strategy, and any recommendations.

7-6-1 Health Hazard Evaluation

The agency will conduct or obtain health hazard evaluations (HHE) for each recall scenario. Precedent HHEs will be used where the product is identical or similar with basically the same defect or violation as a recall action previously classified. Precedent HHEs will be re-evaluated and updated periodically. Established precedent recall policies such as those established by CDRH may also be used.

Upon receipt of each recall recommendation or other information, from any source, which indicates a recall may be necessary, the CRU determines whether an up-to-date health hazard precedent exists covering the situation. If not, it forwards the appropriate information to the Center Health Hazard Evaluation Committee for review. Additional information received during the progress of a recall should also be forwarded to the committee for timely health hazard reevaluation.

The Health Hazard Evaluation Committee in each center should use the Health Hazard Evaluation Worksheet ([Attachment D](#)) to record their evaluations. This evaluation will take into account the factors listed in 21 CFR 7.41(a) and [Attachment D1](#) of this chapter. The health hazard evaluation form must be prepared by knowledgeable center personnel and should reflect their written concurrence. The HHE committee may use a precedent health hazard evaluation in lieu of conducting a new HHE for a similar situation. It is the responsibility of the HHE Committee to ensure itself that all reviewers are familiar with the intent of the evaluation.

The HHE Committee will complete, endorse, and forward the health hazard evaluation form to the center recall unit within two (2) working days after receiving a recall recommendation unless additional information is required. It is the responsibility of the HHE Committee to notify the CRU when further information is needed. If the recall recommendation indicates that the product is no longer in distribution channels, they will complete, endorse, and forward the HHE to the CRU within five (5) working days.

The Health Hazard Evaluation Committee must promptly reevaluate the initial health hazard when additional data regarding injury, illness, medical, or scientific findings is received by the center. Where additional data are being received on a continuing basis, the committee is to routinely meet and reevaluate the health hazard at least biweekly.

The CRU should coordinate their review with other centers when necessary. Any questions about lead center responsibility or jurisdiction should be promptly referred to OSPOP/DE/ROB.

7-6-2 Classification Process

The CRU documents the recall determination and/or recall classification in the appropriate fields in RES.

If the recall determination is made before the recall is classified, then the CRU documents and sends the determination decision in RES and enters the classification as “not yet classified.” Once the action has been determined to meet the definition of a recall, with or without a classification, the information should be posted to the [Enforcement Report](#). The Enforcement Report will display the recall designated as “not yet classified” or the product classification, if available. Once classification occurs, the Enforcement Report designation of “not yet classified” is updated by the CRU to reflect the classification.

For ongoing recalls, the CRU will normally classify recalls within two days after receiving the health hazard evaluation or confirming the classification through precedent review. They will add classification information to the recall document in RES and transmit the classification electronically to the monitoring district and OSPOP/DE/ROB.

The CRU is responsible for reviewing, correcting, editing and or adding necessary information in the RES public information fields.

The ACRA has approval authority for all Class I recalls. However, the ACRA has delegated approval of voluntary firm-initiated Class I recalls to center directors. This has

been done to streamline the recall classification process in the center, expedite the handling of the recall by industry and FDA division offices, and in certain situations, to have it universally understood that these recalls represent potentially serious to life-threatening health hazards. The center director may further delegate within the center compliance office the authority for review and classification of recall actions

NOTE: FDA will normally evaluate, prepare, and approve necessary action memorandum on infant formula manufacturers' notifications submitted in compliance with section 412 of the Act within five calendar days.

The CRU may classify Class II and III recalls without management review. However, unusual and/or potentially high profile recall issues should be brought to center management's attention.

7-6-3 Recall Strategy

Each recall is unique and requires its own recall strategy. The DRC initially works with the firm to develop an appropriate recall strategy. The CRU will review the firm's recall strategy for voluntary recalls and recommend necessary changes. The recall strategy includes the type of notification and depth of the recall. It also contains the depth and level of audit checks and the need for public warning. Recall strategies are based on the individual recall circumstances and are not necessarily dependent on the recall classification.

1. Elements of a Recall Strategy

As specified in 21 CFR 7.42(b), a recall strategy takes into account the following factors, based on the individual recall circumstances.

- A. 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 to which the recall is to extend. In general, Class I recalls may extend to the consumer or user level, Class II recalls may extend to the retail level, and Class III recalls may extend to the wholesale level.
- B. Public warning. See Section 7-7-3
- C. Effectiveness Check Level. The purpose of a firm's effectiveness checks 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. This includes the method(s) to be used for and depth of recall effectiveness checks.

The firm's recall strategy should consider the disposition of recalled products (e.g., carcinogenic products) when normal disposition means, landfill, crushing, denaturing, etc., are inadequate. The DRC should advise firms to follow any applicable regulations regarding disposition, e.g. disposal of hazardous waste.

Firms wanting to recondition their product should develop a written formal reconditioning proposal and submit the proposal to the division for CRU review.

CFSAN requests all reconditioning proposals for recalled FDA regulated food products be submitted through MARCS-CMS. When submitting a reconditioning proposal to CFSAN, division should ensure:

- The division includes a submission memo that describes the problem and the input the division is requesting from CFSAN.
- All pertinent documents are loaded into the MARCS-CMS case file
- Documents are loaded separately under the proper tabs
 - o For example, labels should be loaded under the “Documents - Evidence - Labeling” tab; recommendation memos, FDA Form 766 and attachments under the “Documents - Recommendation - ORA” tab.

2. Recall Strategy Review or Development

In reviewing or developing a recall strategy, the DRC and CRU should take into account the health hazard evaluation, type or use of the product, the ease in identifying the product, the degree to which the product's deficiency is obvious to the consumer or user, the amount of product remaining unused in the marketplace, distribution pattern, planned correction or removal, and the continued availability of essential products.

For firm initiated recalls the CRU will review and recommend or concur with the firm's recall strategy and the division's recommendations for the FDA recall audit strategy e.g. recall audit check level, depth. The center will communicate recommended changes in the firm's recall strategy and effectiveness checks and the FDA recall audit strategy to the Division Recall Coordinator and OSPOP/DE/ROB and update RES.

Instances when a responsible firm is out of business or is unable to conduct a recall for any reason. The CRU, working with the involved division, will consult with OSPOP/DE/ROB.

The Division Recall Coordinator and the CRU should discuss any corrections/modifications to the recall strategy, as necessary, for follow-up and correction by the recalling firm.

7-7 NOTIFICATIONS AND PUBLIC WARNING

7-7-1 Reports and Reporting Procedures

1. Identification of Recall Documents

All units referencing recall actions should identify them by the RES generated “Record Event Number.” After classification, the recall number(s) may be added, but the primary identification will still be the Record Event Number. This will allow all FDA personnel operating in the RES to immediately locate the required recall record.

2. Monitoring Recall Progress

Division recall coordinators will update the "Recall Status" field in RES when they become aware that a recall's status has changed from "Not Initiated" to "Ongoing" to "Completed" to "Terminated."

For certain Class I recalls and Class II recalls, OSPOP/DE/ROB will request the monitoring Division send periodic reports on the progress of the recall to the CRU and OSPOP/DE/ROB until the recall is completed or until advised otherwise by OSPOP/DE/ROB. OSPOP/DE/ROB will specify the details of the progress report.

Once the Division Recall Coordinator has been made aware of a recall and a RES entry is created, the DRC will request that recalling firms begin sending periodic recall status reports. See 21 CFR 7.53(b). The DRC will send a written acknowledgement to the recalling firm including the following: request the firm to submit periodic recall status reports, notify FDA prior to voluntary product destruction or product reconditioning, and to conduct Effectiveness Checks. A model Acknowledgement is attached as Exhibit 7-8. The acknowledgement may be addressed to the firm's recall contact and sent via any preferred method (e.g. e-mail)

3. Division Notification to the Recalling Firm

The monitoring division, upon receiving the recall number, classification, and recall strategies from the center, will then promptly prepare and send a notification letter to the firm stating the agency's position with respect to the recall. Prior to issuing the recall notification letter, the division may notify the recalling firm by telephone of the recall classification and its posting on FDA's Enforcement Report.

This letter will provide the recall number(s), the classification of the recall, product description, codes, the agency recommendation for appropriate recall depth and recall effectiveness check level. It will indicate FDA's determination to verify returned product disposition by stating that the division office should be notified prior to the initiation of reconditioning or destruction of recalled products and that such action should be witnessed by an FDA investigator. (An alternative means, such as verification by appropriate state or local officials, may be used.) The letter should also inform the firm that the recall will be posted FDA's Enforcement Report. The letter should encourage proper corrective action and request periodic status reports from the recalling firm as described in 21 CFR 7.53(b). The letter should include a statement that failure to conduct an effective recall could result in either seizure of the violative product or other legal sanctions under the FD&C Act or related statutes.

The notification letter should be prepared for the signature of the division director or his/her delegate. It should also include the name and telephone number of the division's recall coordinator to assist the firm in answering any questions related to the recall classification.

A model Notification of Classification Letter is attached as Exhibit 7-9. This exhibit serves only as a model. These letters should be written on a case-by-case basis and tailored to each unique recall situation.

In instances where the recall is terminated at the same time it is classified, the division will prepare a combination notification/termination letter to the firm. This letter will provide the recall number(s), the classification of the recall, and indicate that FDA considers the recall terminated. A Combined Recall Notification of Classification and Termination Letter is attached as Exhibit 7-12.

4. Audit Check Reports

Report all recall audit checks on form FDA 3177, Recall Audit Check Report.

7-7-2 Notification to Other Government Agencies

FDA maintains contacts with state and local officials regarding recalls.

FDA is also obligated through existing agreements, to notify certain partner government agencies and foreign governments when recalled products have been distributed to consignees of interest to those agencies or governments. These agreements include, but are not limited to, memorandums of understanding, systems recognition, and Pharmaceutical Inspection Co-operation Scheme (PIC/S). The existing agreements specify which FDA office is responsible for sharing the information and those offices should establish internal procedures to assure their responsibilities are met. Sections below identify certain FDA offices responsible for sharing this consignee information.

The sections below also identify the specific consignees of interest that division offices need to enter in RES "Consignee Details" field that is found on the "Events Detail" page at the time the recall recommendation is submitted. For each consignee identified, enter the consignee's name, complete address and telephone number.

1. Notification of State and Local Officials

1.1 Responsibility of division offices

Division offices should consider appropriate notification to state and/or local officials of recall actions that may be pertinent to them. The divisions should also consider requesting necessary assistance from state and local officials either in conducting or auditing recalls. For more information, see [FMD 50 State Correspondence](#).

1.2 Responsibility of the Office of Communications and Project Management (OCPM)/Division of Communications (DC)/Public Affairs Branch (PAB)

OCPM/DC/PAB informs state and local officials by electronic mail system of selected recalls presenting serious health hazards, where intense publicity is anticipated, and/or where state assistance is requested. The OCPM/DC/PAB also distributes other publicity prepared to these officials.

2. Notification to Foreign Governments

2.1 Responsibility of Division Offices

Division offices should review recalling firm's distribution lists and provide specific direct account foreign consignee information for the following recalls:

- CDER Class I and Class II
- CBER Class I (CBER regulated devices only)
- CFSAN all recalls (food and cosmetic)
- CVM Class I and Class II (animal food and drugs)

2.2 ORA headquarters and center offices responsibility for sharing direct account foreign consignee information with foreign governments

OSPOP/DE/ROB is responsible for sharing consignee information for foods with the Canadian Food Inspection Agency and for cosmetics with Health Canada. CFSAN International Affairs Staff is responsible for sharing consignee information with countries other than Canada.

3. Notification to Department of Defense/Defense Logistics Agency Military

3.1 Responsibility of Division Office

Division offices should review recalling firm's distribution lists and provide specific direct account Defense (DoD) and Veterans Affairs (VA) consignee information for all recalls.

3.2 OSPOP/DE/ROB's Responsibility

OSPOP/DE/ROB is responsible for sharing consignee information for human/animal food, cosmetic, and tobacco recalls with Defense Logistics Agency (DLA).

OSPOP/DE/ROB notifies GWQAP when medical products under recall (Class I, II, and III) have been distributed to Defense Logistics Agency (DLA) and the Department of Veterans Affairs (DVA) facilities.

3.3 Responsibilities and Procedures - Compliance Systems/Enforcement Systems

Branch (HFC-240)

The Government-Wide Quality Assurance Program (GWQAP), managed by DSS/ESB, supplies recall information to applicable government agencies.

- a. Reviewing the RES notices provided from the OSPOP/DE/ROB to assure that it contains VA and/or DoD distribution
- b. Providing the DVA and DLA Troop Support (DLA) formerly the Defense Supply Center Philadelphia (DSCP) the RES when conditions are met.
- c. Assisting the agencies with questions about RES notifications.

4. Notification to United States Department of Agriculture (USDA)

4.1 Division office responsibility

Division offices should review recalling firm's distribution lists and provide the following specific direct account consignee information for all CFSAN food recalls

1. USDA regulated firms who received the recalled FDA regulated product.
2. If the recalling firm knows they have consignees who received product specifically procured for, manufactured for, or distributed to the National School Lunch Program, the DRC will notify OSPOP/DE/ROB via RES.

4.2 OSPOP/DE/ROB responsibility

OSPOP/DE/ROB notifies the USDA Food Nutrition Service (FNS) of recalls of FDA regulated products that have been distributed to any USDA agency that may have involvement with the school lunch program.

7-7-3 Public Warning

The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. FDA recall staff should review [Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C Guidance for Industry and FDA Staff \(PDF - 71KB\)](#). The purpose of this guidance is to assist and provide recommendations to industry and FDA staff regarding the use, content, and circumstances for issuance of public warnings and public notifications for firm-initiated or FDA-requested recalls under 21 CFR Part 7, Subpart C – Recalls (Including Product Corrections) – Guidance on Policy, Procedures, and Industry Responsibilities. The guidance also discusses what information should be included in a public warning, as well as the parties responsible for issuing it.

Note that a firm may wish to issue public recall announcement, such as a press release, for a recall whose hazard level does not meet the threshold for a public warning. In those instances, FDA recall staff should follow the same procedures as for public warning below.

1. Responsibilities and Procedures – Division Recall Coordinators

DRC's will review proposed recall strategies for incoming recalls to determine whether they fit the criteria for public warning. For those instances where it is not clear (no precedent for public warning for previous recalls for a similar product/problem, additional information needed for center to conduct HHE, not clear if a public warning will be beneficial, etc.) the DRC should engage with the CRU and OSPOP/DE/ROB for advice. In instances where no health hazard evaluation precedent exists or where the preliminary information is not sufficient to decide, CRU's may need to request and review additional supporting documentation before deciding the need for public warning.

If a public warning is indicated, the DRC should provide the firm with a model press release. Models are located on [FDA's Industry Guidance](#) page. Note that only certain food press release models already have appropriate hazard statements incorporated into the model. Otherwise the DRC should obtain an appropriate

hazard statement from the CRU to provide to the firm. Additionally, the DRC should encourage the firm to include an image of the recalled product with their public warning.

Once the firm has provided the DRC with a draft public warning, the DRC should review the draft and work with the firm to address deficiencies. When they have been addressed, the district may forward the draft to the CRU and OSPOP/DE/ROB for further review (include CORE Communications for human food recalls associated with outbreaks being coordinated by CORE). However, this is not a requirement, particularly if the draft closely follows the model.

The DRC should request that the firm provide the division with a copy of the final version of the public warning once it has been released. If the firm intends to issue it via their website, request the firm's permission for FDA to capture text and images from the website (since the website is usually copyrighted). If the firm issues the public warning via a press service, obtain a copy directly from the firm - not a copy as it appears on the press service's copyrighted website.

The DRC will send a copy of the firm's final version public warning (or web page link) to OSPOP/DE/ROB with a request that it be posted to FDA's website. Also send an image of the recalled product to be posted but do not delay forwarding the public warning pending receipt of an image of the recalled product – the image can be later sent separately. If the recall involves numerous products, the DRC may consult with OSPOP/DE/ROB regarding the posting of representative images instead of an image of each recalled product.

If the firm has issued its public warning without input from the FDA, the DRC will obtain a copy (or web link with the firm's permission for FDA to copy text and any images that are associated with it) and forward it to OSPOP/DE/ROB for posting.

In instances where the firm issues a corrected or updated public warning or an additional public warning for a recall expansion, the DRC should follow the same procedures for reviewing the public notification and submitting it for posting.

The DRC should engage with the CRU and OSPOP/DE/ROB if there are problems such as:

- The firm declines to issue public warning for a recall which fits the criteria for public warning
- The firm commits to issue public warning but does not issue one in a timely manner
- There are serious deficiencies in the firm's public warning which the firm refuses to address such as incorporating a hazard statement that minimizes the hazard posed by the recalled product

Note: There are some instances where a state government issues a public warning for a recall. FDA may post a copy of the state-issued public warning, particularly if the recalling firm does not issue its own. In such instances, the DRC should obtain a

copy of the state's public warning, along with the state's permission for FDA to post it, and forward the state's public warning to OSPOP/DE/ROB for posting.

2. Responsibilities and Procedures - Center Recall Unit (CRU)

- Advise DRC's regarding the need for public warning for a recall
- When model press releases do not include a hazard statement, provide DRC's with an appropriate hazard statement to provide to the firm
- Promptly review a firm's draft public warning when requested by the DRC
- Advise, when requested by OSPOP/DE/ROB, whether a firm's public warning is appropriate to post to FDA's website
- In instances where a firm declines to issue public warning or when a firm's public warning is inadequate, initiate process for issuance an FDA public warning

3. Responsibilities and Procedures – OSPOP/DE/ROB

- Promptly review a firm's draft public warning when requested by the DRC
- In instances where the firm's public warning appears inadequate, discuss with the CRU whether to post the firm's public warning to FDA's website
- Post firm's, State's or FDA's recall public warning and images to the "Recalls, Market Withdrawals, and Safety Alerts" page of FDA's website
- When necessary, coordinate with FDA Web Staff to set up and populate "Major Product Recall" web pages. These are established to display related public warnings, for example, the recall of an ingredient and downstream firms that utilized that ingredient in a finished product.
- Upon assignment, review FDA-issued recall public warnings and other announcements related to recalls

7-8 FDA's Recall Audit Check (RAC) Strategy

7-8-1 Background

It is the recalling firm's responsibility to determine whether its recall is progressing satisfactorily. The firm has an obligation to conduct effectiveness checks as part of its recall strategy. The purpose of effectiveness checks 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 some instances, a recalling firm may be unable to check the effectiveness of its recall. This could occur when the customer list is non-existent (e.g. cash and carry store customers) or confidential business records of a firm's customers are not accessible, e.g. the sub account does not provide their distribution to the recalling firm. In such cases, FDA may directly assist in this activity by conducting recall audit checks and,

where necessary, seek assistance from cooperating state and local agencies and third party contracts.

Furthermore, the FDA recognizes that effectiveness checks also serve an audit function, and the agency reaffirms its expectation for closely monitoring recalls and assessing the adequacy of a firm's recall efforts. Therefore, as part of its audit responsibilities, FDA may selectively conduct audit checks separately from the effectiveness checks of the recalling firm.

7-8-2 Managing FDA's Recall Audit Check Strategy

The purpose of FDA recall audit checks is to determine if a recalling firm's consignees received notification of the recall, and followed the instructions listed in the notification. The division that is monitoring the recall event is responsible for ensuring the FDA audit strategy is implemented. This section pertains to both voluntary and ordered recalls.

1. Determine if a RAC Assignment is Necessary

The DRC monitoring the recall event will consider issuing an audit check assignment for potential class I and II recalls. Some factors that may cause the DRC to decide not to issue a RAC assignment are:

- Audit checks are not normally performed for Class III recalls. However, in rare situations the CRU or OSPOP/DE/ROB may request RACs be conducted for a class III recall.
- All recalled product was distributed outside the United States
- All recalled product is expired or past shelf life
- The recall was completed before the FDA was made aware of it, and due to the length of time since products were available, RACs are not likely to be beneficial

The DRC will indicate in RES if a RAC assignment is necessary using the drop down option on the Event Details page. If the DRC indicates that a RAC assignment is not needed, a justification is to be entered in RES, and no further action is needed unless the CRU does not concur.

The CRU will review RES during the classification process, and if they do not concur with the DRC's recommendation, they will indicate as such in RES. In this situation, the DRC may need to issue/re-issue a RAC assignment. If the division disagrees with the CRU's recommendation, OSPOP/DE/ROB will assist in making a final determination.

2. Determine Who Should Conduct the RACs

A. FDA Divisions

Depending on the distribution of the product, RACs are conducted by the monitoring division or extended beyond your own division, in order to have the most thorough results from which to determine a recall's effectiveness. The instructions in this section's #4-7 are for recall audit checks conducted by FDA.

B. Third Party Contractors

Depending on availability, there may be third party contractors available to the field to conduct RACs. OSPOP/DE/ROB coordinates and monitors the assigning and completion of third party RAC assignments. You may choose to have a portion of, or all of your RAC assignment completed by the third party. For inquiries related to the third party contract, contact OSPOP/DE/ROB.

C. State Contract

Some states have contracts with the FDA which include conducting audit checks. Follow your division's procedures for coordinating the assignment of state-conducted RACs. See section 7-8-3 of the RPM for more information.

3. Determine How Many RACs to Assign

The DRC needs to determine how many RACs are needed to be able to evaluate the effectiveness of the recall. There are some factors that may be reason to do more RACs, for example: a recalled product is implicated in an ongoing outbreak, the recalled product target population is immunocompromised individuals, the recalled product is a bulk ingredient and may have been used to manufacture new products, etc. There are some factors that may be reason to do less RACs, for example: all consignees of the recalled product are in the same store chain with a streamlined recall communication process, etc.

The monitoring division may consult with the CRU regarding the appropriate level of audit checks but should not delay issuance if CRU concurrence is not received within two working days.

The DRC will recommend a level of RACs to assign in RES. If it seems likely that product was further distributed past the direct accounts, determine how many sub-account RACs to assign and also indicate as such in RES. The CRU will review the level of RACs recommended in RES during the classification process, and if they do not agree with the DRC's recommendation, they will indicate as such in RES. In this situation, the DRC may need to re-issue their RAC assignment. If the division disagrees with the CRU's recommendation, OSPOP/DE/ROB will assist in making a final determination.

4. Preparing the RAC Assignment

The DRC will provide specific instructions using a RAC Assignment Memo (see Exhibit 7-13 for an example format) for RACs conducted by FDA. The memo will include the RES Event ID number, PAC code to be used, recalling firm name and FEI information, recalled product and code information, the reason for recall, the

firm's recall strategy, number of audit checks to be conducted and depth to which they should be conducted, type of audit checks to be conducted (phone, visit, email, etc.), and applicable attachments described below, at a minimum. Some things to consider when creating the RAC assignment are:

- There may be some situations where the DRC will want to indicate specific consignees to be audited, for example if the recalling firm identifies specific consignees who received recalled food product(s) that were purchased for use in a domestic nutrition assistance program (e.g. National School Lunch Program), those consignees should be included in the audit checks. You also may choose to assign audit checks at accounts where certain segments of the population at greatest risk (e.g., infants, children, elderly, surgical patients, pets, and livestock) are exposed to or obtain the recalled products. When specifying what consignees should be audited, try to assign RACs at a variety of locations to make better use of FDA resources. For example, if possible avoid assigning RACs to many locations within one corporate structure which uses an electronic recall notification system. Note: Do not assign RACs at USDA, VA, or DOD facilities, including military commissaries.
- Consideration should be given towards the type of RAC being assigned. Visits, rather than telephone calls, are preferable for recall audit checks especially Class I recalls. However, resource constraints may make it necessary to conduct the audit checks by telephone. Ineffective telephone audit checks may need to be followed by a visit to ensure effectiveness of the recall action. In some cases, audit checks may be initiated by mail and/or email, then completed by telephone (e.g. recalls of dietary supplements purchased online, where limited customer information is provided). When initiating the audit check process by mail or email, take care to protect the privacy of the individual you are trying to contact. See Exhibit 7-14 for an example template for recall audit checks initiated by mail and/or email. Audit checks by visit are not to be conducted at consumer homes unless OSPOP/DE/ROB specifically instructs that they be conducted.
- Some RAC assignments should include specific instructions on additional information the performing divisions should gather. For example, if the recalled product is a bulk ingredient product, consider including instructions for the RAC to cover how the ingredient was used and what documentation should be collected to determine if a new recall is necessary (manufacturing records, labeling, etc.). OSPOP/DE/ROB or the CRU may also request additional information be gathered during a RAC assignment to help assess the scope and/or hazard of the recall.
- Include the due date in your RAC assignment. The due date should be 10 working days from the issuance of the RAC assignment.

- In some cases, OSPOP/DE/ROB or the CRU may request audit check status updates on a regular basis to keep them updated on the status of the RAC assignment. In these instances, you may include that request in your RAC assignment.
- RAC assignments which show there are potential distributors of the recalled product should include instructions for conducting sub-account RACs to the appropriate depth, if the depth is beyond the distributor level. Include the amount of sub-account RACs to conduct in your RAC assignment.
- For those recalls which are corrections where the correction will be completed at a later date, the monitoring division should consider whether it's appropriate to split the assignment with a portion of audit checks conducted to determine consignees have been notified of the correction (e.g. new software/equipment being installed, serviceman's visit to correct item, revised user guides, etc.) and another portion of audit checks to confirm the correction has been completed.
- RAC assignments should include attachments which will aide in conducting the RAC, such as the firm's notification letter, labeling, press release (if applicable), and distribution list when specific consignees are not indicated.

5. Routing the RAC Assignment

In those instances where the monitoring division anticipates that the recall will be classified Class I or II, the audit check assignment should be issued within 10 working days after the distribution chain has been notified of the recall (issuing it earlier may result in ineffective audit checks since consignees may not have received and complied with the formal recall notification). It is critical that the agency ensure that the products are off the market or corrected, and that consignees have been notified of the recall action. This means the audit check assignment will typically be issued before the recall is determined or formally classified. Note: These timeframes do not apply for radiation emitting devices and electronic product recalls. For these recalls, follow CDRH recommended recall audit check strategy.

Email the audit check assignment and attachments using the following subject line: "RAC Request – RES Number – Recommended/Actual Classification – Due Date – Recalling Firm Name" to each division from which you are requesting RACs be conducted. The monitoring division should upload a copy of the RAC assignment memo into RES upon issuance. Indicate in RES the date the RAC assignment was issued on the Event Details page.

6. Conducting and Returning the RAC Assignment

The division receiving audit check assignments should consider them high priority and should accomplish them by the due date listed, if possible. If instructed to in the assignment, provide audit check status updates to the monitoring division at the

requested intervals. It is the responsibility of the performing division to notify the monitoring division of circumstances which will adversely delay the completion of the assignment. Copies of any such communication should be forwarded to the CRU and to OSPOP/DE/ROB.

The performing division will conduct RACs to the depth requested in their RAC assignment. Follow Chapter 7 of the Investigations Operations Manual (IOM) for detailed instructions on conducting RACs. The performing division supervisory investigator will complete and endorse the Form FDA-3177 per the IOM Chapter 7 and send the endorsed form to the monitoring division recall coordinator. Accurate endorsements are necessary as they give the monitoring DRC an idea of the effectiveness of the firm's recall.

Sub-Recalls

A sub-recall is an action taken by a recalling firm's consignee to notify their own consignees of the recall, as long as no changes were made to the recalled product. If the recalling firm's account further manufactured the recalled product (for example, if they used the product as a component of a new product, re-labeled the product to obscure the original product name and/or lot code, repackaged the product, etc.) the account has created a new product which could warrant a new recall, instead of a sub-recall.

If a sub-recall has been or should be initiated (e.g. the consignee further sold the product, and the recall depth has not been met), the performing division will collect documentation and all relative information about the sub-recall. The performing division will also ensure audit checks are performed of subsequent consignees, when applicable. It is preferred that the performing division conduct the sub-recall audit checks themselves, regardless of the geographical location of the sub-accounts. Sub-recall checks may be initiated/conducted by telephone, email, and/or mail in lieu of visits in these instances, unless the assignment states otherwise.

If a consignee of the recalled product refuses to initiate a sub-recall promptly, the performing division supervisory investigator will advise the assigning DRC, OSPOP/DE/ROB, and appropriate CRU of the situation, and indicate what additional steps the division is taking to achieve a satisfactory sub-recall. Options for consideration include meetings between division management and top management of the recalling firm and/or sub-recalling firm, notification of consignees directly, reporting to State and local officials, recommendation for FDA requested or ordered recall, and initiation of administrative proceedings or enforcement actions.

7. Evaluating and Tracking Incoming RACs

The monitoring division will track the completion of the RACs they assigned, evaluate RACs when received to ensure that they are adequate and then retain them. If, during the evaluation, the division discovers any issues with the recall or audit checks, the division must ensure that appropriate and timely follow-up action is taken. If a RAC assignment is late, insufficient information has been collected, or the

endorsement is incorrect, the monitoring division recall coordinator will advise the endorsing supervisory investigator in the performing division and request follow-up or correction.

The monitoring division will follow up with the recalling firm for each recall audit check endorsed as Ineffective Notifying Firm, if the notifying firm is the recalling firm. The recalling firm may have evidence to support that they did notify their consignee, which could be useful in determining the effectiveness of the recall.

If the monitoring division discovers recalled product(s) were purchased for use in a domestic nutrition assistance program (e.g., National School Lunch Program), the division will forward the information to OSPOP/DE/ROB.

The monitoring division recall coordinator is responsible for uploading all Form FDA-3177s into RES Associated Documents. If RACs were conducted by third party, upload the results of the third party RACs into RES Associated Documents.

Reconciliation of Distribution Lists

The monitoring division should consider issuing an assignment to reconcile the direct consignee distribution list provided by the recalling firm if there is suspicion that the list is inaccurate. Discrepancies may be found while evaluating RACs or through other information related to the direct consignees provided by the recalling firm.

These discrepancies may include but are not limited to:

(1) during RAC review, the DRC finds that direct consignees are reporting that they received product, but they were not notified of the recall by the recalling firm. DRC follow up indicates that they should have been notified and the recalling firm cannot provide evidence of the recall notification. This could be an indication that the consignee list used for notification is different than the consignee list provided to FDA.

(2) firm provides a list of known recipients of the recalled product, however during RAC review, the DRC finds that consignees on this distribution list state that they did not receive the recalled product.

(3) the DRC receives information from another source (e.g. industry or State) that a direct consignee was not notified of the recall and the DRC's review of the direct consignee distribution list finds this consignee is not listed. This could be an indication that the consignee list is incomplete.

(4) evidence of malfeasance relating to a firm's records.

The reconciliation can be conducted by evaluating shipping records, bills of lading, invoices, etc. If discrepancies are found, the monitoring division should ask the recalling firm to notify the correct direct consignees. Modification or reissuance of the RAC assignment, based on the corrected direct consignee distribution list, should also be considered.

8. Ineffective Recalls

If the monitoring division recall coordinator's evaluation of the Form FDA-3177s or third party RAC results indicates issues with the effectiveness of the recall, the monitoring division must ensure that appropriate and timely follow-up action was taken with the recalling firm or a downstream consignee (whichever firm's action resulted in the recall being ineffective). If action by the recalling firm is appropriate to improve the effectiveness of the recall, the monitoring division should discuss the situation with the firm and determine what action the firm intends to take to improve its recall efforts such as issuance of additional recall communications, etc. The division may choose to send an Ineffective Recall Letter (see Exhibit 7-9).

If the monitoring division determines the firm's action is not sufficient, the monitoring division will notify the CRU and OSPOP/DE/ROB of the situation and may recommend appropriate action. Actions to be considered include actions such as FDA-requested or ordered recall, initial or further public warning, multiple seizures, and injunction.

The issuance of another recall audit check assignment may be necessary to determine if the recall has become effective after the issuance of additional notification or other actions to improve recall effectiveness.

The monitoring division is responsible for the day-to-day management of a recall. They will ensure adequate progress and timely completion of the recall by the recalling firm. If the firm is not providing necessary information, an establishment visit may be necessary. If the monitoring division encounters unreasonable delays by the recalling firm in conducting the recall, contact the CRU and OSPOP/DE/ROB to discuss options.

7-8-3 State Audits

Food inspection state contract(s) may have an elective for states to conduct recall audit checks. If this elective has been exercised the state will conduct recall audit checks at the direct account level to facilitate collection of direct account distribution records, determine the need for a new recall, and/or to witness any product destruction. States will use the FDA Form 3177 to document the results of audit checks conducted under this elective.

Assignments under the RAC elective can be used to facilitate the submission of direct account consignee lists to the FDA when FDA has determined a need to post retail consignees. Further auditing to the retail level will be conducted by recall audit check assignments to FDA field staff and/or the FDA third party RAC contract.

State food regulatory programs may also conduct recall audit checks separate from the RAC option under state food inspection contracts, in accordance with their state recall procedures. These state recall audit check efforts are not directed or mandated by FDA; collaboration between FDA divisions and state food regulatory programs when conducting recall audit checks is strongly encouraged to support consolidation of recall audit check data and avoid redundancy.

7-9 RECALL TERMINATION

A recall will be terminated when the Food and Drug Administration determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate Food and Drug Administration division office to the recalling firm.

The monitoring division will make this determination by reviewing completed recall audit checks, the recalling firm's status reports, and product disposition records. Additionally, FDA will take into account any additional reports suggesting recalled products may still be on the market.

The division office should advise recalling firms that FDA will not terminate a recall until the firm has brought the product into compliance or disposed of it in an acceptable manner. DRC's will request and review product disposition records, which demonstrate the firm's actions to destroy, rework, or otherwise bring recalled product into compliance. In the case of Class I recalls and high-risk Class II recalls, a limited close-out inspection to verify recall completion and observe/document product disposition, may be conducted at the discretion of the division recall coordinator and division management. For those recalls where FDA or the state has witnessed disposition of the recalled product during a close-out inspection, the DRC will maintain in the recall file a copy of the EIR/investigation memo and/or any other documents created or collected by the investigator, which document disposition of the product.

The division will notify the recalling firm by letter that FDA considers the recall terminated. See Exhibit 7-11 for a Model Recall Termination Letter.

Termination of a Class I recall requires center concurrence. When the monitoring division office concludes that such a recall is ready for termination, the division recall coordinator will enter the information required for termination in RES on the "Summary and Termination" page. This page includes fields to provide the: complete reason for recall, quantity recovered or number of units corrected, product disposition, root cause of the problem, section of the law violated, preventative action taken by the firm, legal action by FDA, and name and date of division official approving the termination recommendation. Centers may request additional documentation. When all required fields have been completed, the coordinator clicks on "continue" at the bottom of the page, which brings up the Summary and Termination validation page. After verifying that all data is correct, clicking on the "Save/Send Termination Recommendation" button will send an email to the CRU recommending termination.

Upon receipt of the termination recommendation email, the CRU will access RES, review the termination information and, if in agreement with the recommendation for termination, provide concurrence in RES (at the bottom of the Summary and Termination page) by inserting the name of the concurring center official. The CRU will change the "recall status" field to "terminated" and click on the "Save/Send Termination Concurrence" button which updates the recall action and generates an email to the division and OSPOP/DE/ROB advising that the recall is terminated.

Center approval is not required for Class II or III recall terminations. The division offices will follow the same basic procedure as outlined above for Class I recalls, but will just change the “status” field to indicate “terminated” and click on the “Save/Send Class II/III Termination” button. The RES then generates an email to the center and OSPOP/DE/ROB that the recall has been terminated by the division office.

FDA should terminate the recall within three months after the firm completes the recall. The division office should not wait for compliance actions to be initiated or executed to terminate a recall. A firm may request termination of a recall. However, recalls may be terminated absent a request from the recalling firm if termination is warranted. If the division office feels that the recalling firm is unable to ensure that violative goods will not reenter channels of distribution, the division office should consult with the CRU and/or OSPOP/DE/ROB for the best course of action. Division offices should contact the CRU and/or OSPOP/DE/ROB for directions on terminating recalls when there is inadequate information to determine recall effectiveness e.g. the recalling firm is out of business.

7-10 ATTACHMENTS, EXHIBITS, AND APPENDIX

Note: For each recall action, the RES provides a single record that is initiated at the beginning of the recall with an Alert. The record is continually updated in order to provide information for the Recall Recommendation, Classification, FDA website posting, any updates, and finally, Termination. The RES requires submission of some information not previously required. As the RES is finalized, detailed instructions will be provided for division and center coordinators. At the present time, the information provided or requested in the following attachments remains pertinent and appropriate for all steps of the recall process.

ATTACHMENTS:

- A Recall Alert Information
- B Recommendation for Recall Classification
- B1 Recommendation for Recall Classification and Termination
- C Recall Termination or Recommendation for Termination
- D Health Hazard Evaluation Worksheet
- D1 21 CFR 7.41(a) Guidance to Health Hazard Evaluation Committees
- E Recalls of Radiation Emitting Electronic Products Under Subchapter C - Electronic Product Radiation Control Of Chapter V Of The Federal Food, Drug, And Cosmetic Act (The Act), Formerly The Radiation Control For Health And Safety Act Of 1968 (RCHSA)
- F Recalls of Infant Formula
- G Recalls of Medical Devices, Section 518(e)
- H Methods for Conducting Recall Effectiveness Checks
- I Recall of Tobacco Products
- J Mandatory Recall Authority for Foods
- J1 Recommendation Memorandum
- J2 Notification of Opportunity to Initiate a Voluntary Recall
- J3 Prehearing Order to Cease Distribution and Give Notice
- J4 Denial of Hearing Request
- J5 Hearing Report Cover Letter
- J6 Hearing Report
- J7 Vacated Order
- J8 Amended Order
- J9 Modified Order

EXHIBITS:

- 7-1 Model Effectiveness Check Letter (Industry)
- 7-2 Model Effectiveness Check Response Format (Industry)
- 7-3 Model Effectiveness Check Questionnaire for Telephone or Personal Visits (Industry)

- 7-4 Model Recall Letter (Generic, All Centers)
- 7-5 Model Recall Return Response Form
- 7-6 Model Recall Envelope
- 7-7 Model FDA Requested Recall Letter
- 7-8 Model Acknowledgement (FDA to Recalling firm)
- 7-9 Model Notification of Classification Letter (FDA to Recalling Firm)
- 7-10 Model Recall Ineffective Recall Letter
- 7-11 Model Recall Termination Letter
- 7-12 Model Combined Recall Notification of Classification and Termination Letter
- 7-13 Model Recall Audit Check Memo Assignment
- 7-14 Initiating RAC by Mail or Email
- 7-15 Weekly Class I Recall Status Report (Optional)

APPENDIX: Forms/Attachments for State Audits**Attachment A – Recall Alert Information**

Submit the information listed below to the CRU and OSPOP/DE/ROB via RES:

- Product(s) Description
- Codes
- Recalling Firm
- Short Reason for Recall
- Division Awareness Date
- Recall Initiation Date, with Type Initial Firm Notification
- Recall Status
- Voluntary or FDA Mandated Pick Lists, with Date

Attachment B – Recommendation for Recall Classification

Update and transmit the electronic record in RES with the required information necessary for the CRU to review and classify the recall. RES will, via Outlook Email, automatically notify the appropriate center and OSPOP/DE/ROB personnel of the recommendation through established Outlook lists. Guidance for information to be included in the recommendation is as follows:

1. Product Description (INT), Trade Name, and Product Usage fields- (Product Details and Center Specific Pages)
 - a. For each product, provide as applicable: Pertinent labeling to identify the product to include the product name (brand and generic) and the intended use or indications. Model and/or catalog numbers which further define the exact product. Describe how it is packaged such as box, flexible plastic, glass bottle or vial; the type such as tablet, sugar coated, or liquid, capsule, or powder; strength; sizes; form; route of administration; shipping or unit package. Provide a brief description of the product and its use. If product labeling does not indicate how the product is to be used, and the health hazard is dependent on use, consult the firm's catalog, the Red Book, or similar sources for the information.

If a drug product, indicate Rx or OTC and include the NDA/ANDA and NDC or UPC codes. For medical devices, obtain and include the 510(k), IDE, or PMA numbers as well as any related Corrections and Removals numbers.

If it is determined that the product must be examined physically for health hazard evaluation and/or to determine the efficacy of the corrective action, collect and ship an appropriate sample to the designated unit via the most expeditious and practical means available. Notify the center of the time, how sent, and estimated time of arrival.

- b. For each product give: brand name; name, address, and type of responsible firm on label; number and description of private labels. Submit a complete copy of all labeling (including product inserts or information sheets) to the appropriate CRU by an expeditious method, such as Facsimile, Federal Express, or Overnight Mail, depending on the circumstances involved.
2. Code Information (RES Product Details page)

Code Information (INT) field - List all lot and/or serial numbers, product numbers, packer or manufacturer numbers, sell or use by dates, etc., which appear on the product or its labeling.
3. Recalling Firm/Manufacturer/Responsible Firm (for the violation) – (RES Firm/Contact Details pages)

Recalling Firm Information fields:

FEI field- provide FEI number and click search. If the firm is in the Official Establishment Inventory (OEI) the firm name and address is provided. Complete any fields not automatically populated. If FEI is unknown, or does not exist, type in "unknown" in the FEI field and then fill in all following information fields. Under the "Comment" box, identify the type of firm, i.e., manufacturer, importer, broker, repacker, own label distributor.

Manufacturer Information field – Same as FEI field. In the "Comment" box, add any information to clarify relationships with either the recalling or responsible firm.

Responsible Firm Information field – Same as FEI field. In the "Comment" box explain the firm's relation to the product such as processor, contract sterilizer, distributor, component supplier, etc.

4. Reason for Recall Recommendation (RES Event Details pages)

Complete Reason for Recall field - provide detailed information as to how the product is defective and violates the FD&C Act or related statutes. Refer to the [IOM](#) Chapter 7, Subchapter 810 for inspectional guidance.

- a. Include any analytical findings in qualitative and/or quantitative terms, indicating whether firm, FDA, State, or private firm analysis. Indicate the analyzing laboratory. Explain all State involvement in the recall, including sample collection or analysis, recall agreement or initiation, recall monitoring, and product disposition.
- b. Provide inspectional (GMP) or other evidence where appropriate.
- c. In cases where a veterinary drug product is being recalled due to sub potency of active ingredients prior to labeled expiration date, provide the following information:
 1. The firm's stability testing plan (including analytical methodology) which established the labeled expiration date.
 2. Specific batch numbers in the stability studies and assay values that are the basis of the firm's recall.
 3. Potency specifications which the firm uses for recall purposes.
 4. Final assay values for the active ingredients which were the basis of the initial release of the batch.

It should be noted whether or not information regarding stability data on file with the firm and the Quality Control procedures used by the firm to determine the potency of the active ingredients, is available in the EIR.

Root Cause field - provide any information available which identifies circumstances which resulted in, or contributed to, the problem which resulted in the recall.

Type of Injury Field – List in chronological order any complaints, injuries, or associated problems with the recalled product(s). Note: specific reference to MDRs and Corrections and Removals Reports are reported elsewhere.

5. Volume of Product in Commerce (RES Event Details page)

Quantity Manufactured field – This calls for the total “event” quantity for the product or products recalled.

Quantity Distributed field (Internet) – This is the total of all products distributed and should be the sum of quantities distributed for all product(s).

Note: Each product has its own field for quantity of product distributed.

Manufactured From field – Provides dates.

Expected Life - This could include products such as pacemakers, which have a calculable life span.

Shelf Life - This primarily references perishable foods but may also be used for medical devices, biologics, and certain drugs.

NOTE: If the recommendation is for a FDA Requested Recall, assure that there is, in fact, product remaining in commerce before preparing and submitting the recommendation.

6. Distribution Pattern (RES Event Details page)

Distribution Pattern field (Internet) – This field is to provide the public with the general area of distribution such as, “Distributors in 6 states: NY, VA, TX, GA, FL and MA; the Virgin Islands; Canada and Japan”. The term “nationwide” is defined to mean the fifty states or a significant portion of them scattered across the United States. The six United States territories, Guam, Puerto Rico, American Samoa, Virgin Islands, and the Canal Zone, are to be reported separately.

Consignee Details fields

List of Consignees or Comments – This field should be used to list U.S. government, military and/or civilian units/agencies to which product(s) has been distributed. This would include the Defense Personnel Support Center (DPSC), Department of Defense (DOD) Hospitals, Department of Veterans Affairs (DVA), US Department of Agriculture (USDA) (especially any product which may reach the school lunch program), or other government agency sales/distribution. If the consignee list is long, it may be submitted separately through the division Recall Coordinator to OSPOP/DE/ROB. Indicate whether these were direct or contract sales. If there have been contract sales, report the contract number, contract date, and implementation date. Any discussion of product sales, products expected to remain on the market at time of recall, or related topics may

be included in comments. (This information is not published on the Internet)

Number of Domestic Consignees – Provide number

Number of Foreign Consignees – Provide Number

Chart - As best you can, check off the types and approximate number of consignees in the chart.

7. Firm's Recall Strategy (RES Event Details page)

Recall Strategy field - If the firm was advised of FDA findings and the problem was discussed with them, report its reactions and recall plans in detail. Similarly, if the firm advised FDA of the problem, report and explain the firm's own analytical results and/or information that resulted in the firm's decision to conduct a recall. Obtain the date that the firm realized the need for recall. (Firm Awareness Date on Start Recall page). Describe the firm's planned recall strategy, comment on its adequacy from the division's viewpoint, and evaluate the firm's ability to complete an effective recall. Sections 7.42 and 7.46 of 21 CFR, Part 7 - Enforcement Policy, Subpart C, provide information to be obtained from the firm for CRU evaluation. The firm's strategy should address the depth of the recall, the consideration of a public warning, and an appropriate effectiveness check division. It should also include the firm's intended course of action when an account which distributed the recalled product is found out of business. Include date recall was initiated, if already underway. If product is to be removed from the market place and recovered, its final disposition should be identified. Provide details of any publicity issued or to be issued by FDA, the firm, the state, or local government.

8. Firm Officials/FDA Contact/Public Contacts (RES Firm/Contact Details page)

Most Responsible Individual field - Provide name, address, and phone number (if available) for the most responsible corporate individual for the recalling firm. If someone other than the most responsible corporate official, or the FDA contact person, are to receive the original or copy of recall classification or termination letters, provide the name(s) under the "Comment" box.

Recall Contact field – list the name, address, phone number, email address, fax number, etc. of the person that is the FDA contact for recall operations.

Public Contact field – list for the recalling firm, either a person or staff such as "Public Relations Staff" that can handle contacts from the public. Include name, address, phone number, facsimile, and email address as applicable.

9. Division Audit Strategy (RES Event Details page)

Effectiveness Check Level field – Provide the firm's planned or division recommended effectiveness level.

Audit Check Level field – Provide the division's recommended audit check level, i.e. the level that the division believes will satisfactorily verify the recall's effectiveness.

Audit/Effectiveness Check Modification box - This box should be used to provide any modifications to the recommended levels, e.g. "Recommend level C (10%) audit checks at distributor accounts and level D (2%) not to exceed five sub accounts of each distributor audited."

Provide the firm's recall effectiveness history when recommending low levels of, or no audit checks, and monitoring of recall status from the firm's own records.

This box may also be used to provide the division's proposed strategy for monitoring the recall, including the time table for follow-up visits or firm contacts for reviewing the recall status. State what actions have already been taken by FDA such as inspections, sample collections, etc.

Attachment B1 – Recommendation for Recall Classification and Termination

Note: Under RES, this information will be a continuation of the electronic recall record and many of these fields will be pre-populated as the recall recommendation data is inputted. However, the following fields need to be completed to justify termination.

Product: See Attachment B.

Codes: See Attachment B.

Recalling Firm/Manufacturer: See Attachment B.

Reason for Recall Recommendation: See Attachment B.

Volume of Product in Commerce, Quantity Recovered, and Disposition:

Provide total volume of product distributed and under the recalling firm's control. Provide quantity of product recovered or corrected by the recalling firm. If no or little product was found in the market, explain why (i.e., expired, short shelf life, rapid turnover, etc.). Indicate the recall was completed and provide verification of disposition or correction of recalled product.

Distribution: See Attachment B.

Firm's Recall Strategy:

Describe the level of distribution to which the recall was extended. Provide complete description of the firm's recall notification and/or correction efforts. List the number of consignees responding to the firm's notification. Provide effectiveness checks accomplished and their findings, and/or other means the firm has to document the recall effectiveness. Provide conclusion as to the adequacy of the firm's actions. If known, indicate steps the firm has taken to prevent similar occurrences.

Violation:

Provide the section of law violated.

Preventive Action:

Provide the action taken by the firm to prevent recurrence of the violation.

Division Audit Strategy:

Describe actions taken by FDA (inspections, sample collections, etc.). Provide details of any publicity issued. Provide results of any FDA audit checks or auditing of records at the firm. List any legal action planned or underway.

Attachment C – Recall Termination or Recommendation for Termination

A Recall Termination (Summary) or Termination Recommendation must be prepared and submitted for those recall actions not terminated at the time of classification. As indicated above under Recommendation for Recall Classification and Termination Format, the Summary and Termination page in RES is also an update to the continuous record. Class I recalls and Safety Alerts require Center concurrence for termination. Class II and III recalls and market withdrawals may be terminated at the division's discretion. RES requires the completion of all fields on the Summary and Termination page as well the recall status being "completed" and a date completed provided. Therefore update the recall record to contain the information listed above under Attachment B1. The division coordinator will have to determine that all applicable and required data is included before submitting the Class I "Recall Termination Recommendation" to the Center recall unit for concurrence. For Class II and III recalls, the division coordinator or other division personnel will prepare and submit, after coordinator review, the recall document to division management for concurrence. The name of the division manager approving the termination and the date of the approval is to be recorded in the recall record.

When the CRU concurs with the Class I recall or Safety Alert termination recommendation in RES, notice of that concurrence will be electronically sent to the field coordinator and OSPOP/DE/ROB.

When the division obtains concurrence from division management for the termination of Class II and III recalls and so updates the RES recall record, the coordinator electronically notifies the CRU and OSPOP/DE/ROB of the termination.

Attachment D – Health Hazard Evaluation Worksheet

Note: The following Health Hazard Evaluation Worksheet has been developed by the agency. This worksheet, or an equivalent form, is to be used by all Center Health Hazard Committee personnel to record HHEs.

HEALTH HAZARD EVALUATION

1. PRODUCT/IDENTIFICATION NUMBER/USAGE (e.g. unit, lot, serial number, catalogue number, order number, etc.)
2. FIRM NAME, ADDRESS, IDENTIFICATION NUMBER(S)
3. NATURE OF PROBLEM

4. (a) Have any adverse reaction reports or other indication of injuries or diseases been reported relating to this problem?

No

Yes - Attach copies or explain

- (b) Have any adverse reaction reports or other indication of injuries or diseases been reported for similar situations?

No

Yes - Attach copies or explain

- (c) Is the problem easily identified by the user?

No

Yes

5. What is the risk to the general population?

- (a) For products not bearing dosage information, what is the normal consumption of the product by the general population and the population most at risk.

6. What segment(s) of the population is most at risk and why?
[e.g. entire population(animals/species), infants, children, elderly, pregnant women, women of child bearing age, nursing mothers, surgical patients, immune suppressed, clinical situations, food producing animals, non-food producing animals, other].

Is there any known/accepted off labeled use(s) that would increase or change the population at risk?

7. Within the population at risk, could individuals suffering from any particular conditions or diseases be more or less at risk and if so, why?
[e.g. Immune system debilities, diabetes, cardiac problem, concomitant medications, etc.]
8. What is the hazard associated with use of the product? Explain and cite literature references when applicable.

_____ Life-Threatening (death has or could occur)

_____ Results in permanent impairment of a body function or permanent damage to a body structure

_____ Necessitates medical or surgical intervention to preclude or reverse permanent damage to a body structure or permanent impairment of a body function

_____ Temporary or reversible (without medical intervention)

_____ -Limited (transient, minor impairment or complaints)

_____ No adverse Health Consequences

_____ Hazard cannot be assessed with the data currently available

Explanation: _____

9. What is the probability of an adverse event occurring?

_____ Every Time _____ Reasonable Probability _____ Remote

_____ Unlikely _____ Unknown

Explanation: _____

Signature _____

Date _____

Signature _____

Date _____

Signature _____

Date _____

Recall Product: _____

MARKET ASSESSMENT

Note: This market assessment is to be done by the Center's medical staff when requested to do so by the Center Recall Coordinator. This assessment should not impact on the health hazard. This assessment will only be used to alert agency personnel to potential drug shortage situations.

Would removal of this product(s) cause a major disruption relative to the treatment/prevention of disease? _____ No _____ Yes* _____ Not Applicable

* Please identify any alternative treatments/procedures that are available.

Center Recall Unit Assessment of Recall

Conclusion: the degree of seriousness of the hazard [real or potential] to the population at risk?

The product is violative and there is a reasonable probability that use of or exposure to the product will cause serious adverse health consequences or death. (Class I)

The product is violative and use of or exposure to the product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences (life threatening/death) is remote. (Class II)

The product is violative and use of or exposure to the product is not likely to cause any adverse health consequences. (Class III)

The product involves a minor violation or no violations. (Market Withdrawal)

Signature(s):

Date:

Attachment D1 – 21 CFR Part 7, Guidance to Health Hazard Evaluation Committees

The Food and Drug Administration's recall regulation (21 CFR Part 7) requires the conduct of an evaluation of the health hazard (actual or potential) presented by a product being recalled or considered for recall. The regulations (21 CFR 7.41(a)) specify the factors to be considered, among others, by the Health Hazard Evaluation Committee in making the health hazard evaluation. The purpose of the health hazard evaluation, in general, is to identify and document:

1. the population at risk,
2. conditions that may exacerbate or attenuate the risk of its occurrence,
3. the risk associated with the product under conditions of use (as labeled), and
4. the likelihood of the risk occurring in the future.

The purpose of these guidelines is to assist the Committee in the identification and documentation of the various factors listed in 21 CFR 7.41(a) that are to be considered in making the health hazard evaluation and to determine what additional data and information should be collected and evaluated during the recall either to confirm or revise the health hazard evaluation. The questions listed below are not all inclusive nor are they relevant to all recall situations. They are intended to focus attention on factors related to the significance of health hazards likely to be associated with a product being recalled or considered for recall.

21 CFR 7.41(a)(1) - Whether any disease or injuries have already occurred from the use of the product.

1. What is the name of the product (trade and generic) and what are its indications for use, where applicable?
2. What deaths, diseases, injuries, or other adverse reactions have already occurred in association with use of the product?
3. What documentation is there to support the association of the deaths, diseases, injuries, or other adverse reactions with the use of the product?
4. Was the product used in conformance with its labeled directions for use? (The Health Hazard Evaluation Committee should review product labeling for sufficiency in light of injuries). If not, did the deaths, diseases, injuries, or other specific adverse reactions result from product misuse?
5. If the product was used according to its labeled directions, were the associated diseases, injuries, deaths, or other specific adverse reactions due to a) product malfunction, b) product formulation, c) product quality (including potency, contamination, etc.), d) product design, e) inadequate directions for use, or f) other known or unknown causes? Specify.

21 CFR 7.41(a)(2) - Whether any existing conditions 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.

1. Name the specific clinical conditions (e.g., diabetes, heart problems, etc.) which, if they exist, might render a person or animal more susceptible to experiencing a health hazard on exposure to the product.
2. How would these clinical conditions contribute to or change the risk of exposure to the products?
3. Could these clinical conditions mask or otherwise disguise the risk of exposure to the product?
4. What other products being used to treat these clinical conditions could contribute to or, conversely, lessen the risk of exposure to the product?

21 CFR 7.41(a)(3) - Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with attention paid to the hazard to those individuals who may be at greatest risk.

1. What is the universe of users by segment of population and what is the relative frequency of use of each, if known. For example, what percentage of the product is used by infants or children?
2. Which segment of the population exposed to the products is at greatest risk of health hazard?
3. Are any of the following high-risk groups likely to be exposed to the product?
 - a. Infants
 - b. Children
 - c. Elderly
 - d. Pregnant Women
 - e. Surgical patients
 - f. Others (specify)
4. For each of the high-risk groups identified, what is the anticipated frequency of exposure to the product?
5. In what setting is the product generally used (e.g., hospital, home, etc.)?
6. How frequently is the product used (e.g., daily, weekly, etc.) and what is the duration of use (e.g., one time only, for a month, over a lifetime, etc.)?

7. What percentage of the population at greatest risk is now under close medical supervision?

Could everyone in this population be easily brought under observation? In practice, would all users be brought under medical supervision if this is needed?

8. What actions or medical interventions could reasonably be expected to decrease the likelihood of occurrence of the health hazard? For example, could patient monitoring detect the product defect before it causes any untoward health consequences and could patient monitoring entirely prevent medical injury?

21 CFR 7.41(a)(4) Assessment of the degree of seriousness of the health hazard to which the population at risk would be exposed.

1. Are the health hazards likely to be acute (lasting several days to a few weeks) or chronic (lasting weeks to months)?

2. Describe the degree of seriousness of the health hazard if it did occur, and which specific segment of the population might be at risk? Express in terms of the following:

- a. Life threatening - death could occur
- b. Severe - permanent significant disability
- c. Moderate - transient but significant disability; permanent minor disability
- d. Limited - transient minor disability; annoying complaints
- e. None - no disability or physical complaints anticipated

21 CFR 7.41(a)(5) - Assessment of the likelihood of occurrence of the hazard.

1. How frequently have deaths, diseases, injuries, or other adverse reactions already occurred? How does the frequency of occurrence relate to the total extent of product exposure (e.g., number of devices implanted, number of prescriptions, etc.)? How has this frequency been documented?

2. If deaths, diseases, injuries, or other adverse reactions have not already occurred, estimate the likelihood of occurrence in each segment of the population at risk.

21 CFR 7.41(a)(6) - Assessment of the consequences (immediate or long range) of occurrence of the hazard.

1. What are the immediate consequences of the health hazard?

2. What are the long-range consequences of the health hazard?

3. If the product being recalled or considered for recall is used to treat a medical condition, are alternate forms of therapy available?

SUMMARY OF HEALTH HAZARD EVALUATION

On the basis of the answers to the questions listed above and any others that relate to the associated risk, state the likelihood of the health hazard occurring following exposure to the product being recalled or considered for recall and the likelihood of exposure to a defective product in all users of the product.

In addition, include in the recommendation specific data and information that should be collected, how and by whom these should be collected and evaluated, and how frequently the health hazard should be reevaluated.

Attachment E – Recalls Of Radiation Emitting Electronic Products Under Subchapter C - Electronic Product Radiation Control Of Chapter V Of The Federal Food, Drug, And Cosmetic Act (The Act), Formerly The Radiation Control For Health And Safety Act Of 1968 (RCHSA)

Recalls conducted under Subchapter C are different from recalls conducted under the Food, Drug, and Cosmetic Act in that Subchapter C has mandated recall provisions written into the Act (Sec. 535(a)). The law requires a manufacturer, when he learns that a product he manufactures is either defective or not in compliance with a published performance standard, to notify the Secretary of Health and Human Services (delegated to CDRH Director), and to notify the first purchaser (and known subsequent transferees) of the defect(s) or noncompliance(s). Subchapter C is specific as to the method of notification and procedure, and also contains "repair, replace or refund" provisions.

Differences may be encountered in dealing with recalls of radiation emitting versus non-radiation emitting medical devices. For medical devices, recall procedures for electrical and mechanical problems generally follow the pattern outlined in this chapter for general recalls. However, both medical and non-medical electronic products follow a different procedure when recalled under Subchapter C for radiation defects or deviations from a radiation safety standard. For example, consider a piece of diagnostic x-ray equipment that displays a mechanical problem not covered by Subchapter C (e.g., instability resulting in the unit falling over). The recall is conducted under the standard recall procedure of recommendation by the field, evaluation and classification by the Center and the usual recall notification, monitoring, and termination by the field. If that same equipment displays a radiation related defect or a noncompliance with the diagnostic x-ray standard (21 CFR 1020.30), the recall falls under Subchapter C, and follows the pattern outlined below:

(Note: The Health Hazard Evaluation Committee does not review recalls involving noncompliance with a standard because the significance of the hazard was considered when the standard was introduced).

Recalls conducted under Subchapter C of the Act

1. Center for Devices and Radiological Health (CDRH) Learns of Defect or Noncompliance

A manufacturer who discovers a radiation related defect or noncompliance is required by Subchapter C to immediately notify CDRH and submit a proposed corrective action plan (CAP). CDRH may also learn of defects or noncompliance from various other sources including establishment inspection, results from FDA field and laboratory testing, and review of reports required to be submitted by the manufacturer. CDRH will inform the manufacturer in writing of the defect or noncompliance and request the firm to propose a CAP as required by Subchapter C. In some cases, special field testing may be necessary in order to define the precise defect or noncompliance. These tests will be arranged by CDRH.

2. Opportunity to Refute Declaration or to Request Exemption from Notification Requirements

As provided by Subchapter C, a manufacturer has the opportunity to refute a defect or noncompliance declaration (Section 535(a)(2)). The manufacturer is usually given 14 days to refute the Center's declaration or to request exemption from notification based on evidence that the defect or noncompliance is not such as to create a significant risk of injury, including genetic injury, to any person. The burden of proof lies with the manufacturer. If the refutation is accepted, or if the exemption is granted, the manufacturer is then exempt from the notification requirements and is relieved of responsibility to "repair, replace or refund."

3. Proposal of Corrective Action Plan by Manufacturer

If no request for exemption has been filed or if the exemption request was denied, the manufacturer must then submit proposals to CDRH for user notification and correction of defective or noncompliant product(s). The notification to users is required to be by certified mail to the first purchaser (or subsequent transferees, if known) and must be mailed within 14 days after CDRH approval. CDRH requires that return receipts be maintained for recall audit purposes. Manufacturers are also required to provide CDRH with copies of all notices, bulletins, and other communications to dealers, distributors, purchasers, or other transferees which they have issued as required by Section 535(d). These notifications to users are required to contain instructions for interim safe operation of the product until such time as corrections can be made.

4. Correction Action Plan (CAP) Review

Upon receipt of the manufacturer's proposed CAP, the Center will review that document for thoroughness and technical accuracy. The following are elements of a typical approved CAP:

- A. Product description (including all model and serial numbers used) and the total number of units of this product that are involved.
- B. Consignee list (foreign and domestic).
- C. Description of the defect (including all reports, documents, memos, etc., of meetings, technical reviews, etc., which pertain to the analysis of the problem and the development of a "fix").
- D. Proposed steps to be taken to correct the product in the field and steps taken to prevent future occurrences.
- E. Proposed effectiveness checks to be conducted.
- F. Proposed date of completion and appropriate interim dates for design, fabrication, and implementation of the correction.
- G. Any and all injury/death investigations or reports. h. Pertinent complaints on file.

Some additional requirements may be included in a CAP if necessary. For example, a CAP may require that the recalling firm obtain a signed statement from their purchaser stating that corrections have been made or it may require that copies of service or work orders be held for FDA review.

In the event that the proposal is insufficient, the Center will request the additional data needed. When sufficient information has been submitted to the Center for review, the plan is evaluated and approved if it appears to be adequate.

5. Mechanics of Conducting Recall

CDRH will assign a recall number and issue a classification memo to the division and the Press Office when the corrective action plan (CAP) and an approval letter is signed and issued to the recalling firm. CDRH will send copies of the CAP approval letter, the corrective action plan and the letter of non-compliance with the classification memo. The home division will then promptly obtain from the firm by phone or a visit any other information required for the Enforcement Report and the Initial Recall Notification message to the field. This will not affect the way the division processes recalls for X-ray assemblers and suntan lamp recalls. The home district office or division will still continue to submit a Recommendation for Recall for cases generated in the field. The division s will approve the corrective action plans for these cases, and submit a copy of the division approval letter with the Recommendation for Recall to CDRH for issuance of a recall number.

The timeliness of audit check issuance will depend on the progress of the CAP and may be determined by recall status reports received from the firm. Audit checks should issue when the recall is approximately 25% complete and continue throughout the completion of the recall. At the point when the recalling firm indicates by way of their status reports to the division that they have completed the recall action at 25% of their consignees, the field will issue a request for a portion of the required audit checks to affected divisions. Upon receipt of the completed audit check reports from the divisions, the lead Recall Coordinator will evaluate the audit checks to determine if the recall is effectively on-going. If apparently effective, the balance of the audit checks need not be requested until the recall is complete, or nearly so. Center consultation is available, if needed, in determining the effectiveness of the recall at the 25% complete mark.

The recalling firm must, in its CAP, provide a target date for completing the recall. The time span is typically six months to one year. If the firm does not or is not likely to complete the recall within the specified time, a Warning Letter should be issued to the firm. The firm may request a time extension to complete the recall. All such requests must be approved by CDRH.

If a request for extension is denied, the home division will send the firm a warning letter when the target completion date expires.

The division will document unsatisfactory results of a CAP and/or other violations of Subchapter C by inspection and field testing. Bimonthly recall status reports will be sent to the Center recall unit and OSPOP/DE/ROB by the division.

At the conclusion of the recall, the division will conduct a termination ("close-out") inspection at the recalling firm, terminate the recall appropriately according to classification, and prepare a recall termination letter to the firm. (See Exhibit 7-10).

6. Time Frames

The timeframes associated with electronic products recalls are considerably different than for general FD&C recalls. At the time the Center identifies a problem, the manufacturer is often unaware that any problem exists. Opportunity is provided to the manufacturer to examine and possibly refute the agency's evidence, or to request exemption, or to locate all products and to formulate a CAP. The time between declaration of noncompliance and CDRH approval of the CAP varies widely depending upon the product, the nature of the problem, and the thoroughness of the proposed correction.

Attachment F – Recalls of Infant Formula

Due to the susceptible nature of the population affected by infant formulas, the recall of a violative infant formula is to receive the highest agency priority.

Normally, within five calendar days, infant formula manufacturers' notifications submitted to FDA in compliance with the Infant Formula Act will be evaluated by the Center, action memorandum prepared, and the recall approved by the ACRA.

Other than the above timeframe, recalls of infant formulas are to be handled under the same procedures as other recalls with two important additions:

1. Section 412(f)(3) of the Act requires that the manufacturer post written notice of the recall of an infant formula at each retail establishment where the infant formula is sold. The content of such notices should be reviewed by the agency prior to the posting, and the duration of posting should be part of the firm's recall strategy with agency concurrence. Audit checks should verify adequate posting.
2. Section 412(f)(1) of the Act requires that the manufacturer submit a report on the recall not later than 14 days after the initiation of the recall and at least every 14 days thereafter until the recall is terminated. The agency is to review these reports at least once every 15 days.

Attachment G – Recalls of Medical Devices, Section 518(e)

Guidance Regarding Mandatory Recalls under Section 518(e) of the Federal Food, Drug and Cosmetic Act.

1. BACKGROUND

On November 28, 1990, the President signed into law the Safe Medical Devices Act (SMDA), which was intended to improve the Medical Device Amendments of 1976. The new law includes provisions designed to expand and strengthen FDA's authority to ensure that devices entering the market are safe and effective. The SMDA, by streamlining procedures and augmenting FDA's authority, refines premarket controls and adds postmarketing controls relating to medical devices introduced into interstate commerce.

One of these provisions is section 518(e), the so-called mandatory recall authority. Section 518(e) requires a two-step process involving an order to a firm to immediately cease distribution of a defective device and notify users to cease using it; and either vacating the order or amending the order to require the product's recall. In the first step, if FDA finds there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA shall order the manufacturer, importer, distributor, retailer, or any appropriate person to immediately cease distribution of the device and to immediately notify health professionals and device user facilities of FDA's order, and to instruct such professionals and facilities to cease use of the device.

"Reasonable probability" means that it is more likely than not that an event will occur.

"Serious adverse health consequence" means any significant adverse consequence, including those which may be either life-threatening or involve permanent or long-term injury, but excluding non-life-threatening injuries that are temporary and reasonably reversible. Injuries attributable to a device that are treatable and reversible by standard medical techniques, proximate in time to the injury, meet this latter definition.

After giving the party subject to the order in step 1, an opportunity for an informal hearing, FDA shall either vacate the order or amend it to include a recall of the device. The opportunity for an informal hearing is contained in the order in step 1. The hearing must be held not later than 10 days after the date of issuance of the order, in accordance with the procedures set out in section 201(y) of the Act and 21 CFR Part 16. Failure to request a hearing will generally result in an amended order requiring recall. The party subject to the order may also request, by written submission, review of an order without an informal hearing.

2. PROCEDURES:

These procedures are final publication of regulations implementing section 518(e). Actions under section 518(e) may be initiated by the Center or recommended by the field.

A. Factors to be considered when deciding to recommend a 518(e) recommendation are:

- Does the hazard meet the criteria for a Class I recall situation, i.e., there is a strong likelihood that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death?
- Are other administrative or enforcement actions more appropriate to address the problem?
- Seizure or detention may be a lesser agency burden and may address the health risk situation more effectively.
- GMP issues alone will not support the contention that use of the device will cause serious adverse health consequences.

If the division office believes this threshold has been met, a recommendation should be submitted to CDRH Office of Compliance (OC). Before the division submits a 518(e) recommendation, the firm should be fully apprised of our concern and have been given an opportunity to initiate corrective action.

B. Content and Format

The 518(e) recommendation should be in an organized Recall Recommendation format, and be flagged, "Recommendation for 518(e) Action". It should include the following:

1. The product labeling, and product advertising and/or newsletters to consumers, if pertinent.
2. The basis for determining that 518(e) criteria have been met, such as:

Any sample analysis that documents that the device does, or may, present a serious health hazard.

Any testing done which substantiates device failure, e.g., firm's in-house and/or FDA testing, independent studies, etc.

The number of known injuries and/or deaths as documented in the firm's files.

Complete documentation of those events should be provided to support the 518(e) criteria. The firm's complaint, litigation and service files are valuable in obtaining this information.

A summary of complaints and description of those complaints such as 20 complaints of electrical shortage, 15 complaints of shock, 13 complaints due to over-infusion, 30 complaints of under-infusion. To say that there are 300 complaints may indicate a problem, but does not necessarily indicate a serious health issue. Provide copies of significant or representative medical device complaints or service

records, if available, and any significant correspondence with customers.

The EIR, if inspectional findings support the problem, especially if testing is inadequate.

f. Any pertinent manufacturing or recall history.

Date of the last visit to the firm, the reason for the visit, and any subsequent correspondence or communications. Is a limited update inspection needed or some other mechanism available to determine whether the hazard condition still exists? Be clear on the firm's regulatory history, conditions of approval of the device, etc., so the firm will not later argue that it did not have advance notice of the problems. It presents problems in demonstrating the case as a serious health risk if the case review has taken months.

Any other pertinent information to document that the device presents a hazard consistent with 518(e) criteria.

3. Because a hearing may take place quickly, include one extra copy of ALL information for the Office of Chief Counsel (OCC). All written materials which FDA will rely on for support at the hearing (for example, the EIR) must be turned over to the opposing side at least one day before the informal hearing.

Do not delay other regulatory actions (e.g., seizure) pending the 518(e) review. In addition, do not stop collecting data, as the issue can still potentially result in a trial, seizure, Congressional hearing, etc.

OC will convene a Health Hazard Evaluation Committee (HHE) to evaluate the information in the recommendation. If the HHE concludes that a 518(e) action is warranted, OC, with Chief Counsel concurrence, will prepare the order for signature of the Director, OC. The order will be faxed to the firm and the division. If the firm cannot receive facsimile transmissions, the order will be hand delivered by the division. In either situation, the division should seek an immediate determination from the firm as to its actions. If the order is not complied with, any product encountered should be administratively detained in accordance with the instructions in [RPM Chapter 5 - Administrative Actions](#), Section 5-4, "Administrative Detention of Devices", and appropriate regulations found in 21 CFR 800.55.

The firm is to provide periodic status reports to the division. The frequency of such reports will be specified in the order. Communications developed by the firm to implement the order must be submitted to CDRH for review and approval prior to distribution. The Center will work with the division and firm so that users comply with the order in a medically safe manner. The firm may need to immediately replace defective devices with equivalent devices, including those of a competitor. The Center will review all "emergency" or "urgent need" requests to permit continued use of the device on a

case-by-case basis. We have found that there may be unique medical conditions for which there is no alternative to the device subject to the order.

In those cases, we have permitted continued use of the device provided certain safety precautions are followed.

3. INFORMAL HEARING

The person receiving the order may, within the timeframe specified in the order, submit a written request to FDA for a regulatory hearing. The request must be addressed to the agency employee identified in the order. Ordinarily, FDA will require that the person named in the order submit the hearing request within 3 days of receipt of the order. When necessary, however, FDA may require that the hearing request be submitted in less than 3 days.

The informal hearing will be conducted as a regulatory hearing under 21 CFR Part 16. Following the hearing, the Hearing Officer will issue a decision to vacate the original "cease and desist" order, modify such order, or amend the order to require recall of the product. An ordered recall should begin on the date of the amended order to recall and, generally, should be at mid-stage in six weeks, and completed no later than three months from the recall's initiation.

CDRH OC will make arrangements for the informal hearing including a conference room and stenographer. The hearing will be held in the Washington area. The Center will identify a hearing officer. The hearing will be held not later than 10 days after issuance of the order, unless both the person named in the order and FDA agrees that the hearing will be held at a later date. Such an agreement is unlikely because of the hazard presented by the device.

As soon as OC determines that a 518(e) action is appropriate, the field fact witnesses should immediately prepare for possible testimony in anticipation of the informal hearing. Each should prepare a narrative memo of findings of facts pertaining to the device, i.e., inspectional findings, analytical findings, etc. The Office of Chief Counsel will need the narrative memo three (3) days before the hearing, and will follow-up with a telephone call to the CSO involved. The Center will also be gathering documentary support and locating expert witnesses to testify at the hearing. Expert identification and preparation is a difficult and time-consuming process. The field office should be alert to potential experts and provide their names to CDRH. A pre-meeting of FDA participants and CC will be held 1-2 days prior to the informal hearing, to discuss the issues and prepare our strategy for the hearing.

If a hearing is to be public, it will be announced on the public calendar. If FDA wants the hearing to be closed to the public, it must state one of the reasons contained in 21 CFR 16.60. If the company wants the hearing to be closed to the public, the company must state its reason under 21 CFR 16.60 in its request for a hearing. The Hearing Officer will make the final determination as to whether a hearing is to be open to the public or closed.

If the person named in the order does not request a hearing within the timeframe specified in the order, the right to a hearing will be deemed waived. In such cases, FDA is free to amend the order to require a recall as it deems appropriate.

The person named in an order may, in lieu of requesting a hearing, submit a written request to FDA asking that the order be modified or vacated. The written request must be addressed to the agency employee identified in the order and must be submitted within the timeframe specified in the order. The agency official who issued the cease distribution and notification order will provide the requestor written notification of the agency decision to affirm, modify, or vacate the order within a reasonable time after completing the review of the request.

If the person named in a cease distribution and notification order does not request a regulatory hearing or submit a request for agency review of the order, or if after conducting a regulatory hearing or completing agency review of a cease distribution and notification order, FDA determines that the order should be amended to include a mandatory recall of the device with respect to which the order was issued, FDA will amend the order. The amended order will contain the requirements of the mandatory recall and the form of patient notification, if required.

The statute does not permit FDA to require the recall of devices in the possession of patients or individuals. However, FDA may require the firm to notify patients, if necessary. Patient notification should be used only where the device is in a home health care setting and notification to doctors would not be sufficient. Patient notification should be evaluated on a case-by-case basis, depending on the type of product being recalled. If a significant number of individuals at risk cannot be identified, FDA may use any technique at its disposal to notify such individuals, i.e., publicity section 705(b) of the Act.

Similarly, an amended order cannot include recall of a device from user facilities if FDA determines that the risk of recalling it from the facilities presents a greater health risk than the health risk of not recalling the device, unless the device can be replaced with an equivalent device by the recalling firm (including a competitor's product equivalent to the device).

Attachment H – Methods for Conducting Recall Effectiveness Checks

1. INTRODUCTION

In the Federal Register of June 16, 1978, (43 FR 26202), The Food and Drug Administration (FDA) issued as a final rule, Recalls (Including Product Corrections) - Guidelines on Policy, Procedures, and Industry Responsibilities. Section 7.42 of these guidelines states that the recalling firm will ordinarily be responsible for conducting recall effectiveness checks. Such checks are for the purpose of verifying that the recalling firm's consignees have received notification about the recall and have taken appropriate action.

To assist the recalling firm in carrying out this responsibility and in accordance with section 7.42(b)(3) of the FDA recall guidelines, the following may be used as a guide on how to use different methods for conducting recall effectiveness checks. The methods described include mail, telephone calls, personal visits, and combinations of these alternatives.

2. METHODS

A. General

All the methods for conducting effectiveness checks have several common aspects: a consignee list, a common identifier, a questionnaire, and a procedure for recording responses.

A consignee list is to be prepared when a recall is initiated by a firm. Each of the consignees notified of the recall is a candidate for a recall effectiveness check. However, if there is suitable documentation that a consignee has been notified and has either made the proper disposition of the recalled product or has submitted a negative report on having the product, it may not be necessary to perform a recall effectiveness check at the consignee.

In order to facilitate the correlation of responses from consignees, each consignee could be assigned a unique number which would serve as an identifier. The consignee's zip code could be used as part of the number. The identifier would be put on any return mail card and provided on any telephone or personal visit list used for effectiveness checks. The number would provide easy match with the consignee list and the reconciliation of the consignee contacts and recall effectiveness.

Reconciliation of the effectiveness checks may be handled in numerous ways. It may be by computer or by a system as simple as preparing pressure sensitive labels for each consignee which contain the name, address, and identifying number assigned to that consignee. The number of labels required for each consignee will vary according to the recall method used, i.e. five labels for mailings (if two mailings are used), and two labels for telephone calls and personal visits. For all methods, one of the labels is to be placed on a 3 X 5 card to be used as the control. The second label is to be used for the consignee questionnaire.

As a questionnaire is returned and/or completed, it is placed with the control file card for the consignee for “logging in” purposes.

B. Mail

There are four elements to the use of mail:

- a. a letter to the consignee,
- b. an envelope prominently inscribed with “IMPORTANT RECALL INFORMATION INSIDE”,
- c. a questionnaire, and
- d. a self-addressed, stamped envelope for the consignee to return the completed questionnaire.

The letter to the consignee should state exactly state the reason for the recall, a complete description of the product being recalled or corrected, instructions regarding the disposition of the recalled product, and a request for cooperation in completing and returning the questionnaire. [Exhibit 7-1](#) provides an example of the type letter that can be used. [Exhibit 7-2](#) provides an example of the questionnaire to accompany the effectiveness check letter. It should be noted that the exhibit questionnaires are only examples and that actual circumstances may necessitate changes in the questionnaire wording. Some pretesting of the questionnaire prior to mass mailing is suggested.

In conducting a recall effectiveness check, there are certain basic questions that need to be asked. The purpose of these questions is to determine whether: the recall notification was received; the product involved was handled as instructed in the recall notification; the product was further distributed by the consignee before receipt of the recall notification; and, if so, were the additional consignees notified. Other questions may need to be asked depending upon the nature of the recall. Also, the design and format of the questionnaire may vary depending upon the method of contact to be used.

Attachment I – Mandatory Recall of Tobacco Products

BACKGROUND

On June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 301 et seq.) to give FDA important new authority to regulate the manufacture, marketing and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

The Tobacco Control Act provides for recalls for violations of FDCA requirements that relate to tobacco products under Sections 908(a) and 908(c) of the TCA.

Section 908 reads as follows:

(a) NOTIFICATION- If the Secretary determines that--

(1) a tobacco product which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk, the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all person who should properly receive such notification in order to eliminate such risk. The Secretary may order notification by any appropriate means, including public service announcements. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

(b) No Exemption from Other Liability-Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided under such order shall be taken into account.

(c) RECALL AUTHORITY.-(1) IN GENERAL.-If the Secretary 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 Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to

require a recall of such tobacco product. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

(2) AMENDMENT OF ORDER TO REQUIRE RECALL.- (A) IN GENERAL.-If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Secretary shall, except as provided in subparagraph (B), amend the order to require a recall. The Secretary shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.”

Attachment J – Mandatory Recall Authority for Foods

PURPOSE

This attachment provides procedures and defines responsibilities for various operations related to the Mandatory Recall of Food under Section 423 of the Act, as amended by section 206 of the Food Safety Modernization Act (FSMA). Use of our mandatory recall tool does not prevent us from using other regulatory tools available to us. At any point during the mandatory recall process the agency may discuss and/or pursue another action as needed.

BACKGROUND

On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) was signed into law. Section 423 of the Federal, Food Drug, and Cosmetic Act (the Act) (21 U.S.C. 350l) as amended by section 206 of FSMA, gives FDA the authority, to order the recall of an article food² (other than infant formula) if FDA concludes that there is a reasonable probability that the article of food is adulterated under section 402 or misbranded under section 403(w) and there is a reasonable probability that use of or exposure to the food article will cause serious adverse health consequences or death to humans or animals (SAHCODHA). The Agency will initiate use of its mandatory recall authority within 24 hour of making the determination that the legal standard has been met and the firm is not willing to voluntarily conduct a recall.

PROCEDURES

Step 1: Basis for Mandatory Recall

A. FDA may exercise its authority to order the recall of an article of food based on information developed internally or from outside sources, including states and other agencies, or gathered through any other means. When considering the need to order a food recall, the recommending organization (the FDA Center or Division) shall notify the Office of Strategic Planning and Operational Policy (OSPOP) and create a Work Activity in the Compliance Management System (CMS) as a Preliminary Assessment. The recommending organization will schedule a conference call for representatives of the team to assess the need for mandatory recall. Additional calls may be necessary if more information is needed to reach a conclusion.

B. The recommending organization will prepare and upload into CMS a recommendation memorandum (**See Attachment J1 - Recommendation**)

² The term “article of food,” as it is used in this document, refers to any article of food for humans or animals, other than infant formula. Infant formula recalls are conducted under separate authority in section 412 of the Act.

Memorandum), a draft 423(a) letter (**See Attachment J2 - Notification of Opportunity to Initiate a Voluntary Recall**) and supporting evidence.

Any FDA office that acquires relevant documentation, including correspondence, concerning the matter is responsible for uploading that documentation into the CMS Work Activity, so that it may be reviewed concurrently by OSPOP, the associated Division(s), the appropriate Center compliance staff, the Office of Chief Counsel (OCC), and, if there is an associated human food-borne outbreak, the Coordinated Outbreak Response and Evaluation Network (CORE), or an outbreak involving animal food, the CVM Complaint Emergency Recall Team (CERT), collectively “the team.” OSPOP will be responsible for coordinating the process flow and document cohesiveness throughout the mandatory recall case processing. If a more than one Center (CFSSAN and CVM) is involved, the centers will determine the lead center for the action.

Center compliance staff will ensure a health hazard evaluation (HHE) is completed prior to making a determination whether or not to proceed with mandatory recall. The HHE may be updated at any point in the process if/when necessary. The HHE to support invoking mandatory recall authority must conclude that there is a reasonable probability of SAHCODHA. This conclusion should be clear in the HHE. The HHE must be done before the 423(a) letter is sent. The HHE will be attached as an exhibit to the 423(a) letter. The HHE can satisfy the need for the administrative record to address the SAHCODHA conclusion, on two conditions: 1) it must be thorough and contain sufficient explanation to make FDA’s basis and conclusions clear and 2) the subject matter expert(s) who signs the HHE is committed to being available to provide their view in real time (at least by phone) during a hearing, should a hearing be necessary. If the HHE fails to meet either of these requirements (e.g., it is cursory and will not be revised, or the expert cannot be available to testify at a hearing), the Center will prepare a separate expert memo regarding the SAHCODHA conclusion, which must meet all the same requirements as the expert memo on adulteration/misbranding. The Center will upload both the HHE and SAHCODHA memorandum into CMS.

Additionally, the Center will begin to prepare an expert memo regarding reasonable probability of adulteration or 403(w) misbranding. This expert memo must be prepared and should be final, signed, and uploaded into CMS before the 423(a) letter is sent. Moreover, the expert who prepares and signs this memo should be isolated from the matter when possible and be made aware of the possible timeframe in which the 423 process will play out and must commit to being available to provide their view in real time (at least by phone) during a hearing, should a hearing be necessary.

The center will prepare a written record of FDA’s conclusion that the firm is required to register under section 415 of the FD&C Act, as well as the basis for that conclusion. This may be informal in nature (e.g., an email) if there are no significant issues, but the analysis must be complete and uploaded to CMS before the 423(a) letter can be sent. The Center should also check the database to see if they have in fact registered and make a record of the result of that search, which should also be uploaded to CMS before the 423(a) letter is sent.

If there are any issues specific to the case (e.g., jurisdiction is challenging such that firm may argue product is not a food; or facility is such that it has a reasonable argument that it is not required to register), all of the following must be prepared, finalized, signed, and uploaded to CMS before the 423(a) letter is sent:

- a. a record memo laying out the legal and factual basis for FDA's position (e.g., the legal argument as to why the products at issue are foods, which for example might rely in part on information on product labels);
- b. a sworn affidavit laying the foundation for any evidence upon which the record memo analysis relies (e.g., investigator declaration that the product labels cited in the record memo are true and accurate copies of the labels collected during inspection of the firm); and
- c. all evidence referenced in the affidavit/memo (e.g., copies of the product labels).

OSPOP will send a request for OCC involvement to the OC OCC FSMA Mailbox and designate the request as "URGENT": Possible Mandatory Recall" in the subject line. OSPOP will notify the FDA Office of Media Affairs and keep them involved as necessary in the process. The OSPOP will keep a chronology of events, including documenting when any letters or order are sent to and received by the responsible party.

OSPOP will identify an appropriate person to serve as a Presiding Officer (PO) if needed. This person must not have been previously involved in decision-making for the matter (including, for example, SCORE calls discussing the matter) and should be advised to maintain separation of functions from the ORA personnel who are working with the OFVM/CFSAN/CVM/ORAs team. OSPOP will determine the availability of the PO and ensure the PO is in contact with OC attorney(s) available to them.

The Center will identify a subject matter expert who has not previously worked on the matter and can advise the PO/Commissioner's Team as needed with respect to the specific types of evidence that form the basis of FDA's case. This person must also be available at the time that will be critical: the day of anticipated issuance of the 423(b) order and at least the next two calendar days (and up to a week) immediately after issuance of the 423(b) order. This person should be advised to maintain separation of functions from the CFSAN/CVM subject matter experts who are working with the OFVM/CFSAN/CVM/ORAs team.

C. Once a decision is made to move forward with the mandatory recall the team will immediately begin reviewing the recommendation memo, draft 423(a) letter, supporting evidence, and once completed, the HHE and SAHCODHA Memorandum, to determine whether there is a reasonable probability that an article of food is adulterated under section 402 of the Act or misbranded under section 403(w) of the Act, and whether there is a reasonable probability that the use of or exposure to such article of food will cause SAHCODHA.

D. When and if the team determines that there is a reasonable probability that the article(s) of food is adulterated under section 402 of the Act or misbranded under section 403(w) of the Act and there is a reasonable probability that the use of or exposure to the article(s) of food will cause SAHCODHA, the recommending office or organization (usually the division) will change the Work Activity in CMS to a case (FSMA – Opportunity to Cease Distribution and Conduct Voluntary Recall: 423(a)) and proceed to Step 2.

Step 2: Notification of Opportunity to Initiate a Voluntary Recall – Section 423(a)

A. The team will concurrently review and recommend necessary changes to the recommending organization's draft 423(a) letter, Notification of Opportunity to Initiate a Voluntary Recall. OSPOP will coordinate with all parties to ensure recommended changes are incorporated into a final draft for review and clearance by OCC. During this time, recommending organization will prepare a draft 423(b) letter (**See Attachment J3 – Prehearing Order to Cease Distribution and Give Notice**) to be finalized in the event the responsible party chooses not to recall voluntarily in accordance with the 423(a) letter.

All of the following steps must be taken before OCC can clear the 423(a) letter:

- Lab test results on which the agency plans to rely must be final and accepted by FDA. If they are preliminary in some form, that must be clearly stated when the results are referenced in other documents (until they become final). Summaries and analytical worksheets need to be uploaded into CMS as soon as they are available.
- If FDA intends to rely on lab work done by a non-FDA-lab as evidence in the matter, an appropriate person at FDA must review the documentation and sign a brief memo regarding the validity of the non-FDA lab's analysis. If FDA experts are not prepared to say that the non-FDA lab's work can be relied upon to show what it purports to show, FDA cannot use that evidence. FDA only needs one such memo. The Center and ORA will decide who is responsible for this analysis so there will be no duplication/conflict.
- Firm websites, if used as evidence in the matter, need to be captured by screen shot and uploaded into CMS as PDFs.
- The HHE, expert memos, memo supporting the violation, documentation supporting the registration requirement, and memos addressing potential challenges to the case must be complete and uploaded into CMS.
- The 423(a) letter must clearly state and support (with attachments including relevant factual evidence such as lab test results, and the HHE) the complete basis for FDA's conclusions of reasonable probability of adulteration/misbranding and reasonable probability of SAHCODHA.

B. After all recommended changes are captured and the above list of steps completed, OSPOP will forward the 423(a) letter final draft to OCC for final review and clearance. Once cleared, OCC will provide a copy of the cleared document to OSPOP. OSPOP

will prepare the letter for signature, with accompanying supporting evidence, and provide the package to the Deputy Commissioner of Food Policy and Response (or designee, if appropriate delegations exist). OSPOP will issue the letter to the responsible party by overnight delivery (with delivery confirmation). If transmitted in a manner other than overnight delivery, e.g., by electronic mail, request a delivery and read receipt. Additionally, a copy of the letter will be sent using the most expeditious method that is available to the responsible party (e.g., by electronic mail or facsimile). OSPOP will email the letter to the team and upload a copy into CMS. When possible, the Program [Division] Director shall also contact the responsible party to convey the information contained in the letter orally.

All communications with the responsible party will be documented in CMS. The two working day timeframe for initiating the voluntary recall, as indicated in the letter, will begin once the Division Office (DO) confirms the responsible party has received the letter.

C. If the responsible party initiates a voluntary recall and ceases distribution of the article of food within 2 working days and in any manner prescribed by FDA, the DO will immediately notify the team. The oversight, processing and tracking of the recall action will follow the procedures for Class I recalls in the RPM, Chapter 7 – Recall Procedures. The recall will be documented in RES. The DRC will select the recall type from the voluntary drop down list, “Voluntary-423(a)” on the “Edit Start Recall” screen. In the Public Reason for Recall, include the statement: “[FIRM] received a 423(a), Notification of Opportunity to Initiate a Voluntary Recall, letter from FDA and is recalling [Product] because [Reason].”

D. If the responsible party refuses to or does not voluntarily cease distribution and recall such article within two working days and in the manner prescribed by FDA, the DO will notify the team and the action shall proceed to Step 3, Prehearing Order to Cease Distribution and Give Notice – Section 423(b).

The team may reconvene at any time to discuss further regulatory action needed to mitigate public health risks. If at any point the process appears to be slowing or stagnating, the team will escalate the issue to senior ORA/Center officials and/or SCORE.

Step 3: Prehearing Order to Cease Distribution and Give Notice – Section 423(b)

A. The team will concurrently review and make necessary changes to the recommending organization’s draft 423(b) letter - Prehearing Order to Cease Distribution and Give Notice, informing the responsible party that it must cease distribution and immediately notify all persons manufacturing, processing, packing, transporting, distributing, receiving, holding or importing and selling the article of food, and to which such food has been distributed, transported, or sold, to immediately cease distribution of the article. The order will also advise the responsible party that it has the

opportunity for an informal hearing, and provide the responsible party instructions on how to request a hearing.

Once all parties have had the opportunity to recommend changes, OEIO will forward the final 423(b) letter to OCC for final clearance.

B. Once OCC provides final clearance of the 423(b) letter and it is signed by the Deputy Commissioner of Food Policy and Response (or designee, if appropriate delegations exist), OSPOP will issue the order to the responsible party with delivery confirmation. FDA should make every effort to issue the 423(b) order EARLY IN THE DAY ON THE DAY IT IS ISSUED (the earlier the better, no later than 12:00 pm Eastern, aiming for an ideal closer to 9:00 am Eastern), with a plan for all of the deadlines that follow. If the 423(b) can't be issued early on the desired day, move issuance to the next day. A copy of the order will be sent using the most expeditious method that is available to the responsible party (e.g., by electronic mail or facsimile). When possible, the Program or Division Director shall also contact the responsible party to convey the information contained in the order orally. Further, the recommending organization will change the action in CMS to FSMA – Prehearing Order to Cease Distribution and Give Notice.

C. The division will attempt to determine whether the responsible party ceased distribution and gave notice.

D. The contact person must be CONSTANTLY monitoring their email/phone during the 24 hours provided to the firm for the hearing request. If the responsible party requests an informal hearing, the request will be forwarded immediately to the PO team and Center team so that all are aware and can begin working on the request and related tasks.

Step 4: Decision to Grant an Informal Hearing– Section 423(c)

A. If the responsible party does not request an informal hearing, the team will proceed to Step 9 (**Amend or Modify the Prehearing Order to Cease Distribution and Give Notice without Holding an Informal Hearing**).

B. If the responsible party requests an informal hearing, the request will be reviewed by the PO team in accordance with the procedures set out in 21 CFR Part 16 (to the extent that those procedures do not conflict with procedures required under section 423 of the Act) to determine whether a hearing should be granted.

The PO needs to decide whether a genuine issue of material fact has been presented:

1. For most types of hearing requests, PO can decide with no opposition brief from Center team.
2. If requesting opposition brief from OFVM/CFSAN/ORR Team (e.g., jurisdictional challenge), PO team should give Center team a deadline, default 3 hours from receipt of hearing request. For example, hearing request received Day 5 at 9:00 am. Center and PO team immediately review request, PO team takes 0.5 hour to determine they need an opposition from Center team because challenge is

jurisdictional (Center team will also be looking during this time and should anticipate same so can begin work immediately). At 9:30 am PO team tells Center Team they have until 12:00 pm to submit opposition if they want to oppose the request.

3. Target for PO decision issuance on hearing request (regardless of outcome): COB Day 5. If PO decides to grant hearing request, issue decision ASAP and include start time for hearing (must be on Day 6, likely in PM), along with room/call-in details/statement of the specific issue(s) on which hearing is being granted. Also include request to both parties for witness lists – default could be for these to be submitted by Day 6, 12:00 pm.

If it is determined that a hearing should be granted, proceed to Step 5 (**Informal Hearing Procedures**).

If it is determined that a hearing should not be granted, the responsible party shall be notified by the presiding officer of this decision by overnight delivery (with delivery confirmation) and by fax or electronic mail. **See Attachment J4 (Denial of Hearing Request)**. The Center/Division/OSPOP/OCC team will be immediately notified of this decision. If the team believes that the removal from commerce of the food subject to the original (i.e. unmodified) order is necessary, or that the Commissioner should modify the prehearing order to cease distribution and give notice and that the removal of the article of food that is the subject of such order is necessary, proceed to Step 9 (**Amend or Modify the Prehearing Order to Cease Distribution and Give Notice Without Holding an Informal Hearing**).

Whether a hearing is granted or denied, documentation of the PO's decision will be captured in CMS.

Step 5: Informal Hearing Procedures

A. FDA will conduct the hearing consistent with section 201(x) of the Act and 21 CFR Part 16 (to the extent that Part 16 is not in conflict with section 423 of the Act).

B. PO team has until COB Day 6 to commence hearing if it is granted. Hearing need not finish on Day 6.

1. FDA prefers to conduct the hearing in person or via video conference, but teleconference is also an option. The hearing will be conducted in a designated hearing room.

2. At the hearing, the parties will have the right to hear a full and complete statement of the action that is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

3. If credibility is a material issue, the presiding officer will assess the credibility of witnesses.
 4. OSPOP will contract with third party services for recording and transcription of the hearing. A copy of the recording/transcript will be uploaded into CMS.
- C. The presiding officer will write a hearing report. **See Attachment J6 (Hearing Report)**. PO team should immediately begin work on post-hearing report, using notes and recording of hearing until transcript is available. The final hearing report must be uploaded into CMS.
- D. If the presiding officer determines following the informal hearing that adequate grounds do not exist to continue the actions required by the prehearing order proceed to Step 6 (**Vacate the Prehearing Order to Cease Distribution and Give Notice Following the Informal Hearing**). If the presiding officer determines that removal of the article from commerce is necessary, proceed to Step 7 (**Amend or Modify the Prehearing Order to Cease Distribution and Give Notice Following the Informal Hearing**).

Step 6: Vacate the Prehearing Order to Cease Distribution and Give Notice Following the Informal Hearing

- A. If the presiding officer determines that adequate grounds do not exist to continue the actions required by the order, the presiding officer will draft an order vacating the prehearing order within 24 hours of the informal hearing. **See Attachment J7 (Vacated Order)**.
- B. The presiding officer will send the proposed final vacated order and the administrative record of the hearing to the Office of the Commissioner (OC) by electronic mail.
- C. As soon as practicable thereafter, the Commissioner will be advised by a designee in the OC on the matter. If the Commissioner approves the vacated order, the Commissioner will sign the vacated order, or revise and sign the order as appropriate, and the OC will send the signed order to the presiding officer. The Commissioner's decision should be made within 24 hours of receipt of the administrative record of the hearing from the PO.
- D. The presiding officer will draft a hearing report cover letter. **See Attachment J5 (Hearing Report Cover Letter)**.
- E. The presiding officer will issue and send the vacated order with a cover letter and the hearing report to the responsible party by overnight delivery (with delivery confirmation). A copy of the vacated order will be sent using the most expeditious method to the responsible party, e.g., by electronic mail or facsimile. When possible, the presiding officer will also contact the responsible party to convey the information contained in the vacated order orally. Additionally, the presiding officer will send the vacated order with the cover letter and the hearing report to the FDA hearing participants by electronic mail

or facsimile. A copy of the vacated order will be uploaded into CMS by either the division or OSPOP.

Step 7: Amend or Modify the Prehearing Order to Cease Distribution and Give Notice Following the Informal Hearing - Section 423(d)

A. If an informal hearing is conducted and the presiding officer determines that it is not necessary to modify the actions of the prehearing order, and that the removal of the article of food that is the subject of the unmodified order from commerce is necessary, the presiding officer will immediately (within 24 hours) draft an amended order that, as appropriate (1) amends the prehearing order to require recall of such article or other appropriate action; (2) specifies a timetable in which the recall shall occur; (3) requires periodic reports describing the progress of the recall; and (4) requires notice be provided to consignees and consumers to whom such article was or may have been distributed. See **Attachment J8 (Amended Order)**. Similarly, if, after an informal hearing is conducted, the presiding officer determines that certain actions in the prehearing order should be modified and that the removal of the article of food that is the subject of that modified prehearing order from commerce is necessary, the presiding officer will immediately (within 24 hours) draft a modified order that, as appropriate (1) amends the prehearing order to require recall of such article or other appropriate action; (2) specifies a timetable in which the recall shall occur; (3) requires periodic reports describing the progress of the recall; and (4) requires notice be provided to consignees and consumers to whom such article was or may have been distributed. See **Attachment J9 (Modified Order)**.

B. The presiding officer will send the proposed final amended order, or modified order as applicable, and the administrative record of the hearing to the OC by electronic mail.

C. As soon as practicable thereafter, the Commissioner will be advised by a designee in OC on the matter. If the Commissioner approves the amended order, or modified order as applicable, the Commissioner will sign the order or revise and sign the order as appropriate, and the OC will send the signed order to the presiding officer. The Commissioner's decision should be made within 24 hours of receipt of the administrative record of the hearing from the PO.

D. The presiding office will draft a hearing report cover letter. See **Attachment J5 (Hearing Report Cover Letter)**.

E. Following the Commissioner's decision, the presiding officer will immediately issue and send the amended order or modified order, as applicable, with a cover letter and the hearing report to the responsible party by overnight delivery (with delivery confirmation). Additionally, a copy of the order will be sent using the most expeditious method to the responsible party, e.g., by electronic mail or facsimile. When possible, the presiding officer will also contact the responsible party to convey the information contained in the order orally. Additionally, the presiding officer will send the amended order, or modified order, with the cover letter and hearing report to the FDA hearing participants by electronic mail. **Proceed to Step 10 (Manage the Recall)**.

Step 8: Vacate the Prehearing Order to Cease Distribution and Give Notice without Holding an Informal Hearing

- A. If at any time after providing opportunity for an informal hearing it is determined that adequate grounds do not exist to continue the actions required by the original (i.e. unmodified and not amended) order to cease distribution and give notice, and that the order should not be modified, the OSPOP will draft an order vacating the order to cease distribution and give notice. **See Attachment J7 (Vacated Order).**
- B. The OSPOP will send a proposed final vacated order to the OC by electronic mail.
- C. As soon as practicable thereafter, the Commissioner will be advised by a designee in OC on the matter. If the Commissioner approves the vacated order, the Commissioner will sign the vacated order, or revise and sign as appropriate, and the OC will send the signed order to the OSPOP.
- D. The OSPOP will issue and send the vacated order with a cover letter to the responsible party by overnight delivery (with delivery confirmation). A copy of the vacated order will be sent using the most expeditious method to the responsible party, e.g., by electronic mail or facsimile with delivery confirmation. When possible, the Director of the OSPOP will also contact the responsible party to convey the information contained in the vacated order orally.

Step 9: Amend or Modify the Prehearing Order to Cease Distribution and Give Notice Without Holding an Informal Hearing – Section 423(d)

- A. If the responsible party does not request an informal hearing or one is not granted, and the OSPOP determines that that it is not necessary to modify the actions of the prehearing order, and that the removal of the article of food that is the subject of the unmodified order is necessary, the OSPOP will immediately (within 24 hours) draft an amended order that, as appropriate (1) amends the order to require recall of such article or other appropriate action; (2) specifies a timetable in which the recall shall occur; (3) requires periodic reports describing the progress of the recall; and (4) requires notice be provided to consignees and consumers to whom such article was or may have been distributed. **See Attachment J8 (Amended Order).** Similarly, if the responsible party does not request an informal hearing or one is not granted, and the OSPOP determines that certain actions in the prehearing order to cease distribution and give notice should be modified and that the removal of the article of food that is the subject of that modified prehearing order from commerce is necessary, the OSPOP will immediately (within 24 hours) draft an amended order that, as appropriate (1) amends the order to require recall of such article or other appropriate action; (2) specifies a timetable in which the recall shall occur; (3) requires periodic reports describing the progress of the recall; and (4) requires notice be provided to consignees and consumers to whom such article was or may have been distributed. **See Attachment J9 (Modified Order).**
- B. OSPOP will send the proposed final amended order, or modified order as applicable, to the OC by electronic mail.

C. As soon as practicable thereafter, the Commissioner will be advised by a designee in the OC on the matter. If the Commissioner approves the proposed amended order, or modified order as applicable, the Commissioner will sign the order, or revise and sign the order as appropriate, and the OC will send the signed order to the Director of the OSPOP. The Commissioner's decision should be made within 24 hours of receipt of the proposed amended order or modified order as applicable from OSPOP.

D. The OSPOP will issue the amended order, or modified order as applicable, to the responsible party by overnight delivery (with delivery confirmation). Additionally, a copy of the order will be sent using the most expeditious method to the responsible party (e.g., by electronic mail or facsimile). When possible, the Director of the OSPOP will also contact the responsible party to convey the information contained in the amended or modified order orally. Proceed to Step 10 (**Manage the Recall**).

Step 10: Manage the Recall

A. The O-SPOP will ensure that FDA provides public notification of the recall to consumers and retailers to whom such article was, or may have been, distributed, in accordance with section 423(g) of the Act.

B. The oversight, processing and tracking of the recall action will follow the procedures for recalls in the RPM, Chapter 7 – Recall Procedures. The recall will be documented in RES. The DRC will select the recall type from the mandatory drop down list, "FDA Ordered-423(d)" on the "Edit Start Recall" screen. In the Public Reason for Recall, include the statement: "[Firm] is recalling [Product] because [Reason], consistent with an FDA Order for FSMA Mandatory Recall of Food under Section 423(d) of the Act."

C. The OSPOP will ensure that FDA indicates the status of the recall (such as whether a recall is ongoing or has been completed) on its website.

D. In accordance with section 423(j) of the Act, the OSPOP will establish an incident command operation or a similar operation that will operate not later than 24 hours after the initiation of a mandatory recall, or the voluntary ceased distribution and recall of an article of food for which there is a reasonable probability that use of, or exposure to, such article will cause serious adverse health consequences or death to humans or animals.

Step 11: Vacate the Amended or Modified Order

A. If after providing opportunity for an informal hearing the Division, applicable Center(s), or OSPOP, or the Commissioner on his/her own initiative, determines that adequate grounds do not exist to continue the actions required by an order made under Step 7 or 9 (**Amend or Modify the Prehearing Order to Cease Distribution and Give Notice Following the Informal Hearing OR Amend or Modify the Prehearing Order to Cease Distribution and Give Notice Without Holding and Informal Hearing**), the OSPOP will draft, at the Commissioner's direction as applicable, an order vacating the order made under Step 7 or 9. **See Attachment J7 (Vacated Order)**.

- B. The OSPOP will send a proposed final vacated order to the OC by electronic mail.
- C. As soon as practicable thereafter, the OSPOP will advise the Commissioner on the matter. If the Commissioner approves the vacated order, the Commissioner will sign the vacated order, or revise and sign the order as appropriate, and the OC will send the signed order to the OSPOP.
- D. The OSPOP will issue and send the vacated order with a cover letter to the responsible party by overnight delivery (with delivery confirmation). A copy of the vacated order will be sent using the most expeditious method to the responsible party (e.g., by electronic mail or facsimile). When possible, the Director of the OSPOP will also contact the responsible party to convey the information contained in the vacated order orally.

Attachment J1 – Recommendation Memorandum

To: Office of Commissioner

From:

Date:

Subject: Formal Recommendation Regarding Whether to Provide [responsible party name and address] With an Opportunity to Cease Distribution and Recall [article of food]

Responsible Party and Contact Information:

Firm Identification #(s):

Description of Article:

Article Identification #(s):

Background:

Evidence:

District Office’s Recommendation - [person’s name]:

Center’s Recommendation - [person’s name]:

OCC’s Recommendation - [person’s name]:

OSPOP’s Recommendation - [person’s name]:

Determination:

Determination Date:

Attachment J2 – Notification of Opportunity to Initiative a Voluntary Recall

[Date]

[Responsible Party Name]

[Firm Name]

[Street]

[City, State Zip]

Dear [Name]:

Pursuant to section 423 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 3501), as amended by the FDA Food Safety Modernization Act, the U.S. Food and Drug Administration (FDA) is providing your firm [firm name], with an opportunity to voluntarily cease distribution and conduct a recall of the below referenced products. Section 423(a) of the FD&C Act provides in relevant part that if FDA “determines...that there is a reasonable probability that an article of food (other than infant formula) is adulterated under section 402 of the Act or misbranded under section 403(w) of the Act and the use of or exposure to [article of food] will cause serious adverse health consequences or death to humans or animals,” before taking further action under section 423 of the FD&C Act, FDA must offer the responsible party the opportunity to voluntarily cease distribution and recall such articles (21 U.S.C. 3501(a)).

[Identify the specific product(s) and code(s) that should be recalled and the basis for FDA’s determination that there is a reasonable probability that the product(s) are adulterated under 402 or misbranded under 403w and the reasonable probability that use of or exposure to the product(s) may result in serious adverse health consequences or death to humans or animals. If there are violative samples, inspectional evidence, adverse events, or other compelling information that the FDA’s determination is based on, they should be included.]

In accordance with section 423(a) of the FD&C Act, we are providing you with an opportunity to voluntarily cease distribution and conduct a recall of the [referenced product(s)]. If you elect to voluntarily cease distribution and conduct a recall of these products, you should do so in the following time and manner:

- Within 2 working days of your receipt of this letter, cease distribution and initiate a recall of the following product(s): [product(s)]
Notify all direct consignees and request that those who further distributed these products conduct a sub-recall to the consumer level.

- Conduct your recall of these products in coordination with the FDA [] Division Recall Coordinator and in accordance with the manner prescribed by FDA.
- Follow the procedures for recalls found in FDA's regulations at 21 CFR Part 7 to the extent that it doesn't conflict with the time and manner prescribed in this letter. A copy of these regulations is enclosed.

If you do not voluntarily cease distribution and conduct a recall within 2 working days and in the manner described in this letter, FDA may, by order require you to immediately cease distribution of [article of food]. Additionally, FDA may, by order require you to immediately notify all persons manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling [article of food] to immediately cease distribution of such article; and to immediately notify all persons to which such article has been distributed, transported, or sold, to immediately cease distribution of [article of food].

Please respond to this letter by contacting [Program [Division] Director Name, Telephone Number and Electronic mail Address] as soon as possible. If a response is not received from you by [deadline], FDA may by order require you to immediately cease distribution and notify applicable parties, as explained above.

Sincerely,

[Deputy Commissioner of Food Policy and Response]

Enclosure: 21 CFR Part 7

Attachment J3 – Prehearing Order to Cease Distribution and Give Notice

[Date]

[Responsible Party Name]

[Firm Name]

[Street]

[City, State Zip]

Dear [Name]:

Pursuant to section 423 of the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the FDA Food Safety Modernization Act, FDA has determined that there is a reasonable probability that [responsible party name]'s [article of food and identifying information] is adulterated under section 402 of the Act or misbranded under section 403(w) of the Act and the use of or exposure to [article of food] will cause serious adverse health consequences or death to humans or animals. FDA notified you of its determination and provided you with the opportunity to voluntarily cease distribution and conduct a recall. At present, you have not [responded to or taken all the actions specified in] FDA's request. Accordingly, FDA is now ordering you to immediately cease distribution of [article of food], and to immediately notify (1) all persons manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such article; and (2) all persons to which such article has been distributed, transported, or sold to immediately cease distribution of [article of food]. You are further required to give any warehouse-based third party logistics provider that may be in possession of [article of food] sufficient information to identify the article of food covered by this order.

You have the right to request that an informal hearing be held at which, if granted, you would have the opportunity to address the actions required by this order and why the article that is the subject of this order should not be recalled. If you would like to request an informal hearing please send a written request to [Program [Division] Director Name, Address, Telephone Number and Electronic mail Address] within 24 hours of receipt of this order. Please submit [describe information to be submitted in the request]. If you request a hearing, you must follow-up your written request with a phone call to [Program [Division] Director Name] to confirm receipt of the hearing request. If you do not request a hearing in writing within [number of days or hours] you will waive your right to a hearing. Enclosed are the regulations covering FDA's informal hearing procedures in 21 CFR Part 16. Please also refer to 21 CFR Part 10, subpart C for information describing FDA's policies and procedures applicable to electronic media coverage of agency public administrative hearings.

Please note that a request for a hearing may not be granted if FDA determines that no genuine or substantial issue of fact has been raised by the material submitted. If you do not submit a timely written request for a hearing, or if your request for a hearing is

denied, you may be required to recall [article of food] within a specified timetable, provide periodic reports on the status of the recall, notify consumers of the recall, and other appropriate action. Moreover, if you do not comply with such a recall order, you will be charged user fees to cover food recall activities associated with such order.

Sincerely,

[Deputy Commissioner of Food Policy and Response]

Attachment J4 – Denial of Hearing Request

[Date]

[Responsible Party Name]

[Firm Name]

[Street]

[City, State Zip]

Dear [Name]:

On [date], pursuant to section 423 of the Federal Food, Drug, and Cosmetic Act, as amended by the FDA Food Safety Modernization Act, FDA sent you a prehearing order to cease distribution and give notice. FDA also informed you that you had the opportunity to request an informal hearing to address the actions required by that order and why the article that is subject to that order should not be recalled.

FDA has reviewed your request for a hearing and has determined [reason for denying the hearing]. [Summary of material submitted and any further explanation for denial.] Therefore, your request for a hearing is hereby denied.

Sincerely,

[Presiding Officer]

Attachment J5 – Hearing Report Cover Letter

[Date]

[Hearing Party's Name]

[Street]

[City, State Zip]

Dear [Name]:

On [date], an informal hearing was held on [the actions required by the order to cease distribution and give notice, and on whether the article of food that is the subject of the order should not be recalled]. Enclosed, please find the [vacated, modified, or amended] order that resulted from that hearing, along with a copy of the hearing report.

Sincerely,

[Presiding Officer]

Attachment J6 – Hearing Report

On [date], I served as the presiding officer in an informal hearing that was attended by [names of parties and titles in relation to the responsible party or FDA]. The hearing was held [on the actions required by the order to cease distribution and give notice, and on whether the article of food that is the subject of the order should not be recalled].

Prior to the hearing, on [date], FDA provided formal notice to [the responsible party name] that it had the opportunity to cease distribution and conduct a voluntary recall of [article of food]. [Responsible party name] did not [recall or cease distribution of the article of food in the time and manner prescribed, if so prescribed]. Subsequently, on [date] FDA sent [by registered mail, facsimile, and/or electronic mail] [responsible party name] a prehearing order to cease distribution and give notice.

At the hearing, I considered the actions required by the prehearing order to cease distribution and give notice and the evidence and testimony presented at the hearing. I was provided with [list of documents and summary of any pertinent information].

[Option: If credibility is at issue, include a finding on the credibility of witnesses (other than expert witnesses) and explain why the finding was made.]

Based on this information, I have determined [choose from options below]

[Option 1: that adequate grounds do not exist to continue the actions required by the order and have decided to vacate the order.]

[Option 2: that the removal of [article of food] from commerce is necessary. The prehearing order to cease distribution and give notice should be amended to, [as appropriate (1) require [responsible party name] to recall [article of food and identifying information] or [take other appropriate action]; (2) [specify a timetable in which the recall shall occur]; (3) require [periodic reports] describing the progress of the recall; and (4) require that notice be provided to consignees and consumers to whom such article was or may have been distributed.]

[Option 3: that the prehearing cease distribution and give notice order should be modified [because], and that the removal of [article of food] subject to the modified order from commerce is necessary. The modified prehearing order to cease distribution and give notice should be modified to, [as appropriate (1) require [responsible party name] to recall [article of food and identifying information] or [take other appropriate action]; (2) [specify a timetable in which the recall shall occur]; (3) require [periodic reports] describing the progress of the recall; and (4) require that notice be provided to consignees and consumers to whom such article was or may have been distributed.]

[Presiding Officer]

Attachment J7 – Vacated Order

[Date]

[Responsible Party Name]

[Firm Name]

[Street]

[City, State Zip]

Dear [Name]:

On [date] you were ordered to immediately cease distribution of [article of food], and to immediately notify (1) all persons manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such article; and (2) all persons to which such article has been distributed, transported, or sold to immediately cease distribution of [article of food]. You were also ordered to give any warehouse-based third party logistics provider that may be in possession of [article of food] sufficient information to identify the article of food covered by the order. [As applicable, [Furthermore, the [date] order was [amended or modified] on [date] to [describe requirements of the amended or modified order]]].

At this time, adequate grounds do not exist to continue the actions required by the [date] order. [Insert any additional information regarding the decision to vacate the order, as desired]. Accordingly, the [date] order is hereby vacated.

Sincerely,

Commissioner, Food and Drugs

Attachment J8 – Amended Order

[Date]

[Responsible Party Name]

[Firm Name]

[Street]

[City, State Zip]

Dear [Name]:

On [date], you were ordered to immediately cease distribution of [article of food], and to immediately notify (1) all persons manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such article; and (2) all persons to which such article has been distributed, transported, or sold to immediately cease distribution of [article of food]. Furthermore, you were ordered to give any warehouse-based third party logistics provider that may be in possession of [article of food] sufficient information to identify the article of food covered by the order.

At this time, the removal of [article of food] from commerce is necessary. Therefore, the [date] order is hereby amended, and you are ordered to [as applicable, recall [article of food] or take other appropriate action [within timetable]; provide [periodic] reports to [designee] describing the progress of the recall; and immediately notify consumers to whom such article was, or may have been, distributed].

Please note that if you do not comply with this order, FDA may impose a civil penalty or pursue other actions, as appropriate. This order is effective immediately. If you have questions regarding this order, you may contact Program [Division] Director Name, Telephone Number and Electronic mail Address.

Sincerely,

Commissioner, Food and Drugs

Attachment J9 – Modified Order

[Date]

[Responsible Party Name]

[Firm Name]

[Street]

[City, State Zip]

Dear [Name]:

On [date], you were ordered to immediately cease distribution of [article of food], and to immediately notify (1) all persons manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling such article; and (2) all persons to which such article has been distributed, transported, or sold to immediately cease distribution of [article of food]. Furthermore, you were ordered to give any warehouse-based third party logistics provider that may be in possession of [article of food] sufficient information to identify the article of food covered by this order.

At this time, the [date] order is modified [insert any specific modifications, e.g. the scope of coverage in terms of articles of food or persons who must be notified]. Additionally, at this time the removal of [article of food] from commerce is necessary. Therefore, you are hereby ordered to [as applicable, recall [article of food] or take other appropriate action [within timetable]; provide [periodic] reports to [designee] describing the progress of the recall; and immediately notify consumers to whom such article was, or may have been, distributed.]

Please note that if you do not comply with this order, FDA may impose a civil penalty or pursue other actions, as appropriate. This order is effective immediately. If you have questions regarding this order, you may contact Program [Division] Director Name, Telephone Number and Electronic mail Address.

Sincerely,

Commissioner, Food and Drugs

Attachment K – Notification, Nondistribution, and Recall of Controlled Substances for Human or Animal Use

PURPOSE

This attachment provides procedures and defines responsibilities for various operations related to the issuance of an order of nondistribution and the mandatory recall of controlled substances under Section 569D of the Act [21 U.S.C. 360bbb-8d], as amended by section 3012 of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). Use of this mandatory recall tool does not prevent the agency from using other available regulatory tools. At any point during the notification, nondistribution and recall process, the agency may discuss and/or pursue another action as needed.

BACKGROUND

Section 3012 of the SUPPORT Act, Notification, Nondistribution, and Recall of Controlled Substances, adds section 569D to the Federal Food, Drug, and Cosmetic Act (FD&C Act) and grants authority for FDA to order a firm to cease distribution of controlled substances in situations where the agency determines there is a reasonable probability that the controlled substance would cause serious adverse health consequences or death in humans or animals. Before the order of nondistribution can be issued, the appropriate person must be given an opportunity to consult with the agency. Following the issuance of an order of nondistribution, the appropriate person may request a hearing. Following a hearing or a failure to request a hearing within the prescribed timeframes, FDA, through the official designated by the Secretary can resolve an order of nondistribution in any of the following ways:

- A. Vacate the order of nondistribution.
- B. Continue the order of nondistribution requiring the appropriate person to cease distribution of the controlled substance until a date specified in such continued order.
- C. Amend the order of nondistribution to require a recall of the controlled substance, including any requirements to notify appropriate persons, a timetable for the recall to occur, and a schedule for updates to be provided to FDA regarding such recall.

According to section 569D(c), “an official may not be so designated under this section unless the official is the Director of the Center for Drug Evaluation and Research or an official senior to such Director.”

PROCEDURES

Step 1: Preparing for the Issuance of the Order of Nondistribution:

- A. FDA may exercise its authority to issue an order of nondistribution (see Attachment K1), which may be followed by a recall of a controlled substance, based on information developed internally or from outside sources, including states and other agencies, or gathered through any other means. When considering the need to issue the order, and once concurrence is obtained from the Center Deputy Director to move forward with providing the appropriate person the opportunity to consult, the FDA Center shall notify the Office of Regulatory Affairs (ORA) Program Division and request the ORA Program Division set up an internal meeting with the Center, the Office of Chief Counsel (OCC), the ORA Division of Enforcement (DE), and all other interested parties for awareness before the firm is contacted to set up an opportunity to consult meeting. The FDA Center will create a case in the Compliance Management System (CMS) as a Compliance Action: Order of Non-Distribution - Support Act.

- B. The FDA Center will prepare and upload into CMS, as appropriate, an order of nondistribution and recall action memo, the health hazard evaluation (HHE), the draft order of nondistribution, and any other supporting memos or evidence.

Any FDA Office that acquires relevant documentation, including correspondence concerning the matter, is responsible for uploading that documentation into the CMS case, so that it may be reviewed concurrently by the ORA Program Division, OSPOP/DE, the appropriate Center compliance staff, and OCC; collectively “the team.” The team reporting to the Center Deputy Director that is involved with the opportunity to consult and possible issuance of the nondistribution order, should not be involved in assisting the Center Director, or delegated authority senior to the Center Director, for order resolution.

The ORA Program Division will be responsible for coordinating the process flow and document cohesiveness throughout the order issuance and mandatory recall case processing. If more than one Center (i.e. CDER and CVM) is involved, the centers will determine the lead center for the action.

Center compliance staff will ensure an HHE is completed prior to deciding whether to proceed with issuing a nondistribution order. The subject matter expert(s) who signs the HHE is committed to being available to testify (at least by phone) during a hearing, should a hearing be requested. If the expert cannot be available to testify at a hearing, the Center will prepare a separate expert memo regarding the determination that the controlled substance would cause serious adverse health consequences or death. The Center will upload both the HHE and, when needed, the serious adverse health consequences or death memorandum into CMS.

All the following must be prepared, finalized, signed, and uploaded to CMS by the appropriate organization (Center or Division) before the order of nondistribution is sent:

- 1) A record memo laying out the legal and factual basis for FDA's position (e.g., the legal argument as to why the products at issue are controlled substances, which for example might rely in part on information on product labels);
- 2) A sworn affidavit laying the foundation for any evidence upon which the record memo analysis relies (e.g., investigator declaration that the product labels cited in the record memo are true and accurate copies of the labels collected during inspection of the firm); and
- 3) All evidence referenced in the affidavit/memo (e.g., copies of the product labels).

The Center will contact OCC to clear the final order. OSPOP/DE will notify the FDA Office of Media Affairs and keep them involved as necessary in the process. OSPOP/DE will keep a chronology of events, including documenting when any communication, such as the order, is sent to and received by the appropriate person.

The OSPOP/DE will identify an appropriate person to serve as a Presiding Officer (PO) if a hearing is requested. This person must not have been previously involved in decision-making for the matter and should be advised to maintain separation of functions from personnel who are working with the team. The OSPOP/DE will determine the availability of the PO and ensure the PO is in contact with OCC attorney(s) available to them.

The Center will identify a subject matter expert who has not previously worked on the matter to advise the PO/Center Director, or delegated authority senior to the Center Director, as needed with respect to the specific types of evidence that form the basis of FDA's case. This person must be available the day of anticipated issuance of the order of nondistribution and at least the next ten calendar days immediately after issuance of the order. This person should be advised to maintain separation of functions from personnel who are working with the team involved in the opportunity to consult meeting and possible issuance of the order.

Step 2: Providing an Opportunity to Consult

The ORA Program Division will reach out to the appropriate person at the firm to set up a meeting to discuss the agency's concerns, give an opportunity to consult and inform the firm of the Agency's intent to issue an order of nondistribution, which may lead to an ordered recall. All Center representatives, OCC, and the ORA DE Recalls Branch will also be invited to this meeting.

- A. The conversation with the appropriate person will provide the agency's reasoning for pursuing the order of nondistribution.
- B. The agency will recommend that the firm voluntarily cease distribution, and as appropriate voluntarily recall the product.
- C. If the firm agrees to stop distribution and recall, ORA will follow normal recall procedures.
- D. If the firm disagrees, FDA will raise the potential for issuance of the order of nondistribution and note that such order may lead to an ordered recall.
- E. The firm will be given 24 hours to respond to the recommendation to stop distribution or recall.

Step 3: Issuance of the Order of Nondistribution

- A. The Center will coordinate with all parties to finalize the draft order for review and clearance by OCC. All the following steps must be taken before OCC can clear the order of nondistribution:
 - 1) Lab test results on which the agency plans to rely must be final and accepted by FDA. If they are preliminary in some form, that must be clearly stated when the results are referenced in other documents (until they become final). Summaries and analytical worksheets need to be uploaded into CMS as soon as they are available.
 - 2) If FDA intends to rely on lab work done by a non-FDA lab as evidence in the matter, an appropriate person at FDA must review the documentation and sign a brief memo regarding the validity of the non-FDA lab's analysis. If FDA experts are not prepared to say that the non-FDA lab's work can be relied upon to show what it purports to show, FDA cannot use that evidence. FDA only needs one such memo. The Center and ORA will decide who is responsible for this analysis so there will be no duplication or conflict.
 - 3) Firm websites, if used as evidence in the matter, need to be captured by a recent screen shot and uploaded into CMS as PDFs.
 - 4) The HHE, expert memos, and memos and affidavits, including referenced evidence, addressing potential challenges to the case must be complete and uploaded into CMS.
 - 5) The order of nondistribution must clearly state and support (with attachments, including relevant factual evidence, such as lab test results when needed, and the HHE) the complete basis for FDA's conclusion that there is a reasonable probability that the controlled substance would cause serious adverse health consequences or death.

- B. After all recommended changes are captured and the above list of steps completed, the Center will forward the order of nondistribution final draft to OCC for final review and clearance. Once cleared, OCC will provide a copy of the cleared document to the Center who will then provide it to the Center Deputy Director, with a cc to the ORA Program Division and OSPOP/DE. Once signed, the Center will provide the signed order to the ORA Program Division. The ORA Program Division will send the order to the appropriate person by overnight delivery (with delivery confirmation). If transmitted in a manner other than overnight delivery, e.g., by electronic mail, request a delivery and read receipt. Additionally, a copy of the order will be sent using the most expeditious method that is available to the appropriate person (e.g., by electronic mail or facsimile). The ORA Program Division will email the order to the team and upload a copy into CMS. When possible, the ORA Program Division shall also contact the appropriate person to convey the information contained in the order orally.
- C. The order will advise the appropriate person that they have the opportunity for an informal hearing and will provide instructions on how to request a hearing. The hearing must be held not later than ten calendar days after the date of issuance of the order. To allow for the hearing to commence within 10 days of the issuance of an order of nondistribution, the order will inform the appropriate person that the request for the hearing must be made within three working days after the date of receipt of the order.
- D. The ORA Program Division will notify OSPOP/DE of the intended action so that a PO can be assigned in the event an informal hearing is requested and transcription services may be obtained.
- E. All communications with the appropriate person will be documented in CMS.
- F. The team may reconvene at any time to discuss further regulatory action needed to mitigate public health risks. If at any point the process appears to be slowing or stagnating, the team will escalate the issue to senior ORA/Center officials.

Step 4: Determination of Process for Order Resolution

- A. If the appropriate person does not request a hearing but ceases distribution and initiates a voluntary recall of the controlled substance within ten working days after the date of the issuance of the order, the ORA Program Division will immediately notify the team. The oversight, processing, and tracking of the recall action will follow the procedures for Class I recalls in the RPM, Chapter 7 – Recall Procedures. The recall will be documented in the Recall Enterprise System (RES). The Division Recall Coordinator (DCR) will select the recall type from the voluntary drop-down list, “FDA Ordered – 569D” on the “Edit Start Recall” screen. In the Public Reason for Recall, include the statement: “[FIRM] received an order of Notice, Nondistribution and Mandatory Recall of Controlled Substance, from FDA and is recalling [Product] because [Reason].”

- B. If the appropriate person requests a hearing, within three working days after the date of issuance of the order, OSPOP/DE will ensure a PO is selected, and a hearing will be held as described in Step 5.
- C. If the appropriate person does not request a hearing within three working days after the date of issuance of the order, the ORA Program Division will alert the Center that the deadline has passed and the Center Director, or delegated authority senior to the Center Director, will be advised to determine order resolution.

Step 5: Informal Hearing

- A. FDA will conduct the hearing consistent with section 201(x) of the Act and 21 CFR Part 16 (to the extent that Part 16 is not in conflict with section 569D of the Act).
- B. The PO and individuals who assist with the hearing have no later than ten calendar days following the order issuance to commence a hearing. The hearing need not finish on Day 10.
- C. The PO will write a hearing report. See Attachment K3 (Hearing Report). The PO should immediately begin work on the hearing report, using notes and recording of the hearing until the transcript is available. The hearing report should include the PO's recommendation to the Center Director, or delegated authority senior to the Center Director, as to whether to vacate the order of nondistribution, continue the order of nondistribution until a specified date, or amend the order of nondistribution to include a recall. The hearing report should include a copy of the appropriate draft order using the corresponding template found in Attachments K4 – K6. The final hearing report and transcript must be uploaded into CMS by the ORA Program Division.
- D. If the PO concludes, following the informal hearing, that adequate grounds do not exist to continue the actions required by the order, proceed to Step 6 (Vacate the Order of Nondistribution). If the PO concludes that removal of the controlled substance from commerce is necessary, proceed to Step 7 (Amend the Order of Nondistribution to Include Recall). If the PO concludes that continued nondistribution is necessary, but a recall is not necessary, proceed to Step 8 (Continue the Order of Nondistribution).

Step 6: Vacate the Order of Nondistribution

- A. Following the informal hearing:
 - 1) If the PO concludes that adequate grounds do not exist to continue the actions required by the order, the PO will make a recommendation to vacate the order and draft a vacated order within 24 hours of the informal hearing. See Attachment K4 (Vacated Order of Nondistribution).

- 2) The PO will send the proposed final vacated order and the administrative record of the hearing to the Center Director's office, or delegated authority senior to the Center Director, by electronic mail.
- 3) As soon as practicable thereafter, if the Center Director, or delegated authority senior to the Center Director, approves the vacated order, the Center Director, or delegated authority senior to the Center Director, signs the vacated order, or revises and signs the order as appropriate, and sends the signed order to the PO. The Center Director's, or delegated authority senior to the Center Director, decision should be made within 24 hours of receipt of the administrative record of the hearing from the PO.
- 4) The PO will draft a hearing report cover letter. See Attachment K2 (Hearing Report Cover Letter).
- 5) The PO will issue and send the vacated order with the hearing report cover letter and hearing report to the appropriate person by overnight delivery with delivery confirmation. A copy of the vacated order will be sent using the most expeditious method to the appropriate person, e.g., by electronic mail or facsimile. When possible, the PO will also contact the appropriate person to convey the information contained in the vacated order orally. Additionally, the PO will send the vacated order with the cover letter and the hearing report to the FDA hearing participants by electronic mail or facsimile. A copy of the vacated order will be uploaded into CMS by the ORA Program Division.

B. If an informal hearing is not requested:

- 1) In the event a hearing is not requested and the Center Director, or delegated authority senior to the Center Director, determines that the order should be vacated, the Center will draft, at the Center Director's, or delegated authority senior to the Center Director, direction, a vacated order, for Center Director, or delegated authority senior to the Center Director, signature. See Attachment K4 (Vacated Order of Nondistribution).
- 2) If the Center Director, or delegated authority senior to the Center Director, approves the vacated order, the Center Director, or delegated authority senior to the Center Director, will sign the vacated order, or revise and sign the order as appropriate, and the Center will send the signed order to the ORA Program Division.
- 3) The ORA Program Division will issue and send the vacated order with a cover letter to the appropriate person by overnight delivery with delivery confirmation. A copy of the vacated order will be sent using the most expeditious method to the appropriate person (e.g., by electronic mail or facsimile). When possible, the ORA Program Division will also contact the appropriate person to convey the information contained in the vacated order orally. A copy of the vacated order will be uploaded into CMS by the ORA Program Division.

Step 7: Amend the Order of Nondistribution to Include Recall

A. Following an informal hearing:

- 1) If the PO concludes that it is necessary to amend the actions of the order, and that the removal of the controlled substance that is the subject of the order from commerce is necessary, the PO will draft an amended order within 24 hours of the informal hearing that amends the order to require recall of such controlled substance, specifies a timetable in which the recall shall occur, requires periodic reports describing the progress of the recall, and requires notice be provided to consignees and consumers to whom such controlled substance was or may have been distributed. See Attachment K6 (Amended Order to Include Recall).
- 2) The PO will send the proposed final amended order, and the administrative record of the hearing to the Center Director, or delegated authority senior to the Center Director, by electronic mail.
- 3) As soon as practical thereafter, if the Center Director, or delegated authority senior to the Center Director, approves the amended order, the Center Director, or delegated authority senior to the Center Director, signs the order or revises and signs the order as appropriate and sends the signed order to the PO. The Center Director's, or delegated authority senior to the Center Director, decision should be made within 24 hours of receipt of the administrative record of the hearing from the PO.
- 4) The PO will draft a hearing report cover letter. See Attachment K2 (Hearing Report Cover Letter).
- 5) Following the Center Director's, or delegated authority senior to the Center Director, decision, the PO will immediately send the amended order, hearing report cover letter and the hearing report to the appropriate person by overnight delivery (with delivery confirmation). Additionally, a copy of the order will be sent using the most expeditious method to the appropriate person, e.g., by electronic mail or facsimile. When possible, the PO will also contact the appropriate person to convey the information contained in the order orally. Additionally, the PO will send the amended order, with the cover letter and hearing report to the FDA hearing participants by electronic mail and upload into CMS a copy of the amended order, cover letter, and hearing report. Proceed to Step 9 (Manage the Recall).

B. If an informal hearing is not requested:

- 1) If the Center Director, or delegated authority senior to the Center Director, concludes that it is necessary to amend the actions of the order, and that the removal of the controlled substance that is the subject of the order, from commerce is necessary, the Center will draft, at the Center Director's, or

delegated authority senior to the Center Director, direction, an amended order that amends the order to require recall of such controlled substance, specifies a timetable in which the recall shall occur, requires periodic reports describing the progress of the recall, and requires notice be provided to consignees and consumers to whom such controlled substance was or may have been distributed. See Attachment K6 (Amended Order to Include Recall).

- 2) If the Center Director, or delegated authority senior to the Center Director, approves the amended order ordering the recall, the Center Director, or delegated authority senior to the Center Director, will sign the amended order, or revise and sign the order as appropriate, and the Center will send the signed order to the ORA Program Division .
- 3) ORA Program Division will issue and send the amended order requiring the recall, with a cover letter to the appropriate person by overnight delivery (with delivery confirmation). A copy of the amended order will be sent using the most expeditious method to the appropriate person (e.g., by electronic mail or facsimile). When possible, the ORA Program Division will also contact the appropriate person to convey the information contained in the amended order orally and upload a copy of the amended order into CMS. Proceed to Step 9 (Manage the Recall).

Step 8: Continue the Order of Nondistribution

A. Following the informal hearing:

- 1) If the PO concludes that the continued nondistribution is necessary, but a recall is not necessary, the PO will make a recommendation within 24 hours of the informal hearing to continue the order of nondistribution until a specified date. See Attachment K5 (Continued Order of Nondistribution).
- 2) The PO will send the proposed final continued order and the administrative record of the hearing to the Center Director office, or delegated authority senior to the Center Director, by electronic mail.
- 3) As soon as practicable thereafter, if the Center Director, or delegated authority senior to the Center Director, approves the continued order, the Center Director, or delegated authority senior to the Center Director, signs the continued order or revises and signs the continued order, and sends the signed continued order to the PO. The Center Director's, or delegated authority senior to the Center Director, decision should be made within 24 hours of receipt of the administrative record of the hearing from the PO.
- 4) The PO will draft a hearing report cover letter. See Attachment K2 (Hearing Report Cover Letter).
- 5) The PO will issue and send the continued order with the hearing report cover letter and hearing report to the appropriate person by overnight delivery (with

delivery confirmation). A copy of the continued order will be sent using the most expeditious method to the appropriate person, e.g., by electronic mail or facsimile. When possible, the PO will also contact the appropriate person to convey the information contained in the continued order orally. Additionally, the PO will send the continued order with the cover letter and the hearing report to the FDA hearing participants by electronic mail or facsimile. A copy of the continued order will be uploaded into CMS by the ORA Program Division.

B. If an informal hearing is not requested:

- 1) In the event a hearing is not requested and the Center Director, or delegated authority senior to the Center Director, determines that the order should be continued, the Center will draft, at the Center Director's, or delegated authority senior to the Center Director, direction, a continued order for Center Director, or delegated authority senior to the Center Director, signature. See Attachment K5 (Continued Order of Nondistribution).
- 2) If the Center Director, or delegated authority senior to the Center Director, approves the continued order, the Center Director, or delegated authority senior to the Center Director, will sign the continued order, or revise and sign the continued order as appropriate, and the Center will send the signed continued order to the ORA Program Division.
- 3) The ORA Program Division will issue the continued order to the appropriate person by overnight delivery (with delivery confirmation). A copy of the continued order will be sent using the most expeditious method to the appropriate person (e.g., by electronic mail or facsimile). When possible, the ORA Program Division will also contact the appropriate person to convey the information contained in the continued order orally. The ORA Program Division will upload a copy of the continued order into CMS.

Step 9: Manage the Recall

The oversight, processing, and tracking of the recall action will follow the procedures for recalls in the RPM, Chapter 7 – Recall Procedures.

Attachment K1- Order of Nondistribution

[Date]

[Appropriate Person Name]

[Firm Name]

[Street]

[City, State Zip]

Dear [Name]:

Pursuant to section 569D of the Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 3012 of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act, FDA has determined that there is a reasonable probability that [controlled substance(s) and identifying product information] could cause serious adverse health consequences or death of [humans and/or animals]. The Agency provided you the opportunity to consult on [date,] during which, FDA discussed our concerns and recommended that you cease distribution and voluntarily recall the product. At present, you have not [responded to or taken all the actions specified in] FDA's recommendation. Accordingly, FDA is now ordering you to immediately cease distribution of [controlled substance(s)], and to immediately notify all manufacturers, importers, distributors, or pharmacists, who distribute such controlled substance to immediately cease distribution of such [controlled substance(s)].

You have the right to request that an informal hearing be held, at which you would have the opportunity to address the actions required by this order. If you would like to request an informal hearing, please send a written request to [ORA Program Division Director Name, Address, Telephone Number and Electronic mail Address]. Please submit [describe information to be submitted in the request]. If you request a hearing, you must follow-up your written request with a phone call to [ORA Program Division Director Name] to confirm receipt of the hearing request. If you do not request a hearing in writing within three working days after the date of issuance of this order, you will waive your right to a hearing. Enclosed are the regulations covering FDA's informal hearing procedures in 21 CFR Part 16. Please also refer to 21 CFR Part 10, subpart C for information describing FDA's policies and procedures applicable to electronic media coverage of agency public administrative hearings.

If you do not submit a timely written request for a hearing this order may be amended to continue this order until a date specified or require you to recall [controlled substance(s)], including any requirements to notify appropriate persons of the recall, a timetable for the recall to occur, and a schedule for updates to be provided to FDA regarding such recall.

Sincerely,

[Center Deputy Director]

Attachment K2 – Hearing Report Cover Letter

[Date]

[Hearing Party's Name]

[Street]

[City, State Zip]

Dear [Name]:

On [date], an informal hearing related to [controlled substance(s) and identifying product information] was held on [the actions required by the order of nondistribution, and on whether the controlled substance(s) that is the subject of the order should not be recalled]. Enclosed, please find the [vacated or amended] order that resulted from that hearing, along with a copy of the hearing report.

Sincerely,

[Presiding Officer]

Attachment K3 – Hearing Report

On [date], I served as the Presiding Officer in an informal hearing related to [controlled substance(s) and identifying product information] that was attended by [names of parties and titles in relation to the appropriate person or FDA]. The hearing was held [on the actions required by the order of nondistribution].

Prior to the hearing, on [date], FDA provided to [the appropriate person name] the opportunity to consult. [Appropriate person name] did not [cease distribution and/or recall the controlled substance(s)]. Subsequently, on [date] FDA sent [by registered mail, facsimile, and/or electronic mail] [appropriate person name] an order of nondistribution.

At the hearing, I considered the actions required by the order of nondistribution and the evidence and testimony presented at the hearing. I was provided with [list of documents and summary of any pertinent information].

[Option: If credibility is at issue, include a finding on the credibility of witnesses (other than expert witnesses) and explain why the finding was made.]

Based on this information, I recommend the following [choose from options below]

[Option 1: Adequate grounds do not exist to continue the actions required by the order and therefore I recommend vacating the order.] Specifically, [list reasons to justify this recommendation.]

[Option 2: The order of nondistribution of [controlled substance(s)] from commerce is necessary, but the removal of the [controlled substance(s)] from commerce is not necessary. Specifically, [list reasons to justify this recommendation.] I recommend the order of nondistribution be amended to continue until [date].

[Option 3: The order of nondistribution should be amended to require recall of the [controlled substance(s)] (removal of the controlled substance from commerce) [because]. Specifically, [list reasons to justify this recommendation.] The order should be amended to, [as appropriate (1) require [appropriate person name] to recall [controlled substance and identifying information]; (2) [specify a timetable in which the recall shall occur]; (3) require [periodic reports] describing the progress of the recall; and (4) require that notice be provided to consignees and consumers to whom such article was or may have been distributed.]

[Presiding Officer]

Attachment K4 – Vacated Order of Nondistribution

[Date]

[Appropriate Person Name]

[Firm Name]

[Street]

[City, State Zip]

Dear [Name]:

On [date] you were ordered to cease distribution of [controlled substance(s)] and to immediately notify manufacturers, importers, distributors, or pharmacists who distribute such controlled substances, to immediately cease distribution of [controlled substance(s)]. [Furthermore, the [date] order was [amended] on [date] to [describe requirements of the amended order]].

At this time, adequate grounds do not exist to continue the actions required by the [date] order. [Insert any additional information regarding the decision to vacate the order, as desired]. Accordingly, the [date] order is hereby vacated.

Sincerely,

[Center Director (or delegated authority senior to the Center Director)]

Attachment K5 – Continued order of Nondistribution

[Date]

[Appropriate Person Name]

[Firm Name]

[Street]

[City, State Zip]

Dear [Name]:

On [date], FDA notified you that there is a reasonable probability that [controlled substance(s) and identifying product information] could cause serious adverse health consequences or death of [humans and/or animals] and you were ordered to immediately cease distribution of [controlled substance(s)] and to immediately notify manufacturers, importers, distributors, or pharmacists who distribute such controlled substance, to immediately cease distribution of [controlled substance(s)].

[Based on the hearing held on date, if one was held] continued nondistribution of [controlled substance(s)] is necessary. Therefore, the [date] order is hereby amended, and you are ordered to immediately notify manufacturers, importers, distributors, or pharmacists who distribute such controlled substance, to cease distribution of [controlled substance(s)] until [date].

Please note that if you do not comply with this order, FDA may pursue other actions, as appropriate. This order is effective immediately. If you have questions regarding this order, you may contact [ORA Program Division Director Name, Telephone Number and Electronic mail Address].

Sincerely,

[Center Director (or delegated authority senior to the Center Director)]

Attachment K6 – Amended Order to Include Recall

[Date]

[Appropriate Person Name]

[Firm Name]

[Street]

[City, State Zip]

Dear [Name]:

On [date], FDA notified you that there is a reasonable probability that [controlled substance(s) and identifying product information] could cause serious adverse health consequences or death of [humans and/or animals] and you were ordered to immediately cease distribution of [controlled substance(s)] and to immediately notify manufacturers, importers, distributors, or pharmacists who distribute such controlled substance, to immediately cease distribution of [controlled substance(s)].

At this time, the removal of [controlled substance(s)] from commerce is necessary. Therefore, the [date] order is hereby amended, and you are ordered to [as applicable, recall [controlled substance(s) and scope] or take other appropriate action [within timetable]; provide [periodic] reports to [designee] describing the progress of the recall; and immediately notify consignees and consumers to whom such article was, or may have been, distributed.]

Please note that if you do not comply with this order, FDA may pursue other actions, as appropriate. This order is effective immediately. If you have questions regarding this order, you may contact [ORA Program Division Director Name, Telephone Number and Electronic mail Address].

Sincerely,

[Center Director (or delegated authority senior to the Center Director)]

Exhibit 7-1 Model Effectiveness Check Letter (Industry)

Consignee
Name and Address

Date

(Pressure Sensitive Label)

Dear Sir:

On (date), you were notified by letter that John Doe Company, Someplace, Somewhere 12345, is recalling (product name), container size, code number. All products were manufactured by John Doe Company and distributed solely under the manufacturer's label.

Recall of the product was initiated following a change in their formulation which resulted in products in distribution channels having the same brand name but different ingredients. The old formulation contained X and there is concern that consumers may receive the old formula. Use of the old formulation by some consumers represents a potential health hazard.

The recall notice from John Doe Company requested consignees (wholesalers and retailers) to discontinue selling their existing stock of the old formulations and return existing inventories of the recalled formulations to John Doe Company.

In order to advise the Food and Drug Administration about the effectiveness of this John Doe Company recall, you are requested to complete and return the enclosed questionnaire promptly using the prepaid self-addressed envelope.

If you have any questions or problems with this request, please call (name and telephone number).

Thank you for your cooperation.

Sincerely,

NOTE: If this letter is sent to distributors who may have further sold the product to other distributors or to retail outlets, the third paragraph should include the fact that the recall notice requested the direct consignees to conduct sub-recalls by notifying their customers of the recall situation.

Exhibit 7-2 Model Effectiveness Check Response Format (Industry)

Consignee Name and Address

(Pressure Sensitive Label)

Recall Effectiveness
Checks-Mail Method

JOHN DOE PRODUCT RECALL

PLEASE READ EACH QUESTION AND CHECK THE PROPER ANSWER YOU HAVE CHOSEN. PLEASE CHECK WITH ANYONE WHO MAY HAVE RECEIVED THIS NOTIFICATION BEFORE ANSWERING.

DATE _____

1. Did your firm receive notification that the John Doe Company is recalling its (Name) _____ product?

YES__ NO__

2. Did your firm receive shipments of the product being recalled? (If no, please sign and return).

YES__ NO__

3. Do you now have any of the recalled product on hand? (Please check inventories before answering).

YES__ NO__

4. If the answer to question 3 is YES, do you intend to return the product to the John Doe Company as requested?

YES__ NO__

5. If the answer to question 4 is NO, please explain your intentions

6. Have you received any reports of illness or injury related to this product?

YES ___ NO ___

If yes, please provide details.

Name of person completing questionnaire:

Exhibit 7-3 Model Effectiveness Check Questionnaire for Telephone or Personal Visits (Industry)

Consignee Name and Address

(Pressure Sensitive Label)

JOHN DOE PRODUCT RECALL

After contacting the consignee and locating the person responsible for handling recall notifications and/or the product involved, an opening similar to the following may be used.

This is (Name of Interviewer). I am calling for (recalling firm) to check on the effectiveness of the company recall of (product description, including codes). On (date), (recalling firm) notified (how: letter, telephone, visit, mailgram, etc.), all firms which may have purchased (product) that all stock should be (returned, destroyed, modified, relabeled, etc.). I have the following questions to ask you about this recall:

DATE _____

1. Did your firm receive notification that (product name) products manufactured by John Doe Company are being recalled?

YES__ NO__

2. Did your firm receive shipments of the product being recalled?
(If no, terminate questioning and go to the closing).

YES__ NO__

3. Do you have any of the recalled product on hand?
(Please check inventories before answering).

YES__ NO__

4. If the answer to question 3 is YES, do you intend to return the product to the John Doe Company as requested?

YES__ NO__

5. If the answer to question 4 is NO, please explain your intentions.

6. Have you received any reports of illness or injury related to this product?

YES___ NO___

If yes, please provide details.

Thank you for your cooperation.

And your name is _____

And what is your title please? _____

Interviewer _____

Date _____

IF RESPONDENT HAS ANY FURTHER QUESTIONS, ASK HIM/HER TO CONTACT THE JOHN DOE COMPANY, SOMEPLACE, SOMEWHERE 12345

Exhibit 7-4 Model Recall Letter (Generic, All Centers)

Company Letterhead

Date (Month, Day, Year)

URGENT

[Insert FOOD, DRUG, MEDICAL DEVICE, BIOLOGIC, COSMETIC, TOBACCO]

RECALL

[]

Contact Name or Department

Firm Name

Street Address

City, State, Zip Code

Dear [Insert Customer/Distributor/Manufacturer, etc.], This is to inform you of a product recall involving

[Insert: **PRODUCT NAME, BRAND NAME, DESCRIPTIONS, UPC CODES, LOT NUMBERS AND ETC.**]

See enclosed product label [for ease in identifying the product at retail/user level].

This recall has been identified due to [problem]. Use of [or consumption of] this product may [include any potential health hazard].

We began shipping this product on [date]. Use of [or consumption of] this product may [include any potential health hazard].

Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter, or [Enclosed is a letter you should use in notifying your customers].

[Your notification must include instructions on what customers should do with the recalled product.]

This recall should be carried out to the [wholesale], [retail], [consumer], [user] level.

Your assistance is appreciated and necessary to prevent [i.e. consumer illness or patient harm].

Please complete and return the enclosed response form as soon as possible. If you have any questions, call [name and telephone number].

This recall is being made with the knowledge of the Food and Drug Administration.

Enclosures:

Name: (Print)

Signature:

Title:

Exhibit 7-5 Model Recall Return Response Form

[COMPANY LETTER HEAD]

Insert [Product] Insert [Lot numbers]

Please check ALL appropriate boxes.

 I have read and understand the recall instructions provided in the [date of] letter. I have checked my stock and have quarantined inventory consisting of [] units or cases. Indicate disposition of recalled product:

- returned (specify quantity, date and method)/held for return;
- destroyed (specify quantity, date and method);
- relabeled (specify quantity and date);
- quarantined pending correction (**specify quantity**);
- transfused - Blood or blood products (**specify quantity and date**);
- implanted (specify quantity and date)

Attached is a list of customers who received/ may have received this product. Please notify my customers.

Any adverse events associated with recalled/failed product? Yes No

If yes, please explain: _____

I have checked my stock and have performed the appropriate method of disposition to the inventory consisting of _____ [units, cases, etc.].

Please check the appropriate box(es) to describe the nature of your business:

- | | |
|---|--|
| <input type="checkbox"/> Wholesaler/distributor | <input type="checkbox"/> Food service/restaurant |
| <input type="checkbox"/> Grocery corporate headquarters | <input type="checkbox"/> Manufacturer |
| <input type="checkbox"/> Repacker | <input type="checkbox"/> Hospital/Medical facility |
| <input type="checkbox"/> Pharmacy-retail | <input type="checkbox"/> Medical laboratory |
| <input type="checkbox"/> Hospital pharmacies | |
| <input type="checkbox"/> Retailer | |
| <input type="checkbox"/> Other: _____ | |

Name/Title	
Telephone	
Email address	

Firm Name	
Address	
City/State	

PLEASE FAX COMPLETED RESPONSE FORM TO Tel. # [INSERT TELEPHONE NUMBER], ATTN: [INSERT NAME] OR MAIL TO: [INSERT FIRM NAME AND ADDRESS]

NOTE: This MODEL is intended to serve as guidance for recalling firms. It may not conform to your firm's recall strategy. Please make any appropriate modifications to the response form. IT IS ADVISABLE TO SUBMIT THE PROPOSED RECALL LETTER AND RESPONSE FORM TO YOUR LOCAL FDA RECALL COORDINATOR FOR REVIEW, PRIOR TO ISSUANCE.

Exhibit 7-6 Model Recall Envelope

FIRST CLASS MAIL

JOHN DOE
Somewhere, U.S.A. 12345

A. B. C. Pharmacy
Anywhere, U. S. A.

(red print) **URGENT: DRUG RECALL**

Exhibit 7-7 Model FDA Requested Recall Letter**FDA REQUESTED RECALL**

Responsible Official
Company
Address

Dear Responsible Official,

The U.S. Food and Drug Administration (FDA) requests that, in the interest of public health, you immediately initiate a recall of all [Product Name and Codes]. This request is based on [Evidence supporting violation].

[Products] that are produced at [Firm] are [adulterated/misbranded] within the meaning of section [Act/Regulation violation(s)].

During [inspection/sample] of your [facility/product] FDA investigators observed the following:

- [Inspectional Observations and support OR Sample Findings]

[If the firm has provided correspondence regarding the violation/observations/sample findings include acknowledgement of receipt and assessment of the firm's correspondence]

FDA has determined that due to [violation], these product(s) present a risk of illness or injury to consumers. To date, your firm has failed to initiate a recall of [products and codes]. FDA action is necessary to protect the public health and welfare.

FDA will classify this FDA Requested action as a [recall classification] recall. A [recall classification] recall is a situation in which [For Class I use: "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death" For Class II use: "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"]. FDA recommends [Effectiveness Check Level and percent] effectiveness checks be performed to the [depth: user/retail] level.

FDA's recall policy and guidance is found in Title 21 Code of Federal Regulations (CFR), Part 7. [FDA Division Office] will provide guidance in implementing and assuring the effectiveness of your recall, including reviewing the proposed recall communication to your consignees. We are requesting that you work closely with the division and that you provide all necessary information regarding the recall in a timely manner. Title 21

CFR, Part 7 provides for, among other things, publishing your recall in an upcoming issue of the weekly FDA Enforcement Report.

Please respond to this letter within two working days of receipt. Your response to this letter should be directed to:

[Division Director Name and Address]

Due to the seriousness of this situation, FDA will issue a press release [date the PR will issue], advising consumers of the FDA Requested Recall letter and again warning consumers and retailers to discontinue use or sale of these products and of the health risk associated with the use of these products.

Failure to comply with this request may result in further regulatory action against you, your firm, and the adulterated products distributed by your firm.

Sincerely,

[ACRA Name]
Associate Commissioner for Regulatory Affairs

Exhibit 7-8 Model Acknowledgement (FDA to Recalling firm)

This is to acknowledge your initial report of a removal or correction. The Food and Drug Administration (FDA) will review information submitted by your firm and determine whether your action meets the definition of a recall (21 CFR 7.3(g)).

Add product information especially in instances where firm has more than one recall.

Your action has been assigned event number _____. Refer to this event number when corresponding with FDA.

Your contact within FDA for this event is [insert division contact info].

If your action meets the definition of a recall (21 CFR 7.3(g)), it will be listed in the FDA Enforcement Report. Note that for some recalls, FDA may first determine the action meets the definition of a recall and then classify (21 CFR 7.3(m)) the recall later and update the Enforcement Report with the classification. You will be notified in writing of FDA's recall determination and classification.

FDA requests the following:

- Work with your FDA contact (above) to develop your recall strategy and to submit documentation of your recall.
- Monitor the progress of your recall, including conducting effectiveness checks. The purpose of effectiveness checks 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.
- Submit periodic recall status reports (21 CFR 7.53) to your FDA recall contact above. Your firm's first status report is expected to be submitted within a month, and at monthly intervals thereafter unless otherwise requested by your FDA contact. The recall status reports should contain the following information:
 1. Number of consignees notified of the recall, and date and method of notification.
 2. Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.
 3. Number of consignees that did not respond (if needed, the identity of nonresponding consignees may be requested by the Food and Drug Administration).

4. Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.
 5. Number and results of effectiveness checks that were made.
 6. Estimated time frames for completion of the recall.
- For those recalls where recalled product is being returned to you or to a third party:
 - Assure all returned product is promptly inventoried, handled, and stored in such a manner as to assure its separation from acceptable materials so it will not be inadvertently be used or shipped.
 - Prior to destroying or reconditioning returned product, notify your FDA recall contact (above). FDA may want to witness the products destruction or review proposed reconditioning.
 - Submit a written request for recall termination to your FDA recall contact (above) once all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. FDA will notify you in writing when we concur with your termination request.

Note that failure to conduct an effective recall could result in seizure of the violative product or other legal sanctions under the Federal Food, Drug, and Cosmetic Act (or other acts as appropriate).

FDA will remain in contact with your firm until this matter is resolved.

Exhibit 7-9 Model Notification of Classification Letter (FDA to Recalling Firm)

Mr. John Doe,
President J. D. Laboratories, Inc.
Somewhere, U. S. A.

Re: Recall No. D-000-9

Dear Mr. Doe:

We agree with your firm's decision to recall (Product), Code Nos. _____ due to (Reason for Recall).

We have reviewed your action and conclude that it meets the formal definition of a "Recall." This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove your defective product from the market. This recall will be reported in an upcoming issue of the weekly FDA Enforcement Report.

It is suggested that you follow the FDA's "Enforcement Policy-Recalls (including Product Corrections) -- Guidelines on Policy, Procedures and Industry Responsibilities" in conducting your recall. Enclosed is a copy of this Enforcement Policy as well as a copy of the FDA's "Methods for Conducting Recall Effectiveness Checks."

This recall has been classified by the FDA as a Class _____ recall. This means (Insert Definition).

Our judgment regarding the effectiveness of your recall will largely be based upon your implementation of the enclosed recall guidelines. Please be advised that failure to conduct an effective recall could result in seizure of the violative product or other legal sanctions under the Federal Food, Drug, and Cosmetic Act (or other acts as appropriate).

Your cooperation in this matter is important for the protection of the general public.

Sincerely yours,

Program Division Director

_____Program

Enclosures

Exhibit 7-10 Model Recall Ineffective Recall Letter

Mr. John Doe, President
J. D. Laboratories, Inc.
Somewhere, U.S.A.

Dear Mr. Doe:

This confirms our telephone conversation/visit with you that our audit of your firm's class _____ recall of (Product) indicates that the recall is ineffective at the (Distributor, Wholesale, Retail, etc.) level. This determination is based on the fact that: (detail all audit findings, for example):

1. Review of your submitted recall status reports found that (number and type of consignees) have not responded to your recall communication.
2. Review of documentation at your firm found that sub-recall was not initiated by (number) wholesale distributors.
3. Audit checks conducted by FDA found that [explain].

It is therefore reasonable to assume that the defective product could still be in the hands of these consignees.

It is requested that you advise us in (*) days of the steps you plan to take to rectify this situation.

- (*) Two days for class I
Five days for class II
Ten days for class III

Sincerely,

Program Division Director

_____Program

Exhibit 7-11 Model Recall Termination Letter

Mr. John Doe, President
J. D. Laboratories, Inc.
Somewhere, U.S.A.

Dear Mr. Doe:

The Food and Drug Administration has completed the audit of your firm's actions concerning the recall of (Product), (Code Number) (s), (Recall No.)(s). We conclude that the recall has been completed and there has been proper disposition of the recalled articles. Therefore, FDA considers the recall terminated.

This letter is not intended to imply that the FDA will not recommend civil or criminal legal action related to this matter. It does not relieve you or your firm from the responsibility of taking all necessary steps to assure compliance with the Federal Food, Drug, and Cosmetic Act (or other acts as appropriate) in the future.

Sincerely,

Program Division Director

_____ Program

Exhibit 7-12 Model Combined Recall Notification of Classification and Termination Letter

Re: Recall No. Z-000-5

Mr. John Doe
President
John Doe Enterprises, Inc.
4321 Enterprise Lane
Johnsontown, New York 12345-6789

Dear Mr. Doe:

This is to advise you that the Food and Drug Administration (FDA) agrees with your decision to (retrieve from the market to the retail, user, hospital, consumer, etc. level, or conduct a field correction of) (product), lot/code numbers due to (reason for action taken).

We have reviewed your action and conclude that it meets the FDA definition of a Class (I, II, or III) recall. This is a situation in which (quote appropriate classification definition from section 7.3(m) of Title 21 CFR). This recall has been posted on the FDA's recall web site. (When appropriate, a statement on the Center's suggested effectiveness check level and the firm's satisfactory completion of same may be added at this point.)

Information provided to FDA indicates that (the recall has been completed and there has been proper disposition of the recalled product, or your corrective action has been completed). Therefore, FDA considers the recall terminated.

This letter is not intended to imply that the FDA will not recommend civil or criminal legal action related to this matter. It does not relieve you or your firm from the responsibility of taking all necessary steps to assure compliance with the Federal Food, Drug, and Cosmetic Act (or other acts as appropriate) in the future.

Sincerely,

Program Division Director

_____ Program

-Press Release

Exhibit 7-13 Model Recall Audit Check Memo Assignment

Date [Insert Date of Assignment]

From [Name, Title, and Division of Monitoring Division Recall Coordinator]

Subject Request to Conduct Audit Checks, Probable [Class I/II]

To Attention: Recall Coordinator: List Divisions Receiving Assignment

RES Event: [RES Event ID]

PAC: [PAC code for recall audit check]

Recalling Firm: [Recalling Firm name, address, and FEI]

1. Product/Codes(s): [List the names and coding for the recalled products]
2. Reason for Recall: [Include a short reason for recall]
3. Firm's Recall Strategy: [Detail the firm's recall strategy and include the recall notification instructions]
4. Audit Checks: [Discuss the FDA audit check strategy, including how many you are requesting, the type of audit checks, depth to which audit checks should be conducted, and any additional instructions. For example: "Please audit each of the attached consignees by visit. If the product was further distributed, please conduct checks at three subaccounts by visit or phone to the consumer level. Please return all 3177s electronically to (monitoring division email address). This audit check assignment is due on (10 days from issuance)."]
5. Attachments:
 - RES Event
 - Recall Notification Letter
 - Labeling
 - Distribution List

Exhibit 7-14 Initiating RAC by Mail or Email

The following script may be included in the RAC assignment memo when requesting divisions to initiate recall audit checks by mail or e-mail. The audit check itself should be done on the phone, but the mail/e-mail is to initiate contact between the consumer and FDA in a way that best protects the consumer's privacy.

Only complete FDA-3177s for the mail/e-mails which result in an audit check, not those that were sent and never responded to.

Dear Consumer,

We are writing to inform you of a voluntary recall of FDA-regulated products initiated in [Month, Year of recall initiation]. The firm may have sent you a recall notice via e-mail on or around [recall initiation date] and you may be affected by this recall.

The products are being recalled because they may be misbranded, adulterated, or contain unapproved new drug claims which have not been approved by the U.S. Food and Drug Administration.

We hope to verify your awareness of the product recall and to ensure no adverse experiences have occurred.

It is important you contact us at the [Name of Division performing the RAC] of the U.S. Food and Drug Administration.

Please call me back at my contact information.

Your full name

Title and Division Name

Contact Information

If you would like to verify this email is from the FDA and our contact information, please go to the FDA.gov website at this link <https://www.fda.gov/AboutFDA/ContactFDA/default.htm>, Find an FDA Staff Member (Search the HHS employee directory), click on the last name, call the number and ask to speak with the person listed above.

Exhibit 7-15 Weekly Class I Recall Status Report (Optional)

Divisions monitoring certain Class I certain recalls may be requested to submit a weekly status report by either the CRU or OSPOP /DE/ROB. (Weekly status reports may also be required for certain Class II recalls per the audit strategy.) When reports are requested, they should be prepared and submitted by close-of- business each Friday.

Data to be submitted may vary depending upon individual recall circumstances, but should usually contain the following points:

Subject: Status Report, Class I (or II), Recall No. _____

Product: Recalling Firm:

I. Summary of Firm's Activities

1. Number and type of consignees notified, date and method of notification.
2. Number of consignees responding to the recall communication.
3. Number of consignees not responding.
4. Number and results of effectiveness checks made.
5. Significant problems firm is experiencing in the recall.
6. Any additional steps the firm is taking to complete the recall.

II. Summary of FDA's Audit Activities

1. Date and No. of audit checks assigned.
2. Number of audit checks completed.
3. Number of audit checks finding the recall effective.
 - a. Direct Accounts
 - b. Sub-accounts
4. Number of audit checks finding the recall ineffective.
 - a. Direct Accounts
 - b. Sub-accounts
5. Significant problems encountered during the checks.

Provide any additional information pertinent to Center and OSPOP /DE/ROB evaluation of the recall's progress or effectiveness.

Appendix A FDA Food Recall/Action Initiation Process Flow/Timeline for Class I Human Food Recalls (SAHCODH)

