U.S. FOOD & DRUG ADMINISTRATION

Regulatory Procedures Manual

Chapter 7 – Recall Procedures

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This chapter contains the following sections:

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 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, OEIO/DE, 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

[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."

7-3-1 Responsibilities of the Office of Enforcement and Import Operations/Division of Enforcement

OEIO/DE responsibilities are detailed in SMG 1121.81. OEIO 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 CRU or OEIO 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 OEIO 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. 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 program:

- 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 program, as soon as possible, but preferably within 24 hours, after learning of a recall either planned or in progress, should notify the appropriate CRU and OEIO/DE Recall Operations Staff. The program 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. Additionally, the program will scan and e-mail or fax to the CRU a copy of the recalling firm’s recall communication and press release, if any. A copy of the press release is also to be forwarded to OEIO/DE, to the Liaison for ORA’s Office of Communications and Project Management/Division of Communications (OCPM/DC), and to the liaison for the Office of External Affairs/Office of Media Affairs. 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.

   OEIO/DE will promptly notify the ACRA of significant recall actions and will provide copies of recall documents where appropriate.

2. Recall Recommendation and Related Information

The program must submit a complete Recall Recommendation (RR) through RES within five working days after submitting the recall alert or as soon as 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 OEIO/DE via e-mail. See Attachment B for guidance on the information required by the CRU to review and classify the recall. The program may submit the Recall Alert and Recommendation up to 10 working days after the program learns of a "completed" recall.

A. In conjunction with the recall recommendation, the program will submit to the appropriate CRU, as soon as possible:

1. legible copies of all labeling, including operations manuals, brochures, flyers, or any other product related literature that will aid in determining the violation and evaluation of the product problem;

2. product specifications, formulation and related documents;

3. FDA and/or state laboratory worksheets and/or the firm's pertinent quality control or analytical records for all products involved;

4. if the program does not have a physical sample to demonstrate the defect and the potential hazard, other documentation of the justification for recall, such as a copy of the FDA-483 documenting serious violations of GMPs, or epidemiological evidence; and,

5. if not previously submitted at time of the Alert, a copy of all of the recalling firm's communications to the CRU. For potential Class I recalls, also forward a copy to OEIO/DE.

This material should closely follow the submission of the RR and should be submitted by the fastest means possible, for example, by scan delivered via e-mail, by fax, or by guaranteed overnight delivery.

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

B. Notes:

1. When requested by OEIO/DE 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. The program 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 regulated products manufactured by U.S. firms for foreign distribution and which are in violation of United States laws will be processed, classified, and published the same manner as domestic recalls.

3. FDA regulated products manufactured by foreign firms recalled in the U.S. will be processed, classified and published (including entered in RES) the same as products manufactured in the U.S. If the U.S. Agent initiates the recall on behalf of the foreign firm, the U.S. Agent gets copies of the FDA correspondence on the recall. However, if the US agent refuses (or, otherwise fails) to initiate the recall and the foreign firm performs the notification to its first line distributors, then the foreign firm is the recalling firm and receives the classification and termination letters from the ACRA, center or program.

4. If the CRU or OEIO/DE finds the RR information lacking in any way, either may request that the program obtain the additional information. This may be done by telephone, email, or the electronic return of the recall record with comment.

3. **Establishment Inspection**

The program 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 If appropriate corrective action is not being implemented, and evaluate overall compliance. See the IOM Chapter 7 – Recall Activities for information on conducting recall related inspections.

The establishment inspection should, in addition to other activities:

A. Obtain the recalling firm's proposed recall strategy [21 CFR 7.46(a)], if not previously submitted by the firm.

B. Collect copies of all labeling associated with the product.

C. Obtain complete distribution of all shipments of the suspect lot(s), including complete names and addresses of all foreign consignees.

D. Obtain supporting documentation that will assist the agency in identifying and evaluating the problem such as product complaints, product specifications and test results, including the methods used to obtain the results.

E. For medical device recalls, obtain marketing status of the device being recalled, that is, 510(k) or PMA number(s), or preamendment device with proof of status.

F. Assess the root causes of the problem. Determine how and when the problem occurred and how and when it was discovered. Obtain the firm's corrective action to prevent future occurrences.

G. Verbally apprise management that the program office should be consulted prior to the reconditioning or destruction of any returned product. Management should also be advised that FDA must witness or otherwise verify product disposition. Prior to initiating an establishment inspection, program personnel should determine whether similar complaints have been entered into the Field Accomplishments and Compliance Tracking System (FACTS). For devices, search CDRH's MAUDE database or contact CDRH's Office of Surveillance and Biometrics, Information Analysis Branch to retrieve complaints. For drugs, contact CDER's Office of Medication Error Prevention and Risk Management in the Office of Surveillance and Epidemiology, regarding complaints reported in the Drug Product Defect Reporting system. Center offices managing other reporting systems may be contacted where applicable to a particular problem.

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 unit will contact the unit where the violation occurred and request an inspection of the responsible establishment. The investigating unit, in turn, should keep the monitoring unit 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 program office should not urge the firm to expand or reduce its recall efforts. In all discussions of violative or potentially violative products with the responsible firm, avoid any misunderstanding that FDA is formally requesting recall action. FDA requested recalls may be authorized only by the ACRA or by center directors delegated that authority.

If the recall has been completed before FDA's knowledge of it, program 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 program 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 program should notify the CRU and OEIO/DE. The program 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 program 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 program management prerogative unless required by specific headquarters' initiated assignments, or the occasional direct request from the CRU or OEIO/DE. Samples collected should document interstate movement as well as the violation.

5. Firm Recall Communication and Notification

The FDA Program Office Recall Coordinator 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 OEIO/DE staff are available, if necessary, to assist the Program Office Recall Coordinator. 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 Program Office Recall Coordinator before issuance. The possible need for bilingual or multilingual communications should be explored between the FDA Program Office Recall Coordinator 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, 7- 7, FDA Recall Industry Guidance webpage for model letters, envelopes, and recall return response forms.)

7-5-2 FDA Requested Recall

This section only applies to FDA requested recalls in accordance with 21 CFR 7.45. An FDA request that a firm recall a product is ordinarily reserved for urgent situations. The request is directed to the firm that has primary responsibility for the manufacture or marketing of the product when the responsible 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 recall action, the agency will have evidence capable of supporting legal action, i.e., seizure. Exceptions include situations where there exists a real or potential danger to health, or in emergency circumstances such as outbreak of disease involving epidemiological findings. 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. except that in some cases certain center officials are also authorized to approve FDA requested recalls (see *SMG 1410.412 Medical Device Recall Authority*).

FDA requested recalls may begin with various communications between the field and headquarters units, but will implemented by submitting an Alert and a FDA Requested Recall Recommendation in RES in the same manner as for voluntarily initiated recalls. All data and documentation related to the problem, as indicated above under the Recall Recommendation and the Establishment Inspection paragraphs, will be obtained and submitted to the CRU. The CRU will process the recommendation as outlined in the following paragraphs on Recall Classification and Strategy and submit an Action Memorandum to the ACRA through OEIO/DE.

OEIO will review the Action Memorandum and promptly prepare and forward a recommendation to the ACRA.

If the center's recommendation is approved by the ACRA and the letter to the recalling firm signed, the ACRA or his/her designee will notify the firm by letter of FDA's determination of the need to immediately begin a recall. The letter will specify the violation(s), health hazard involved, and recommended recall strategy. It will provide any other instructions appropriate to effectively conduct the recall.

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

The program office will offer the same guidance to the recalling firm as outlined above and will assist the firm in arranging the text of recall communications to consignees so that the product will be promptly removed or corrected.

7-5-3 FDA Mandated Recalls

Various sections of the law authorize FDA to order a firm to recall a product. Each is discussed separately below. If the recall is FDA ordered, the agency will issue a written order to the firm to recall. This order should state the violation and the section of the Act or regulations that gives FDA the authority to order the recall. It should clearly describe the product, lots, serial numbers, etc. to be recalled and provide a time frame for the firm's reply.

FDA ordered recalls often have timeframes and procedures specified by regulation. The program should familiarize themselves with these before proceeding with assistance to the firm. The center compliance office normally takes the lead in negotiations with firms on FDA ordered recalls. The program should plan its strategy with direction from the center.

1. **Mandatory Device Recalls**

   Under Section 518(e) of the Act, if the agency finds that there is a reasonable probability that a device intended for human use would cause serious adverse health consequences or death, FDA has the authority to order the manufacturer, importer, distributor, retailer, or any appropriate person to immediately cease distribution of the device, 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. The Secretary delegated the authority to issue Section 518(e) orders to the Center Directors and Deputy Center Directors and to the Directors and Deputy Directors of the Offices of Compliance in the Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, and Center for Devices and Radiological Health (21 CFR 5.411). Such orders must have the concurrence of the Office of Chief Counsel (see procedures in Attachment G). The implementing regulations are found in 21 CFR 810. After giving the party subject to the order an opportunity for a regulatory hearing, FDA must either vacate the order or amend it to include a recall of the device.

SMG 1410.412 *Medical Device Recall Authority* indicates that, for medical devices assigned to their respective organizations, the Director, Deputy Director, and certain other officials, in CDRH, CDER and CBER, are authorized to perform all of the recall functions under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)), that have been delegated to the Commissioner. In those cases, the center director is responsible for appropriately advising the ACRA. In all cases of FDA requested recalls, the center director must concur with Action Memoranda required to be submitted to the ACRA.

2. Mandatory Recall of Biological Products

The National Childhood Vaccine Injury Act of 1986 amended the Public Health Service Act (PHS Act) to provide recall authority for biological products (42 U.S.C. 262). 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 Secretary has the authority to issue an order for its immediate recall.

3. Mandatory Recall of Human Tissue Intended for Transplantation

On November 21, 2004, FDA issued regulations requiring human cell, tissue, and cellular and tissue-based product (HCT/P) establishments to follow current good tissue practice (CGTP), which governs the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps; record keeping; and the establishment of a quality program (GTP final rule 69 FR 68612 (Nov 24, 2004)). FDA promulgated the new regulations under the legal authority of section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264). The regulations at 21 CFR 1271.440 include a provision for orders of retention, recall, and/or destruction, and a new provision for orders of cessation of manufacturing in certain circumstances. Such orders are intended for use in situations when needed to prevent the introduction, transmission, or spread of communicable diseases. HCT/Ps subject to the provisions in 21 CFR 1271.440 include, but are not limited to bone, ligaments, skin, dura mater, heart valves, corneas, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen and other reproductive tissue. The regulations at 21 CFR 1271.440 do not apply to vascularized organs such as livers, hearts, and kidneys, human milk or any tissues currently regulated by FDA as human drugs, medical devices, or licensed biological products. See RPM 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), for detailed procedures.

4. Infant Formula

The Infant Formula Act of 1980 and its 1986 amendments mandate that an infant formula manufacturer promptly notify the Secretary if the manufacturer has knowledge that reasonably supports the conclusion that an infant formula shipment may not provide the required nutrients or may be otherwise adulterated or misbranded.

If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately recall shipments. It is a prohibited act [Section 301(s)] for a manufacturer of infant formula who engages in a recall to fail to request that retailers post notice of recall for a length of time specified by the Secretary and to fail to report to FDA every 14 days on the progress taken to implement the recall.

Guidelines delineating the responsibilities of industry in conducting mandatory infant formula recalls are in the 21 CFR, Part 107, Subpart E.

5. **Tobacco Products**

Under Sections 908(a) and 908(c) of the Act, if the agency 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 agency 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 on the actions required by the order and on whether the order should be amended to require a recall of such tobacco products. After providing an opportunity for a hearing, FDA must vacate the order if inadequate grounds exist to support the actions required by the order. See SMG 1410.1107 - *Tobacco Product Recall Authority*.

6. **Mandatory Food Recalls**

FDA will exercise its authority under section 423(a) of the Act and provide a responsible party (as defined in section 417 of the Act) an opportunity to voluntarily cease distribution and recall a food when FDA has determined that there is a reasonable probability that the 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 such article will cause serious adverse health consequences or death to humans or animals (SAHCODHA).

FDA may exercise its authority to mandate a recall under section 423(b)-(d) if FDA has provided the responsible party with an opportunity to voluntarily cease distribution or recall the article of food; and the responsible party has refused to or has not voluntarily ceased distribution or recalled the article of food within the time and manner prescribed, if so prescribed, by FDA.

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 not delegated to the center, prepares an Action Memorandum for Center Director or his/her designee concurrence before forwarding it to OEIO/DE and the ACRA; 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 OEIO/DE.

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, he 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 OEIO/DE.

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 certain 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 program 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 previously established by the ACRA as Class I. Specifically, for CFSAN, this includes precedent situations such as Listeria monocytogenes, salmonella species, various allergens, and pathogens in ready to eat foods.

The CRU will prepare the recall Action Memorandum in all situations requiring ACRA or center director approval. Attach copies of the following: health hazard evaluation, the firm's or FDA's recommended recall strategy, FDA audit program, and the initial recall recommendation. As appropriate, attach product analytical results, medical records, evaluations, etc., which are pertinent to the hazard evaluation and subsequent recall classification. In the case of FDA requested recalls, propose a course of action in the memorandum to be taken if the firm elects not to recall. Submit the Action Memorandum to the center’s compliance director for review and concurrence in all Class I recall recommendations prior to submission to the center director.

The center director approves all Action Memoranda required to be submitted to the ACRA for concurrence with Class I recommendations and FDA requested recalls.

OEIO/DE may review the Action Memo and discuss it with the CRU before submitting it to the ACRA. When the center and ORA/OEIO disagree on aspects of a recall or when

the ACRA believes the health hazard evaluation or recall classification warrants additional medical review, OEIO/DE may request that an ad hoc committee be formed to review and recommend changes to the health hazard evaluation or recall classification.

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 Classification Notification and Routing

When the ACRA approves the Recall Action Memorandum, the center and the program office are informed by OEIO/DE (via e-mail) of the ACRA's decision. The classification letter when signed by the ACRA will be mailed to the firm by DE. Distribution copies of the final approved documents will be sent to the center and the program office as soon as they are available. The original action memorandum with appropriate signatures and comments will become a permanent part of the center's recall file.

When the CRU receives the ACRA approved Action Memorandum and letter to the recalling firm, the CRU will update the RES recall application, including the center Internet Release page. The classification information is then transmitted to the program and OEIO/DE.

7-6-4 Recall Strategy

Each recall is unique and requires its own recall strategy. The CRU will review the firm's recall strategy for voluntary recalls and will develop a strategy for FDA requested recalls. 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.

For FDA requested recalls, the center's compliance director ensures that the regulatory strategy cited in the recall recommendation and the action memorandum is supportable in the event the firm refuses the ACRA's request to recall or fails to complete the recall effectively or in a timely manner.

If the agency approves an industry Corrective Action Program (CAP) for a radiation emitting electronic product, the agency will notify the responsible firm that its CAP is classified as a recall and will stress the need for prompt corrective action. These corrective actions are taken to correct either product defects or non-compliance with standards. See Attachment E, Recalls of Radiation Emitting Electronic Products.

1. Elements of a Recall Strategy

As specified in 21 CFR 7.42(b), a recall strategy should include a statement on and the reasons for recommending the desired option under each of the following elements:

A. Depth of recall. The recall may extend to the consumer or user level, the retail level, or the wholesale level.

B. Public warning. In urgent situations, consideration should be given to the need for a press release that could be nationwide or to affected geographical areas only. In some cases, special communication with specific segments of the population (e.g., physicians, pharmacists, veterinarians, and hospitals) may be appropriate. When the CRU believes that there is a need for a FDA press release or a Talk Paper, in addition to the FDA Recalls web page posting, they should coordinate with the appropriate press officer on OEA/OMA. Similar Information may also be posted on Med Watch.

C. Effectiveness Check Level. This includes the method(s) to be used for and depth of recall effectiveness checks.

The recall strategy should consider the disposition of recalled products (e.g., carcinogenic products) when normal disposition means, landfill, crushing, denaturing, etc., are inadequate.

2. Recall Strategy Review or Development

In reviewing or developing a recall strategy, the 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, validated salvage or rework plan, and the continued availability of essential products.

For firm initiated recalls the CRU will review and change as indicated or concur with the firm's recall strategy and the program's recommendations for the FDA audit program. For firm initiated recalls, center coordinators should obtain current assessment of recall effectiveness from the field. The center will communicate recommended changes in the firm’s recall strategy and effectiveness checks and the FDA audit program to the Program Recall Coordinator and OEIO/DE and update RES.

For FDA requested recalls the CRU will develop a recall strategy and include it in the center’s Action Memo.

FDA may have to conduct the recall when a responsible firm is out of business or is unable to conduct a recall for any reason. The CRU, working with the involved program, will consult with OEIO/DE about strategy to implement recall action by FDA.

The CRU, when necessary, will develop an interim strategy to cover the time between notification of a known or potential health hazard and completion of a final formal strategy. Interim strategies are frequently part of recalls conducted for radiation emitting devices and electronic products, and for device recalls requiring replacement of components or software that must be developed.

The interim strategy will indicate the immediate actions to be taken on the part of the responsible firm to ensure prompt warning to the appropriate depth of distribution. Such warning must identify the hazards involved and the steps to be taken to minimize exposure to the product hazard pending completion and implementation of the recall strategy.

The Program 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 PRIOR to completing the recall classification in RES. If these corrections are not made prior to classification, the recalling firm may interpret the center's classification as acceptance of their inappropriate recall strategy.

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. **Status Reports**

Program recall coordinators will update the status of recall actions in RES when they become aware that a recalls status has changed from "ongoing" to "completed" to "terminated."

For certain Class I recalls and Class II recalls, when required by the audit program, the program office will send a weekly progress report to the CRU and OEIO/DE until the recall is completed or until advised otherwise by OEIO/DE.

Monthly or bi-monthly status reports on recall actions within the programs are not required by headquarters, but may be prepared at the discretion of program management for program recall operation monitoring purposes only.

1. Program Notification to the Recalling Firm

The monitoring program, 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 program may notify the recalling firm by telephone of the recall classification and its posting on FDA's website.

This letter will provide the recall number(s), the classification of the recall, an agency assessment of the firm's recall strategy, i.e., type of notification, depth of recall, and level of effectiveness checks, as well as any suggested strategy revisions. It will indicate FDA's determination to verify returned product disposition by stating that the program 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 has been posted on the FDA website. 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 program director or his/her delegate. It should also include the name and telephone number of the program's recall coordinator to assist the firm in answering any questions related to the recall classification.

A sample Notification Letter is attached as Exhibit 7-7. 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 situations where there is an urgent need for a more prompt notice, i.e., FDA requested recalls, Class I recalls, or pending FDA press release, the program office will visit or telephone the firm, and follow-up with a confirmatory letter as appropriate.

In instances where the recall is terminated at the same time it is classified, the program 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 sample Notification/Termination letter is attached as Exhibit 7-10.

2. Audit Check Reports

Report all recall audit checks on form FDA 3177, Recall Audit Check Report. See Exhibit 7-12A for a copy of the report and Exhibit 7-12 for the audit check report instructions.

7-7-2 Notification of Other Governments and Agencies

OEIO/DE is responsible for maintaining contacts and notifying headquarters organizations about significant recalls. These include the Center Recall Unit, Office of Partnerships (OP), Office of International Programs (OIP), OEA/OMA, and OEA/OMA. In emergency recall situations, DE will keep FDA's Emergency Operations center apprised of recall status. DE advises the USDA, DOD, and other federal government agencies of recalls in which they are involved. DE also advises government officials in Canada and Mexico of recalls, in accordance with existing MOUs and CUMCIG (Canada-United States- Mexico-Compliance Information Group).

1. **Notification of State and Local Officials**

Program offices should consider appropriate notification to state and/or local officials of recall actions that may be pertinent to them. The programs should also consider requesting necessary assistance from state and local officials either in conducting or auditing recalls.

The Office of Partnerships 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 Office of Partnerships also distributes other publicity prepared by OEA/OMA to these officials.

2. **Foreign, Military, and Other Federal Government Distribution**

The program coordinator should submit a list of foreign, military, and other federal government consignees to OEIO/DE in RES with the Recall Recommendation submission, or, if this information is known at the time, with the 24 hour alert.

OEIO/DE notifies OIP of all Class I recalls where product was distributed to foreign countries except Canada. OEIO/DE informs OIP of specific foreign consignees. OEIO/DE also responds through OIP to all requests for recall information from American embassies.

OEIO/DE notifies Canadian food, drug, and device regulatory authorities of every recall, in accordance with established communication agreements. They inform Canada of recalls of products shipped to Canada and of recalls of Canadian products in the United States.

OEIO/DE notifies OIP of recalls of imported products to expedite locating all importers of the violative product.

OEIO/DE notifies the USDA, Food Safety and Inspection Service (FSIS) and the 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.

3. **Responsibility and Procedures - OC, Office of International Programs, (OIP)**

For all Class I recalls involving foreign consignees other than Canadian, OIP summarizes and transmits essential information to the appropriate counterpart agency in the foreign country. It provides a copy of the foreign notification to the CRU and OEIO/DE.

At the request of OEIO/DE, OIP contacts appropriate counterpart foreign agencies to have them contact foreign manufacturers or distributors in order to determine name(s) and location(s) of United States importers of the firm's product(s) found to be violative and under recall in the United States. It provides foreign agency responses to OEIO/DE.

OIP coordinates the development of responses to foreign embassy inquiries with the centers and OEIO/DE.

OIP provides the CRU and OEIO/DE with foreign counterpart agency responses regarding the effectiveness of recall actions, so that the effectiveness of the recall notification to foreign consignees may be properly evaluated.

4. **Responsibilities and Procedures - Division of System Solutions (DSS)/Enforcement Systems Branch**

OEIO/DE notifies ESB when medical products under recall (Class I and Class II) have been distributed to any federal agency and advises about impending Class I and other serious recalls of drugs and devices shipped to the Department of Defense (DOD), Department of Veterans Affairs (DVA), or General Service Administration (GSA) facilities.

ESB uses established systems and relationships with DOD, DVA, and the GSA to provide information or obtain cooperation relative to drugs, biologics or devices shipped to these agencies and presenting serious health risks.

ESB notifies appropriate federal purchasing agencies (DVA, GSA, and DOD) of all Class I recalls and of those Class II recalls of medical products which have been distributed to federal agencies. They receive and coordinate Class I recall audit check data from other government agencies and forward the data to OEIO/DE.

7-7-3 Public Warning

Certain recall information (e.g., press releases) are posted on FDA’s Internet website (“Recalls, Market Withdrawals, and Safety Alerts”). In addition, all industry product removal or corrective actions classified by the agency as recalls will be included in FDA’s weekly Enforcement Report web page.

It is FDA’s practice that press releases issue for Class I recalls unless specific circumstances indicate that a press release would not be beneficial to the public. Publicity may be issued by either the recalling firm or by FDA. Agency procedure is that the recalling firm the first opportunity to prepare and issue publicity concerning its recall.

The field recall coordinators will work with the recalling firm to prepare a press release. OEA/OMA, the CRU and/or OEIO/DE Recall Staff are available to provide assistance. The CRU will also assist the OEA/OMA, along with the program recall coordinator and OEIO/DE, in the preparation of FDA publicity.

If hazardous products contain defects that require extensive design and/or test time to ensure both the firm and FDA that a certain recall or corrective action program is appropriate, the agency will require prompt, preliminary communication to consumers/users to prevent unnecessary injury.

Program recall coordinators will promptly provide (electronically if possible) copies of all recalling firm or state agency issued press releases to the OEA/OMA Field Liaison Officer, the FDA Website Management Staff, the CRU and OEIO/DE. The Website Management Staff will update the recall website URLs to link users to the press releases.

When appropriate, the CRU will forward press releases and/or other recall documents for posting on the center's and/or the MedWatch website.

Additionally, notices or warnings may be issued to health professionals, trade associations, etc., for the purpose of alerting these populations to either serious health hazards or other situations deemed to be in the public interest.

As appropriate, FDA will provide information to help the public identify a recalled product, such as product photographs, brand names, and the distribution of the products.

1. **Responsibilities and Procedures – Office of External Affairs**

   A. Advises the ACRA on the appropriateness of publicity for all recall actions;

   B. When a recall's strategy includes FDA publicity, prepares and issues publicity with the assistance of the appropriate center, program, and OEIO/DE. Obtains ACRA concurrence on all recall publicity;

   C. In cooperation with the CRU and OEIO/DE, prepares "Talk Papers" on high interest recalls that do not warrant a press release;

   D. Evaluates the effectiveness of recall publicity and, if determined to be inadequate, initiates action to ensure effective notice; and,

   E. Handles or coordinates responses to all media calls regarding recall situations.

7-8 MONITORING AND AUDITING RECALL EFFECTIVENESS

7-8-1 Recall Effectiveness

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. Effectiveness checks assist in the verification that all known, affected consignees have received notification about a 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 a recall extends to the consumer-user level, the confidential business records of a firm's customers are not accessible, wholesalers, distributors, or retailers do not cooperate, or, because the urgency of the situation requires an all-out effort. In such cases, FDA will directly assist in this activity and, where necessary, seek assistance from cooperating state and local agencies.

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 will selectively conduct audit checks separately from the effectiveness checks of the recalling firm.

7-8-2 Managing FDA's Audit Program

1. FDA Recall Audit Program Development

The CRU reviews the program recommendation and finalizes the FDA audit program for the recall.

In Class I or other significant recall situations, the CRU should regularly review and update the audit program to ensure its adequacy and to reflect changes in the health hazard evaluation, classification, effectiveness of firm's recall, etc.

Factors in Audit Program Development include:

A. Special procedures for monitoring the recall at the firm

B. Level and type of audit checks to be conducted, including ensuring that consignees who received recalled product(s) that were purchased for use in a domestic nutrition assistance program (e.g., National School Lunch Program), are included in audit checks.

C. Special reporting requirements.

OEIO/DE concurs in the use of personnel resources for audit checks for Office of Operations.

2. Program Responsibilities

In summary, the programs:

A. Issue audit check assignments (monitoring program)

B. Complete assigned audit checks (monitoring and other programs)

C. Notify the CRU and OEIO/DE of progress on recalls and ineffective recalls

The monitoring program director has the overall responsibility for ensuring that the FDA audit program is implemented. The recall coordinator and appropriate supervisory personnel are responsible for the day-to-day management of a recall. They will ensure that the firm's status reports are received and reviewed in a timely manner and that the disposition of recalled products is monitored or verified. They will ensure adequate progress and timely completion of the recall by telephone or establishment visit, as appropriate.

If the monitoring program office encounters unreasonable delays by the recalling firm in conducting the recall, an administrative or legal action should be recommended to the appropriate center compliance branch. The CRU and OEIO/DE should be kept informed of such recommendations.

3. Audit Check Issuance

Normally within 10 days of issuance of the firm’s recall communication, the monitoring program will issue audit check assignments at the level in the FDA audit program. Exceptions to the ten day time frame would be made for Class I situations when the recall is to the consumer/user level and it is critical that the agency be certain that the products are off the market or that consumer/users have been notified of the recall action. Audit checks are often issued within 24-48 hours after the program learns of a precedent class I food recall. Exceptions to the 10 day time frame are also to be expected in certain radiation emitting devices and electronic product recalls. In these cases, follow CDRH recommended strategy. When the program considers the 10-day requirement inappropriate, they should recommend to the CRU a new date for issuing the audit checks. The monitoring program must provide specific instructions as appropriate when issuing an assignment to another program office. The assignment should be flagged "Request for Audit Check--Class I or II, Audit Check--Level A, B, C, or D". (See Exhibit 7-11 for format). The program should forward a copy of Class I audit check assignments to the CRU and to OEIO/DE.

4. Audit Check Completion

The program receiving audit checks assignments should consider them high priority and should accomplish them as soon as possible. Submit copies of audit check reports to the monitoring program. If possible, complete assignments within 10 working days from receipt of the assignment. For Class I recalls, provide audit check reports to the monitoring program at least once a week or more often if so directed.

Visits, rather than telephone calls, are preferable for Class I recall audit checks. Visits are also preferred for Class II audit checks. However, resource restraints 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. Exceptions to Class I and II audit checks will be made only when circumstances indicate that such checks will be of no significant value in FDA’s audit of the recall. Audit checks are not normally performed for Class III recalls. However,

the responsible program and CRU must consider the need for such checks in each recall situation.

The issuing program will evaluate audit check reports when received to ensure that they are adequate and then retain them. The program shall document its evaluation of the audit check reports. If, during its evaluation of the audit check reports, the program discovers any issues with the recall or audit checks, including any problems affecting consignees that received recalled product(s) that were purchased for use in a domestic nutrition assistance program (e.g., National School Lunch Program), the program must ensure that appropriate and timely follow-up action is taken. If insufficient information has been collected, the issuing program recall coordinator will advise the endorsing supervisory investigator.

It is the responsibility of the receiving program to notify the issuing program of circumstances which will adversely delay the completion of the assignment. Copies of any such communication should automatically be forwarded to the CRU and to OEIO/DE.

5. Conducting Audit Checks – Direct and Sub-Accounts

The extent of follow-up and information obtained from consignees of recalled products depends on several factors, including the depth of the recall and the type of recall action requested such as return, field correction, or destruction.

Prior to conducting audit checks for complicated or significant recalls, the program may either prepare information handout sheets or copy the recalling firm's recall communication so that copies may be left with consignees.

A. No Sub-Recall Indicated.

When sub-recall is not indicated by the consignee, determine how and when the consignee was notified of the recall and whether the consignee followed the recall instructions. If the consignee failed to follow instructions and recalled product is being held for sale or use, the investigator should request immediate compliance with the instructions. If the consignee has not received the recall notification, give the consignee a copy of the recall information to perform the requested recall action.

B. Sub-Recall Indicated.

Where sub-recall is indicated by the consignee, determine how and when they received the notification. If the consignee conducted a sub-recall, determine and report in detail the quantity of product involved, the timeliness of the action, and other data pertinent to the sub-recall. If the consignee has not received notification of the recall, provide the consignee with all pertinent recall data. If the consignee has elected not to conduct the sub-recall action, request that recall instructions immediately be followed, including notification of sub-accounts. Provide any assistance or guidance needed by the consignee to get a sub-recall underway.

C. Sub-Recall Refusals.

If the direct or sub-account refuses to initiate recall promptly, the program performing the audit check will advise the monitoring program, OEIO/DE, and appropriate CRU of the situation, and indicate what additional steps the program is taking to achieve a satisfactory sub-recall. Options for consideration include meetings between program management and top management of firms, notification of consignees directly, reporting to State and local officials, recommendation for FDA requested recall, and initiation of administrative proceedings or enforcement actions.

D. Responsibility.

The program in which the direct or sub-account is located is responsible for convincing the consignee to conduct an effective sub-recall or for recommending administrative or legal action, if indicated, to achieve compliance. The monitoring program, the CRU, and OEIO/DE should be kept advised of such recommendation.

E. Injury/Illness/Data.

Injury/illness reports or other product related complaints should be reported promptly (separately from the audit check report) to the monitoring program and OEIO/DE. The monitoring program should inquire whether or not the adverse event(s) has/have been reported to FDA through programs such as MedWatch.

6. **Ineffective Recall**

If at any time during FDA audit of the recall it is apparent that the recalling firm's recall effort is ineffective, the monitoring program should discuss the situation with the firm. Such additional contact can be made by visit, telephone, letter, facsimile, etc., depending upon the circumstance. Determine what action the firm intends to take to improve its recall efforts such as issuance of additional recall communications, etc. A model letter regarding ineffective recalls is attached as Exhibit 7-8. This type of letter should be developed by the program on a case-by-case basis working closely with the CRU.

If, after this notification, the firm is unwilling to extend or modify its recall, the monitoring program will notify the CRU and OEIO/DE of the situation and recommend appropriate action. Actions to be considered include actions such as FDA-requested recall, initial or further public warning, multiple seizures, and injunction.

7-8-3 State Audits

1. **Purpose**

A state recall audit (state audit) is an audit of the effectiveness of a recall, which is conducted by a state at FDA’s request. State audits may be used in highly complex

recall situations or during urgent public health events, or where it is otherwise in the best interest of public health for FDA to call upon its regulatory counterparts at the federal, state, or local levels for assistance. State audits enhance FDA's capacity to determine the effectiveness of a recall, and assure that FDA's and state(s)' efforts are timely, efficient, and documented so that a timely evaluation can be made and additional follow-up activities can be considered when necessary.

2. When State Audits are Considered

FDA may consider state audits in any of the following situations:

A. The volume of audits approved by center(s) demonstrates the need for state help to accomplish audit check activities in a timely manner. ("Timely" is based on the health risk of the product subject to the recall.)

B. FDA is receiving numerous complaints about recalled product still on retail shelves after a firm has issued a recall notification or public warning.

C. FDA determines that the recall is ineffective based on audit check results.

D. The recalling program determines that an ineffective recall letter may be necessary.

3. Planning and Initiation of a State Audit

The Recall Coordinator for the recalling firm will make the initial recommendation to OEIO/DE Recalls and the Center Recall Unit (CRU) for state audit assistance. When the need for state audits is identified, OEIO/DE Recalls will convene and lead a recall operational planning group that includes representatives from OEIO/DE Recalls, the recalling program, CRU, OEA/OMA, and the Office of Partnerships and as appropriate Office of Human and Animal Food Operations (OHFO) or Office of Medical Products and Tobacco Operations (OMPTO).

The recall operational planning group will determine the state audit procedure and strategy (see Strategy for State Audits, below). This group may have to work within an Incident Command System structure depending on the situation surrounding the recall.

The Program Recall Coordinator for the recalling firm should coordinate the recall strategy by issuing a state audit assignment to the participating state(s) within their own program. Issuance of assignments may also involve other Program Recall Coordinators, the Office of Partnerships and/or OEIO/DE Recalls when multi-program assistance is needed.

When multi-program assistance is required, the Office of Partnerships will request state assistance according to RPM 7-7-2, ("Notification of Other Governments and Agencies," "1. Notification of State and Local Officials".

4. **Strategy for State Audits**

The state audit strategy should include, but is not limited to, determining:

A. What consignees have done to discontinue the use and/or distribution of all intact containers of recalled product and the segregation of these products from those products not subject to the recall.

B. The methods distributors use for handling and/or disposing of undistributed recalled products in their warehouse.

C. Whether distributors have communicated recall instructions to their consignees, and, if so, by what mechanism (e.g., phone, letter).

D. How users may identify (or have identified) recalled products; especially when the products do not have a lot code printed on the individual unit.

A state audit can be conducted by a personal visit, telephone call, or other timely means of communication.

5. **Reporting Audit Results**

A. General

The recall operational planning group will determine who will receive and evaluate the state audit forms. Original FDA audit checks assigned for the recall should continue to be performed and completed per the original recall audit plan. Separate reports should be prepared to document FDA's audit results and each individual state's audit results, for use in preparing an overall, comprehensive report.

B. Reports by States

States will be encouraged to use FDA audit check forms (Form FDA-3177, Recall Audit Check Report), however, this is a voluntary system. If a state chooses not to document its audit check results on FDA Form-3177, FDA will request specific information from the state so that FDA can determine the effectiveness of the firm's recall. States will be asked to return audit forms to their local, assigning program office, or provide sufficient information to determine recall effectiveness if they did not use the audit check form.

C. Reports by Programs

All program offices will return state audit check forms or equivalent information to the recalling program office's recall coordinator.

The recalling program should send periodic progress reports, weekly if possible, to the CRU and OEIO/DE Recalls.

State activities performed in FDA programs other than the recalling firm's program shall be coordinated by the assisting FDA programs' recall coordinators to minimize duplication of activities by the states and FDA.

6. **Follow**-up to **State Audits** – Recall Expansion**, Ineffective** Recall Letter, etc**.**

   A. Recall Expansion

   If a recalling firm expands its recall, the recalling program will coordinate new audit assignments with OEIO/DE Recalls and CRU concurrence.

   B. Additional state audits

   Additional state audits may be considered during the course of the recall.

   C. Issuance of Ineffective Recall Letter

   If state audits reveal and ineffective recall, the recalling program should consider issuance of an ineffective recall letter as per Exhibit 7-8 with the concurrence of the CRU and OEIO/DE Recalls.

   D. Public Information

   The recall operational planning group will update and relay public information to all relevant offices, as necessary.

7. **Revisions to this Procedure**

Each recall presents its own set of circumstances, many of which change on a constant basis, therefore modifications to these recommended procedures based on the nature of any specific recall may be considered by the recall operations planning group handling the current recall, where necessary. These modifications should be documented by OEIO/DE Recalls as approved and should then be communicated to the recalling program office as accepted.

8. **Relationship of this Procedure to CFR Part 7**

These procedures are intended to supplement, not replace, those cited in 21 CFR Part 7.

7-9 RECALL TERMINATION

FDA will terminate a recall when the monitoring program office determines that the recalling firm has completed all recall activity, including monitoring and final product disposition. The program should advise the 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. The program will notify the recalling firm by letter that FDA considers the recall terminated. See Exhibit 7-9 for a Model Recall Termination Letter.

Termination of a Class I recall and a Safety Alert requires center concurrence. When the monitoring program concludes that such a recall or Safety Alert has been completed, the program 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 program official approving the termination recommendation. 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 program and OEIO/DE advising that the recall is terminated.

Center approval is not required for Class II or III recall terminations. Field coordinators 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 OEIO/DE that the recall has been terminated by the program.

As a rule, FDA should terminate the recall within three months after the firm completes the recall. If the program feels that the recalling firm is unable to ensure that violative goods will not reenter channels of distribution, the program should consult with the CRU and/or OEIO/DE for the best course of action.

NOTE: Before any FDA approval or concurrence is provided to plans for the disposition of recalled products, the program must follow established procedures governing the coordination of toxic wastes/product disposal programs with other federal or state agencies.

The information provided in the Summary/Termination portion of the RES recall record is very important as it not only provides finality to the recall process but provides information used by headquarters to determine trends and to identify or evaluate new problem areas in manufacturing, processing, etc.

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 program 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

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 Notification of Classification Letter (FDA to Recalling Firm)

7-8 Model Recall Ineffective Recall Letter

7-9 Model Recall Termination Letter

7-10 Model Combined Recall Notification of Classification and Termination Letter

7-11 Request for Audit Check Format

7-12 Audit Check Report Instructions/Explanation By Section

7-12A Audit Check Report

7-13 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 OEIO/DE via RES:

- Product(s) Description
- Codes
- Recalling Firm
- Short Reason for Recall
- Program 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 OEIO/DE 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 8, 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 subpotency 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 program R&E Coordinator to OEIO/DE. 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 program'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 program. 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. Program Audit Program (RES Event Details page)

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

Audit Check Level field – Provide the program's recommended audit check level, i.e. the level that the program 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 program's proposed program 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.

a. Product: See Attachment B.

b. Codes: See Attachment B.

c. Recalling Firm/Manufacturer: See Attachment B.

d. Reason for Recall Recommendation: See Attachment B.

e. 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.

f. Distribution: See Attachment B.

g. 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 program conclusion as to the adequacy of the firm's actions. If known, indicate steps the firm has taken to prevent similar occurrences.

h. Violation:
Provide the section of law violated.

i. Preventive Action:
Provide the action taken by the firm to prevent recurrence of the violation.

j. Program Audit Program:
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 program'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 program 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 program coordinator or other program personnel will prepare and submit, after coordinator review, the recall document to program management for concurrence. The name of the program 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 OEIO/DE.

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

   (a) 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 particular 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 program 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 district or program 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 program processes recalls for X-ray assemblers and suntan lamp recalls. The home district office or program will still continue to submit a Recommendation for Recall for cases generated in the field. The programs will approve the corrective action plans for these cases, and submit a copy of the program 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 program 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 programs. Upon receipt of the completed audit check reports from the programs, 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 district or program will send the firm a warning letter when the target completion date expires.

The home district or program 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 OEIO/DE by the home district or program.

At the conclusion of the recall, the home district or program 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 7-9).

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. Actually, 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.

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

A. 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?

B. Are other administrative or enforcement actions more appropriate to address the problem?

C. Seizure or detention may be a lesser agency burden and may address the health risk situation more effectively.

D. GMP issues alone will not support the contention that use of the device will cause serious adverse health consequences.

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

1. **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:**

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

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

C. 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.

D. 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.

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

F. f. Any pertinent manufacturing or recall history.

G. 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.

H. 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 program. If the firm cannot receive facsimile transmissions, the order will be hand delivered by the program. In either situation, the program 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 program. 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 program 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.

4. **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

3. 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."

Exhibit 7-1

4. 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

5. **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

6. **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 check 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:

☐ Wholesaler/distributor
☐ Grocery corporate headquarters
☐ Repacker
☐ Pharmacy-retail
☐ Hospital pharmacies
☐ Retailer
☐ Other: _____
☐ Food service/restaurant
☐ Manufacturer
☐ Hospital/Medical facility
☐ Medical laboratory

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 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" revised April 1, 2011 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 evaluation indicates that this recall should be conducted to the (Consumer or User, Retail, Wholesale, etc.) level and that level _____ effectiveness checks should be conducted by your firm. Level___ effectiveness checks are (Definition).

In addition to your recall efforts, it is equally important to assure that all returned merchandise is promptly inventoried, handled, and stored in such a manner as to assure its separation from acceptable materials so it will not inadvertently be used or shipped.

Our past experience in similar situations has shown that the longer a defective product is held between the initiation and termination of a recall, the greater the chance of its accidental misuse. We, therefore, urge you to immediately begin making plans to destroy the product or recondition it to bring it into compliance with the law.

Either method should be done under the supervision of an investigator from this office.

(Note: The paragraph above may be modified to reflect concern about appropriate disposition of toxic materials.)

We request that you advise us within ten days of the steps you have taken or will take to ensure that the recalled merchandise is properly inventoried and maintained to prevent unintended use or shipment, and provide your proposed method of disposition of the returned goods.

In addition, we request that you submit to our (City) Program office a recall status report at (Monthly or Bi-Weekly) intervals. These 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

(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

These periodic status reports should be addressed to:
(The program will determine who receives the firm's responses.)

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 response to this letter should be addressed to: (Program Director).

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

Sincerely yours,

Program Director

_____Program

Enclosures

Exhibit 7-8

MODEL 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 Director

_____Program

Exhibit 7-9

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 Director

_____Program

Exhibit 7-10

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 Director

_____Program

Exhibit 7-11

REQUEST FOR AUDIT CHECK FORMAT

Flag: "REQUEST FOR AUDIT CHECK - CLASS I, II, or III, LEVEL A, B, C, or D"

Include the following Information:

1. Recall number
2. Description of product being recalled including model numbers
3. Codes: lot, or serial number(s)
4. Recalling firm/manufacturer
5. Reason for recall
6. Number, level, and type of audit checks to be conducted
7. Direct consignees, whenever possible
8. FEI# of recalling firm

Furnish the consignee program a copy of the firm's recall communication or quote appropriate portions of it so that the person performing the check can determine if the consignee has complied with the recalling firm's directions. When possible, include the name, title, and department to whom the recall communication was directed.

List any additional data required but not entirely included on the audit check report form. Provide any specific reporting instructions.

Exhibit 7-12

AUDIT CHECK REPORT INSTRUCTIONS/EXPLANATION BY SECTION

NOTE: COMPLETE ONE FORM PER AUDIT CHECK; HOWEVER, PROGRAM DATA MAY COVER NUMEROUS AUDIT CHECKS.

1. Recall Information:

   a. Recall Number - Enter the recall number assigned by the Center. If more than one number is involved, enter the lead number.

   b. Recalling Establishment - Provide the name and address of the firm responsible for issuing the recall notification.

   c. Recalled Codes - Provide the lot, batch, or serial number under recall.

   d. Product - Provide the name of the product under recall. If numerous products are involved, use generic term, e.g., ice cream, dried fruit, etc.

2. Program Data:

   Completion of Section 2 is required only if the credit sheet is to be used for program data reporting. Form FDA 2123 may also be used for reporting audit check data. If time is reported on either a FDA 2123 or another FDA 3177, check the box and do not complete Section 2.

   a. Accomplishing Program - Enter the code for the program conducting the audit check.

   b. Home District or Program- Enter the code for the home district or program of the recalling establishment listed in 1b.

   c. Operation Code for Audit Checks - Operation 17, has been pre-printed.

   d. Operation Date - Provide the date the audit check was conducted. When multiple checks are reported, use the date of the last audit.

   e. Central File Number or FEI - Provide the CFN or FEI for the recalling establishment listed in Block 1b.

   f. PAC Code - Enter appropriate PAC code.

   g. Employee - Self-explanatory.

   h. Provide a breakdown of the number of visits and phone audits conducted. Time for each type of check should be listed under the Hours column.

3. Audit Accounts: The form has been designed so that it may be used at the tertiary level of distribution, that is, as far down the distribution chain as consignees of secondary distributors.

4. Consignee Data: "Consignee" is the account at which the check is being conducted.

   Data requested is self-explanatory.

5. Notification Data: Fill in appropriate blocks. Did consignee receive a specific written, verbal, or personal contact providing recall notification; from whom and when was notice received?

6. Action and Status Data: Self-explanatory

7. Sub-Recall Needed: Describe firm’s sub-recall procedures in Block 10 or give reason for not conducting sub-recall. If firm has refused to sub-recall properly without justification, include program follow-up in Block 10 or separate memo.

8. Self-explanatory.

9. Self-explanatory.

10. Remarks: Provide all information not covered in 1-9 which aids in the evaluation of recall effectiveness at this consignee.

The Recall Audit Check Report is to be signed by the individual conducting the check as well as the individual endorsing the report to the monitoring program.

Exhibit 7-12A

AUDIT CHECK REPORT

1. RECALL INFORMATION

a. RECALL NUMBER

b. RECALLING ESTABLISHMENT

c. RECALLED CODE(S)

d. PRODUCT

2. PROGRAM DATA (CHECK BOX IF PREVIOUSLY SUBMITTED) (DO NOT COMPLETE IF REPORTED UNDER FDA 2123)

a. ACCOMP PROGRAM CODE

b. HOME DISTRICT OR PROGRAM CODE

c. OPERATION CODE - 17

d. OPERATION DATE - MO DA YR

e. CENTRAL FILE NUMBER OF RECALLING ESTABLISHMENT

f. PAC CODE

g. EMPLOYEE - HOME OR PROGRAM DIST. POS. CLASS NUMBER

h. TYPE - VISITS/PHONE

OF CHECKS HOURS

3. AUDIT ACCOUNTS

a. DIRECT PHONE NO _____

b. SUB-ACCOUNT (SECONDARY) PHONE NO _____

c. SUB-ACCOUNT (TERTIARY) PHONE NO _____

4. CONSIGNEE DATA Contacted by: [ ] Phone [ ] Visit [ ] Other

a. NAME OF PERSON CONTACTED, TITLE, & DATE

b. TYPE CONSIGNEE

[ ] Wholesaler [ ] Physician

[ ] Retailer [ ] Hospital [ ] Other

[ ] Processor [ ] Pharmacy [ ] Consumer [ ] Restaurant

c. DOES (DID) THE CONSIGNEE HANDLE RECALLED PRODUCT?

[ ] YES [ ] NO

5. NOTIFICATION DATA

a. FORMAL RECALL NOTICE RECEIVED? (IF "NO" SKIP TO ITEM 6c)

[ ] YES [ ] NO [ ] CANNOT BE DETERMINED

b. RECALL NOTIFICATION RECEIVED FROM: [ ] Recalling Firm

[ ] Direct Account

[ ] Sub-Account

[ ] Other (Specify) _____

c. DATE NOTIFIED

d. TYPE OF NOTICE RECEIVED (e.g. letter, phone)

6. ACTION AND STATUS DATA

a. DID CONSIGNEE FOLLOW THE RECALL INSTRUCTIONS?
(IF "NO", DISCUSS IN ITEM 10, ACTION TAKEN UPON FDA CONTACT)
[ ] YES [ ] NO

b. AMOUNT OF RECALLED PRODUCT ON HAND AT TIME OF NOTIFICATION

c. CURRENT STATUS OF RECALLED ITEMS

[ ] Returned [ ] Destroyed

[ ] Corrected [ ] None on Hand

[ ] Was Still Held For Sale/Use(*) [ ] Held For Return/Correction(*)

(*) = Ensure Proper Quarantine/Action

d. DATE AND METHOD OF DISPOSITION

7. SUB-RECALL NEEDED?

Did Consignee Distribute to any other Accounts?

(If "Yes give Details in "Remarks" or Memo) [ ] YES [ ] NO

8. AMOUNT OF RECALLED PRODUCT NOW ON HAND.

9. INJURIES/COMPLAINTS

IS CONSIGNEE AWARE OF ANY INJURIES, ILLNESS, OR COMPLAINTS? [ ] INJURY [ ] COMPLAINT

[ ] ILLNESS [ ] NONE

IF ANSWER IS OTHER THAN "NONE" REPORT DETAILS IN A SEPARATE MEMO TO MONITORING PROGRAM AND COPY TO OEIO/DE.

10. REMARKS (INCLUDE ACTION TAKEN IF PRODUCT WAS STILL AVAILABLE FOR `SALE OR USE)

TO:_____ DATE:_____

ENDORSEMENT:_____

SIGNATURE OF SCSO OR RECALL COORDINATOR:_____

SIGNATURE OF CSO/CSI:_____

PROGRAM:_____ DATE OF CHECK:_____

Exhibit 7-13

WEEKLY CLASS I RECALL STATUS REPORT (OPTIONAL)

Programs monitoring certain Class I certain recalls may be requested to submit a weekly status report by either the CRU or OEIO/DE. (Weekly status reports may also be required for certain Class II recalls per the audit program.) 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 OEIO/DE evaluation of the recall's progress or effectiveness.

Appendix A

1. Form FDA 3177

Form FDA 3177 (Recall Audit Check Report), can be obtained by contacting the local FDA recall coordinator.

Follow the directions below to complete the form.
NOTE: COMPLETE ONE FORM PER AUDIT CHECK.

Block 1. Recall Information:

a. Recall Number: Leave Blank

b. Recalling Establishment: Provide the name and address of the firm responsible for issuing the recall notification.

c. Recalled Code(s): Provide the lot, batch, or serial number under recall.

d. Product: Provide the name of the product under recall. If numerous products are involved, use generic term, e.g., ice cream, dried fruit, etc.

Block 2. Program Data: Leave Blank

Block 3. Audit Accounts: The form has been designed so that it may be used at up to the third level of distribution. Complete the appropriate block for your visit, if known.

Block 4. Consignee Data: “Consignee” is the account at which the check is being conducted. Data requested is self-explanatory.

Block 5. Notification Data: Fill in appropriate blocks. Did consignee receive a specific written, verbal, or personal contact providing recall notification; from whom and when was notice received?

Block 6. Action and Status Data: Self-explanatory.

Block 7. Sub-Recall Needed? Describe firm’s sub-recall procedures in Block 10 or give reason for not conducting sub-recall. If firm has refused to sub-recall without proper justification, include program follow-up in Block 10 or separate memo.

Block 8. Amount of Recalled Product Now on Hand: Self-explanatory.

Block 9. Injuries/Complaints: Self-explanatory.

Block 10. Remarks: Provide all information not covered in 1-9 which aids in the evaluation of recall effectiveness at this consignee.

Signature Block: The Supplemental Audit Report is to be signed by the individual conducting the effectiveness check in the block noted “Signature of CSO/CSI”; as well as by the individual endorsing the report to the monitoring program.

2. Other Forms

If state personnel wish to use a different form to capture the information obtained during their recall audit visits, they should assure that at least the following information is obtained, plus any additional information requested by the monitoring or home FDA district or program office:

1. Name and title of person interviewed.
2. Was notification received, understood, and followed?
3. Date and method of notification.
4. Amount of recalled product on hand at time of notification.
5. Amount returned and the method of return.
6. Amount destroyed and method of destruction.
7. Amount presently on hand and its status (held for sale, awaiting return, etc.).
8. Date of anticipated return or destruction, and planned method (if applicable).
9. Was sub-recall conducted? (If so, obtain a list of consignees from which to select your sub-recall check locations).
10. Have injury reports or complaints been received? If so, report details.

3. Other Materials

FDA recall monitoring programs may provide state personnel with audit assignments (and level of recall effectiveness checks) in addition to any supporting recall materials, e.g., Press Releases, Technical Guidance, etc.