

Chapter 7 RECALL PROCEDURES

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7-1 PURPOSE

This chapter provides policy, definitions, responsibilities, and procedures for Agency units 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 8, Recall Activities.)

7-2 BACKGROUND

Recalls are an appropriate alternative method for removing or correcting marketed consumer 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 civil actions, especially when the product has been widely distributed.

Manufacturers and/or distributors 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, or as ordered by FDA.

All Agency units are expected to follow the requirements of this chapter. Some deviation from the procedures may occur in the initiation of device recalls ordered under section 518 of the Federal Food, Drug, and Cosmetic Act, corrective action programs (recalls) involving radiation emitting medical devices and electronic products, infant formula recalls, human tissue recalls, or other situations as they arise.

Guidelines delineating the responsibilities of industry in conducting recalls are in 21 CFR 7.40-7.59. An additional document titled “Product Recalls, Including Removals and Corrections -

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

The FDA recall program gives recalls the proper attention at all levels of the Agency and provides adequate resources to process, to classify, and to publicize recalls in a timely manner. FDA responsibilities are summarized below. This chapter is arranged according to the following outline:

- Initiation of a Recall. Includes voluntary, FDA requested, and FDA mandated.
- Classification and Strategy. FDA formalizes the recall action by reviewing the information, including the recall strategy provided by the firm, assessing the health hazard presented by the recalled product, and classifying the recall.
- Notification and Public Warning. FDA notifies the firm of the classification and necessary changes in its recall strategy, including the need for press releases for those recalls conducted voluntarily. The Agency notifies the firm of FDA requested or mandated recalls and the need for publicity. FDA publishes all recalls on the FDA Internet site and assures that the public is warned about products that are hazardous to health. FDA provides recall information to other federal and state government agencies and to foreign governments.

Monitoring and Auditing the Recall. FDA develops and implements a recall audit program to assure that the recall action has been effective.

- Termination of a Recall. FDA determines when a recall should be terminated and, upon such determination, provides written notification of termination to the recalling firm.

Finally, FDA will take appropriate regulatory action or other measures when the firm fails to recall violative product or when a recall action fails. These actions will be taken in consultation and coordination with the district compliance branch, the appropriate center recall and compliance staffs, OE/DCMO, and when indicated, the Office of Chief Counsel, when: a firm refuses to recall or sub-recall after being requested to do so by the FDA

- a firm fails to complete a recall in a timely fashion
- the Agency has reason to believe that a recall strategy is not effective

7-3-1 Responsibilities Of The Office Of Enforcement/Division Of Compliance Operations And Management (HFC-210)

OE/DCMO is the Agency’s headquarters contact and focal point for information, advice, and direction for field recall operations and remains involved with each recall throughout its process. If required, OE/DCMO may direct appropriate follow up actions by the field. OE/DCMO, with the district coordinators and Center Recall Unit (CRU) evaluates firms’ recall performance. The recall staff encourages timely district and industry action on recalls. In the case of FDA requested recalls, as well as all Class I recalls for which the ACRA has not delegated classification authority to Center Directors, OE/DCMO is the liaison between the districts, the CRUs and the ACRA. The recall staff reviews and makes recommendations to the ACRA regarding concurrence with the Action Memoranda. OE/DCMO will forward its

recommendation to the ACRA within one working day unless additional or supplemental review of the health hazard evaluation or recall classification or status is required. OE/DCMO periodically reviews all Agency recall activities to assure that current policy and procedures are being applied to recalls and recommends changes as appropriate. OE/DCMO evaluates the overall effectiveness of recall activities. OE/DCMO communicates trends, common causes of recalls, control weakness, etc., to units having the need for this information.

7-3-2 Responsibilities And Procedures – Office Of Enforcement/Division Of Compliance Policy (HFC-230)

OE/DCP reviews and resolves compliance policy issues related to recalls. The division reviews recall action memorandums when requested by OE/DCMO, particularly when a policy issue has been identified. OE/DCP provides written response to OE/DCMO.

7-4 RECALL ENTERPRISE SYSTEM

The Recall Enterprise System (RES) is to be used by district and center recall personnel to submit, update, classify, publicize, and terminate recalls. Basic recall guidance and procedures remain essentially unchanged from those used prior to the initiation of RES. RES User Guides on CD have been provided to field and center recall coordinators. The RES application currently has some help information available for each screen. Additional detailed guidance will be developed and added to the application.

The RES increases efficiency in processing recall information by:

- Allowing field coordinators to input recall information via an on-line, Intranet system.
- Combining five separate documents for a recall event into a single system, allowing users to build a record of the entire recall by entering information as it becomes available thus reducing preparation time and providing consistency throughout the agency.
- Reducing duplication of efforts between the Field Offices, OE, the Centers, and Office of Public Affairs.
- Increasing communication of recall information between the field and headquarters offices.
- Providing a central, searchable database to more efficiently track information and generate and disseminate reports of recall activities.
- Using a uniform Health Hazard Evaluation (HHE) form to promote consistency in evaluating potential health hazards and/or risks agency-wide while supporting wider use of electronic precedent health hazard assessment files to expedite recall classifications.
- Providing the public with “real-time” information about the FDA recall process.

7-5 INITIATION OF A RECALL

A manufacturer or distributor may voluntarily initiate a recall at any time. Under certain urgent situations, FDA may request that a manufacturer or distributor recall a product. Under certain authorities, FDA may mandate a recall.

7-5-1 Firm Initiated Recalls

In summary, if a recall is firm initiated, the Agency will obtain and 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, to its recall notification and to its press release (if necessary). The Agency will conduct a health hazard evaluation (HHE), (precedent HHEs or written classification policies may be used), classify the recall and 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, advise the firm that its recall will be placed on the FDA web site and, when appropriate, otherwise publicized, such as issuing a press release or talk paper and posting on MedWatch. FDA will also assign audit checks as appropriate, monitor the effectiveness of the recall notification, correction or removal, verify appropriate product disposition, and terminate the recall.

The District:

- 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.
- Terminates Class II and III or recommends termination for Class I recalls.

Recall Alert

The district, 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 OE/DCMO Recall Operations Staff (HFC-210). The district 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 district will fax or email to the CRU a copy of the recalling firm's recall notification and press release, if any. A copy of the press release is also to be forwarded to OE/DCMO and to the OPA Field Liaison. Alerts have not been required for device recalls under section 518(e), blood product 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.

OE/DCMO will promptly notify the ACRA of significant recall actions and will provide copies of recall documents where appropriate

Recall Recommendation and Related Information

The district must submit a complete Recall Recommendation (RR) 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 OE/DCMO via e-mail. See Attachment B for guidance on the information required by the CRU to review and classify the recall. The district may submit the Recall Alert and Recommendation up to 10 working days after the district learns of a “completed” recall.

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

- 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.
- Product specifications, formulation and related documents.
- FDA and/or state laboratory worksheets and/or the firm's pertinent quality control or analytical records for all products involved.
- If the district 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, must be submitted.
- If not previously submitted at time of the Alert, submit a copy of all of the recalling firm's communications to the CRU. For potential Class I recalls, also forward a copy to OE/DCMO.

This material should closely follow the submission of the RR and should be submitted by the fastest means possible, i.e. facsimile, FedEx, attaching a scanned portable document file (.pdf) to an e-mail, etc.

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

Notes:

- When requested by OE/DCMO or the CRU, submit a Recall Recommendation 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 District should recommend the action be classified as a market withdrawal as, although the situation may present a health hazard, there is no one identified as responsible for the violation. This will allow documentation and monitoring of specific corrective actions meeting the market withdrawal definition but considered significant to the agency.
- 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 as domestic recalls.
- If the CRU or OE/DCMO finds the RR information lacking in any way, either may request that the district obtain the additional information. This may be done by telephone, email, or the electronic return of the recall record with comment.

Establishment Inspection

The district will contact the firm to obtain recall information and may elect to conduct an establishment inspection. See the IOM Chapter 8 – Recall Activities for guidance in

conducting recall related inspections.

The establishment inspection should, in addition to other activities:

1. Obtain the recalling firm's proposed recall strategy [21 CFR 7.46(a)], if not previously submitted by the firm.
2. Collect copies of all labeling associated with the product.
3. Obtain complete distribution of all shipments of the suspect lot(s), including complete names and addresses of all foreign consignees.
4. 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.
5. 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.
6. 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.
7. Verbally apprise management that the district 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, district personnel should determine whether similar complaints have been entered into FACTS. For devices, search CDRH's MAUDE database or contact CDRH's Division of Surveillance Systems, Information Analysis Branch (HFZ-531) to retrieve complaints. For drugs, contact CDER's Division of Compliance Risk Management and Surveillance, (HFD-330) 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 district will contact the district where the violation occurred and request an inspection of the responsible establishment. The investigating district, in turn, should keep the monitoring district 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 district 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, district personnel should obtain documentation of actions taken to dispose of or recondition the recalled products. This documentation may include processing records or laboratory analysis, signed destruction receipts, salesperson's written receipts, corporate official's signed statement on firm's stationery, etc. The district 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 district should notify the CRU and OE/DCMO. The district 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.

Official Samples

The district 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 district management prerogative unless required by specific headquarters' initiated assignments, or the occasional direct request from the CRU or OE/DCMO. Samples collected should document interstate movement as well as the violation.

Guidance to the Recalling Firm

The monitoring district office will offer guidance to the recalling firm and will assist the firm in composing the text of recall communications to consignees so that the product will be promptly removed or corrected. The notification should be brief and to the point. It should clearly identify the product, potency, dosage, type, model and/or lot number(s), contain a concise statement of the reason for the recall, the known or potential hazard(s), the initial shipping date, and instructions for consignees to follow in handling the recall. If the depth of the recall is to the retail, hospital, physician or consumer level, the direct accounts should be instructed by the recalling firm to contact any sub-accounts that may have received the product. See attached Exhibit 7.4 for a model letter. The possible necessity for bilingual or multilingual notifications should be explored with the firm.

The instructions should also request direct accounts that are involved in further distribution of the recalled product to promptly initiate recall communications with sub-accounts. The written communiqué to sub-accounts should be in addition to any other means of notification, such as monthly sales bulletins, manufacturer representative visits, or recorded phone messages on order taking equipment. These actions may aid in a sub-recall effort, but they are an inadequate notification of the recall.

Assure that the recalling firm flags the envelope containing a recall letter, mailgram, telegram, or other type of message as "URGENT DRUG (or FOOD, BIOLOGIC, DEVICE, etc.) RECALL (or CORRECTION)." Letters should be sent first class and, where appropriate, by certified mail.

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. If none of the product is on hand, the letter should direct that the consignee submit a negative report. It should stress prompt return of the card or other report. (See Exhibits 7-4, 7-5, 7-6, and 7-7 for model letters, envelopes, and cards.)

7-5-2 FDA Requested Recall

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 in those limited circumstances when the authority is delegated to a Center Director. In the latter case, the Center Director is responsible for keeping the ACRA appropriately advised. In any event the Center Director must concur with all Action Memoranda required to be submitted to the ACRA for FDA requested recalls.

FDA requested recalls may begin with various communications between the field and headquarters units, but will be 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 OE/DCMO.

DCMO 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 district receives a copy of the letter sent to the responsible firm by either the ACRA or a Center Director, district 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.

NOTE: FDA requested recalls for radiation emitting electronic products may not always follow this procedure. See Attachment E for special instructions.

The district 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 Ordered 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 district 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 district should plan its strategy with direction from the center.

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.

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.

Mandatory Recall of Human Tissue Intended for Transplantation

On December 14, 1993, FDA issued an interim rule (21 CFR Part 1270) establishing a requirement for certain infectious disease testing, donor screening, and recordkeeping to help prevent the transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) through the transplantation of human tissues. Section 1270.43 specifically provides procedures under which FDA may order the recall or destruction of human tissue that has been collected or distributed in violation of the regulations. FDA developed these regulatory requirements under the legal authority of section 361 of the Public Health Service Act (42 U.S.C. 264). The rule applies to banked human tissue such as bone, ligaments, tendons, cartilage, skin, fascia, and corneas intended for transplantation. It does not apply to vascularized organs such as livers, hearts, and kidneys. It does not apply to bone marrow, semen, and human milk or any tissue currently regulated by FDA as a human drug, to medical devices such as heart valves, corneal lenses and dura mater, or to biologicals such as blood and blood products. See RPM Chapter 5, Section 5-6 - Order for Retention, Recall, and/or Destruction of Human Tissue.

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.

Interstate Milk Shipments

The FDA does not ordinarily classify or audit interstate milk shippers (IMS) product recalls where such actions have been, or are being, handled expeditiously and appropriately by the state(s). The FDA district office in which the recalling firm is located must be assured that all states involved in an IMS plant's recall are participating in ensuring removal of the product from commerce and that, when appropriate, states issue warnings to protect the public health. In the event that FDA determines that the states are unable to effect the recall actions necessary, the Agency will classify, publish, and audit the recall, including issuance of a public warning when indicated.

7-6 RECALL CLASSIFICATION AND STRATEGY

The Center Recall Unit (CRU):

- Initiates a health hazard evaluation.
- Finalizes a recall strategy.
- Classifies the recall.
- For Class I recalls, prepares an Action Memorandum for Center Director or his/her designee concurrence before forwarding it to OE/DCMO and the ACRA.
- Updates RES with classification, audit strategy, and any recommendations, and posts the information to the Internet.

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 assure 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 OE/DCMO.

7-6-2 Classification Process

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 OE/DCMO.

The CRU will then review, correct, edit or add information necessary for the FDA Recall web page and then submit it for updating. (The actual updating will occur automatically, once daily, at midnight, so all updates from the previous day will be available the following morning.)

The ACRA has approval authority for all Class I recalls. However, the ACRA has delegated approval of certain Class I recalls to Center Director. This has been done to streamline the recall classification process in the center, expedite the handling of the recall by industry and FDA district 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 or ordered 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.

OE/DCMO may review the Action Memo and discuss it with the CRU before submitting it to the ACRA. When the Center and ORA/OE disagree on aspects of a recall or when the ACRA believes the health hazard evaluation or recall classification warrants additional medical review, OE/DCMO 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 district office is informed by OE/DCMO (via phone) of the ACRA's decision. The classification letter when signed by the ACRA will be mailed to the firm by DCMO. Distribution copies of the final approved documents will be sent to the Center and the district 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 district and OE/DCMO, and the updated information for the FDA website is forwarded for posting.

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 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 assures 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)

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:

1. Depth of recall. The recall may extend to the consumer or user level, the retail level, or the wholesale level.
2. Public warning. All recalls are to be posted by the CRUs to the Internet on FDA's Recall Web page as soon as practical after receiving the RES alert to recall and will be updated by reposting as additional information is received or the recall status changes significantly. However, 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 OPA's Media Relations Staff (HFI-20). Similar Information may also be posted on Med Watch.
3. 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.

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, 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 district'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 District Recall Coordinator and OE/DEMO 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 district, will consult with OE/DCMO 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 assure 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.

7-7 NOTIFICATIONS AND PUBLIC WARNING

7-7-1 Reports And Reporting Procedures

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.

Status Reports

District 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." They will so advise the CRU, which will then update the FDA web page by reposting the recall record.

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

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

District Notification to the Recalling Firm

The monitoring district, 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 district 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 district 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 district director or his/her delegate. It should also include the name and telephone number of the district'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 district 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 district 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.

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

OE/DCMO is responsible for maintaining contacts and notifying headquarters organizations about significant recalls. These include the CRU, Division of Federal State Relations (DFSR), International Relations Staff (IRS) in the Office of International Programs, Media Relations Staff in the Office of Public Affairs, and the Division of Compliance Information and Quality Assurance (DCIQA) in the Office of Enforcement. In emergency recall situations, DCMO will keep FDA's Emergency Operations Center apprised of recall status. DCMO advises the USDA, DOD, and Canada of recalls in which they are involved.

Notification of State and Local Officials

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

DFSR 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. DFSR also distributes other publicity prepared by the Office of Public Affairs (HFI-3), to these officials.

Foreign, Military, and Other Federal Government Distribution

For Class I recalls, the district coordinator should submit a list of foreign, military, and other federal government consignees to OE/DCMO. Submit Canadian, military, and other federal government consignees involved in Class II recalls. In addition, provide OE/DCMO with Canadian consignees of Class III recalls. If Canadian distribution is refused, provide the name and phone number of the responsible individual at the recalling firm so that it may be provided to Canadian officials. Distribution information may be submitted separately by facsimile or email, or may be included in the appropriate field in RES.

OE/DCMO notifies the International Relations Staff of the Office of International Programs of all Class I recalls where product was distributed to foreign countries except Canada.

OE/DCMO informs IRS of specific foreign consignees. OE/DCMO also responds through IRS to all requests for recall information from American embassies.

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

OE/DCMO notifies IRS of recalls of imported products to expedite locating all importers of the violative product.

OE/DCMO 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.

Responsibility and Procedures - OC, Office of International Programs, International Relations Staff (HFG-1)

For all Class I recalls involving foreign consignees other than Canadian, OIP/IRS 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 OE/DCMO.

At the request of OE/DCMO, OIP/IRS 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 OE/DCMO.

OIP/IRS coordinates the development of responses to foreign embassy inquiries with the

centers and OE/DCMO.

OIP/IRS provides the CRU and OE/DCMO 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.

Responsibilities and Procedures - Division of Compliance Information and Quality Assurance (HFC-240)

OE/DCMO notifies the Division of Compliance Information and Quality Assurance (DCIQA) 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.

DCIQA 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.

DCIQA 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 OE/DCMO.

7-7-3 Public Warning

All industry product removal or corrective actions classified by the Agency as recalls will be posted on FDA's Recalls and Safety Alerts web page. All recall alerts and recommendations submitted to the CRUs will, unless determined by the CRU at the outset to be market withdrawals or non-classifiable, be immediately posted by the CRU on FDA's Recalls web page. These recall postings will then be updated by the CRU as they are classified and/or when significant changes, recall extensions, etc., are provided by the district coordinators or otherwise brought to the attention of the CRU. Additionally, the Office of Public Affairs (OPA) web page manager will update the recall document with Internet addresses for any press statements issued either by FDA, a state agency, and/or the recalling firm.

It is FDA's policy 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 policy gives 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. The OPA Media Relations Staff, the CRU and/or OE/DCMO Recall Staff are available to provide assistance. The CRU will also assist the OPA Media Relations Staff, along with the district recall coordinator and OE/DCMO, in the preparation of FDA publicity.

If hazardous products contain defects that require extensive design and/or test time to assure 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.

District recall coordinators will promptly provide (electronically if possible) copies of all recalling firm or State agency issued press releases to the OPA Field Liaison Officer, the FDA Website Management Staff, the CRU and OE/DCMO. 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.

Responsibilities and Procedures – Associate Commissioner for Public Affairs

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

When a recall's strategy includes FDA publicity, prepares and issues publicity with the assistance of the appropriate center, district, and OE/DCMO. Obtains ACRA concurrence on all recall publicity.

Alerts the appropriate home district of the expected release of publicity.

Through the Media Relations Staff (HFI-21), assures that recall actions are included in the FDA Enforcement Report until such time as the Internet portion of RES is made available to the public on FDA's website, and the Agency concludes that the Enforcement Report may be discontinued.

Specifically, the staff will:

- Complete the recall entry for the FDA Enforcement Report upon receipt of the recall classification and number(s) from the CRU.
- Coordinate the development of the draft and final report with the CRUs and OE/DCMO.
- Distribute the report to ORA headquarters and field offices, the press, other federal government agencies, consumers, and the CRUs.

Note: As soon as the Internet portion of RES is released to the public, recall information provided by the field and centers will be uploaded on a real time basis onto a FDA web page without OPA involvement with one exception. The Website Management Staff will be provided press releases from recalling firms and/or state agencies. The link to the press release will then be provided on the specific recall web page.

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

Evaluates the effectiveness of recall publicity and, if determined to be inadequate, initiates action to assure effective notice. 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 policy of 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

FDA Recall Audit Program Development

The CRU reviews the district 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 assure its adequacy and to reflect changes in the health hazard evaluation, classification, effectiveness of firm's recall, etc.

Factors in Audit Program Development include:

- Special procedures for monitoring the recall at the firm
- Level and type of audit checks to be conducted
- Special reporting requirements

OE/DCMO concurs in the use of personnel resources for audit checks for ORA.

District Responsibilities

In summary, the districts:

- Issue audit check assignments (monitoring district)
- Complete assigned audit checks (monitoring and other districts)
- Notify the CRU and OE/DCMO of progress on recalls and ineffective recalls

The monitoring district director has the overall responsibility for assuring 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 assure 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 district 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 OE/DCMO should be kept informed of such recommendations.

Audit Check Issuance

Normally within 10 days of issuance of the firm's recall communication, the monitoring district 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 district 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 district considers the 10-day requirement inappropriate, they should recommend to the CRU a new date for issuing the audit checks. The monitoring district must provide specific instructions as appropriate when issuing an assignment to another district 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 district should forward a copy of Class I audit check assignments to the CRU and to OE/DCMO.

Audit Check Completion

The district 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 district. If possible, complete assignments within 10 working days from receipt of the assignment. For Class I recalls, provide audit check reports to the monitoring district 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 assure 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 district and CRU must consider the need for such checks in each recall situation.

The issuing district will evaluate audit check reports when received to ensure that they are adequate and then retain them. If insufficient information has been collected, the issuing district recall coordinator will advise the endorsing supervisory investigator.

It is the responsibility of the receiving district to notify the issuing district 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 OE/DCMO (HFC-210).

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 district may either prepare information handout sheets or copy the recalling firm's recall communication so that copies may be left with consignees.

1. 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.

2. 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.

3. Sub-Recall Refusals.

If the direct or sub-account refuses to initiate recall promptly, the district performing the audit check will advise the monitoring district, OE/DCMO, and appropriate CRU of the situation, and indicate what additional steps the district is taking to achieve a satisfactory sub-recall. Options for consideration include meetings between district 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.

4. Responsibility.

The district 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 district, the CRU, and OE/DCMO should be kept advised of such recommendation.

5. Injury/Illness/Data.

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

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 district 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 district 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 district will notify the CRU and OE/DCMO 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.

7-9 RECALL TERMINATION

FDA will terminate a recall when the monitoring district office determines that the recalling firm has completed all recall activity, including monitoring and final product disposition. The district 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 district 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 district concludes that such a recall or Safety Alert has been completed, the district 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 district 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 district and OE/DCMO 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 ClassII/III Termination" button. The RES then generates an email to the Center and OE/DCMO that the recall has been terminated by the district.

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

the best course of action.

NOTE: Before any FDA approval or concurrence is provided to plans for the disposition of recalled products, the district 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 AND EXHIBITS

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 district 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 Mandatory Recalls of Human Tissue Intended for Implantation
- I Methods for Conducting Recall Effectiveness Checks

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)

Attachment A – Recall Alert Information

Submit the information listed below to the CRU and OE/DCMO via RES:

- Product(s) Description
- Codes
- Recalling Firm
- Short Reason for Recall
- District 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 OE/DCMO 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. For biological recalls obtain the recalling firm's License/Registration number. These items are to be inserted on the appropriate Center specific pages.

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 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), DOD Hospitals, Department of Veterans Affairs (DVA), 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 district R&E Coordinator to OE/DCMO. 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 district'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. District Audit Program (RES Event Details page)

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

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

1. **Product:** See Attachment B.
2. **Codes:** See Attachment B.
3. **Recalling Firm/Manufacturer:** See Attachment B.
4. **Reason for Recall Recommendation:** See Attachment B.

5. 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.

6. **Distribution:** See Attachment B.

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

8. Violation:

Provide the section of law violated.

9. Preventive Action:

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

10. District 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 district'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 district 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 district coordinator or other district personnel will prepare and submit, after coordinator review, the recall document to district management for concurrence. The name of the district 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 OE/DCMO.

When the district obtains concurrence from district management for the termination of Class II and III recalls and so updates the RES recall record, the coordinator electronically notifies the CRU and OE/DCMO of the termination.

Attachment D - Health Hazard Evaluation Worksheet

Note: The following Health Hazard Evaluation Worksheet has been developed by the Agency to provide uniformity in HHEs. **It 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**
-

For use only by the Center for Food Safety and Applied Nutrition

(a) _____ Product is statutorily* unsafe within the meaning of _____ >
(Sign form on page ____)

* Product contains an ingredient/additive that is not used in accordance with the regulations that provide for safe conditions of use.

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

___ Temporarily 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 policy (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),
4. and 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.

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.

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?

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? Others above risk for "normals?"
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?

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

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.

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 district and the Press Office (HFC-21) 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 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 district processes recalls for X-ray assemblers and suntan lamp recalls. The home district office will still continue to submit a Recommendation for Recall for cases generated in the field. The districts will approve the corrective action plans for these cases, and submit a copy of the district 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 district 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 districts. Upon receipt of the completed audit check reports from the districts, the home district 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 will send the firm a warning letter when the target completion date expires.

The home district 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 OE/DCMO by the home district.

At the conclusion of the recall, the home district 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.

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.

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:

1. 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?

2. Are other administrative or enforcement actions more appropriate to address the problem?
Seizure or detention may be a lesser agency burden and may address the health risk situation more effectively.
3. GMP issues alone will not support the contention that use of the device will cause serious adverse health consequences.

If the district office believes this threshold has been met, a recommendation should be submitted to OC, HFZ-300. Before the district submits a 518(e) recommendation, the firm should be fully apprised of our concern and have been given an opportunity to initiate corrective action.

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

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.

The Office of Compliance (OC), CDRH, 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 – Mandatory Recalls of Human Tissue Intended for Transplantation

If, following issuance of an Order for Retention, Recall, and/or Destruction pursuant to the regulation at 21 CFR 1270, a firm initiates a recall of human tissue intended for transplantation, the Office of Compliance and Biological Quality, CBER, has determined the following to be appropriate.

1. A recall recommendation should be generated by the field and forwarded to CBER for evaluation. It is not necessary for the district office to send copies of documents already submitted to HFM-650 in support of the original recall order; however, the firm's recall letter and complete distribution information should be forwarded with the recall recommendation.
2. Considering the authority provided by the regulation to issue a recall order prior to a health hazard evaluation, it has been determined that assignment of class I, II, or III, under 21 CFR Part 7 may be unnecessary. However, CBER will perform a health hazard evaluation based on information regarding the donor population, extent of processing the tissue, viral marker testing, and donor suitability.
3. CBER will assign a recall ("B") number to the FDA ordered recall action.
4. The recall action will be published in the FDA Enforcement Report in a section entitled, "Human Tissue Mandatory Recall" which will be inserted under the "BIOLOGICS" heading before the "class I" heading.

CBER's review and processing of tissue recalls is consistent with 21 CFR Part 7.

Attachment I – Methods for Conducting Recall Effectiveness Checks

INTRODUCTION

In the Federal Register of June 16, 1978, (43FR26202), 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.

METHODS

1. 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.

2. 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.

Exhibit 7-1
MODEL EFFECTIVENESS CHECK LETTER (INDUSTRY)Consignee
Name and Address

Date

(Pressure Sensitive
Label)

Dear Sir:

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

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

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

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

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

Thank you for your cooperation.

Sincerely,

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

Exhibit 7-2
MODEL EFFECTIVENESS CHECK RESPONSE FORMAT (INDUSTRY)

Consignee Name and Address
(Pressure Sensitive Label)

Recall Effectiveness
Checks-Mail Method

JOHN DOE PRODUCT RECALL

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

DATE _____

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

YES _____ NO _____

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

YES _____ NO _____

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

YES _____ NO _____

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

YES _____ NO _____

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

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

YES _____ NO _____
If yes, please provide details.

Name of person completing questionnaire:

Exhibit 7-3**MODEL EFFECTIVENESS CHECK QUESTIONNAIRE FOR TELEPHONE OR PERSONAL VISITS (INDUSTRY)**

Consignee Name and Address
(Pressure Sensitive Label)

JOHN DOE PRODUCT RECALL

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

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

DATE _____

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

YES _____ NO _____

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

YES _____ NO _____

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

YES _____ NO _____

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

YES _____ NO _____

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

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

YES _____ NO _____

If yes, please provide details.

Thank you for your cooperation.

And your name is _____

And what is your title please? _____

Interviewer _____

Date _____

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

Exhibit 7-4
MODEL RECALL LETTER (GENERIC, ALL CENTERS)

<COMPANY LETTERHEAD>

URGENT: < *Insert FOOD, DRUG, MEDICAL DEVICE, BIOLOGIC, COSMETIC, etc.* > **RECALL**

<DATE>

<Contact name or Dept.>

<Firm Name>

<Address>

<City/state/zip>

Dear < >:

This is to inform you of a product recall involving:

<Insert: PRODUCT NAME, BRAND NAME, DESCRIPTION, UPC CODES, LOT NUMBERS>

See enclosed product label <for ease in identifying the product at retail/user level>.

This recall has been initiated due to <problem>. Use of <or consumption of> this product may <include any potential health hazard>.

We began shipping this product on <date> (or) This product was shipped to you on <date>. (If possible, provide consignee with shipping dates and quantities shipped.)

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.

Enclosure(s)	Name Title
--------------	---------------

Exhibit 7-5
MODEL RECALL RETURN RESPONSE FORM

<COMPANY LETTERHEAD>

<insert product>
 <insert lot numbers>

Please check ALL appropriate boxes.

- I have read and understand the recall instructions provided in the <date> letter.
- I have checked my stock and have quarantined inventory consisting of _____ <units or cases>.
- Indicate disposition of recalled product:
- returned (**specify quantity, date and method**)/held for return;
 - destroyed (**specify quantity, date and method**);
 - relabeled (**specify quantity and date**);
 - quarantined pending correction (**specify quantity**);
 - transfused – Blood or blood products (**specify date and quantity**);
 - implanted (**specify date and quantity**)
- I have identified and notified my customers that were shipped or may have been shipped this product by (**specify date and method of notification**); <or>

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

Any adverse events associated with recalled product? Yes NO

If yes, please explain: _____

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

- | | |
|---|--|
| <input type="checkbox"/> wholesaler/distributor | <input type="checkbox"/> retailer |
| <input type="checkbox"/> grocery corporate headquarters | <input type="checkbox"/> food service/restaurant |
| <input type="checkbox"/> repacker | |
| <input type="checkbox"/> manufacturer | |
| <input type="checkbox"/> pharmacy - retail | <input type="checkbox"/> hospital/medical facility |
| <input type="checkbox"/> hospital pharmacies | <input type="checkbox"/> medical laboratory |
| <input type="checkbox"/> Other: _____ | |

Name: _____

Title: _____

Tel. number: () _____

Firm name: _____
address: _____
city/state: _____

PLEASE FAX COMPLETED RESPONSE FORM TO Tel. # < >, ATTN: < >

OR MAIL TO: 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" issued June 16, 1978 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) District 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 district will determine who receives the firm's responses.)

Our judgement 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 (in other acts as appropriate).

Your response to this letter should be addressed to: (District Director).
Your cooperation in this matter is obviously important for the protection of the
general public.

Sincerely yours,

District Director
_____ District

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 ...

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,

District Director
_____ District

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,

District Director
_____ District

**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,

District Director
_____ District

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 district 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 District - Enter the code for the district conducting the audit check.
 - b. Home District - Enter the code for the home district 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 district 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 district.

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 DISTRICT CODE
 - b. HOME DISTRICT CODE
 - c. OPERATION CODE - 17
 - d. OPERATION DATE - MO DA YR
 - e. CENTRAL FILE NUMBER OF RECALLING ESTABLISHMENT
 - f. PAC CODE
 - g. EMPLOYEE - HOME 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 DISTRICT AND COPY TO OE/DCMO (HFC-210)

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: _____

DISTRICT:

DATE OF CHECK:

Exhibit 7-13
WEEKLY CLASS I RECALL STATUS REPORT (OPTIONAL)

Districts monitoring certain Class I certain recalls may be requested to submit a weekly status report by either the CRU or OE/DCMO. (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 OE evaluation of the recall's progress or effectiveness.