CHAPTER 7 - RECALL ACTIVITIES

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SUBCHAPTER 7.1 - RECALLS

7.1.1 - DEFINITIONS

7.1.1.1 - Recall

A Recall is a firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers, and against which the Agency would initiate legal action (e.g., seizure). Recall does not include a market withdrawal or a stock recovery. See the Agency recall policy outlined in 21 CFR 7.1/7.59 - Enforcement Policy - General Provisions, Recalls (Including Product Corrections) - Guidance on Policy, Procedures, and Industry Responsibilities.

7.1.1.2 - Recall Classification

Means the numerical designation, i.e., I, II, or III, assigned by the FDA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

7.1.1.2.1 - CLASS I RECALL

A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

7.1.1.2.2 - CLASS II RECALL

A situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

7.1.1.2.3 - CLASS III RECALL

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

7.1.1.3 - Recall Type

A designation based on whether the recall is Voluntary, FDA Requested (at the request of the Commissioner or his designee), or ordered under section 518(e) of the FD & C Act [21 U.S.C 360h (e)].

7.1.1.4 - Recall Strategy

A planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

7.1.1.5 - Depth of Recall

Depending on the product's degree of hazard and extent

of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, i.e., wholesaler, retailer, user/consumer.

7.1.1.6 - Recall Number

Number assigned by a responsible Center for each recalled product they initiate. This number consists first of a letter designating the responsible Center (see letter Codes below), a 3-digit sequential number indicating the number of recalls initiated by that Center during the fiscal year, and a 1-digit number (the Center for Devices and Radiological Health (CDRH) uses 2-digit numbers) indicating the fiscal year the recall was initiated. For example: F-100-2 identifies the 100th recall initiated by the Center for Food Safety and Applied Nutrition (CFSAN) in FY-2002. The following letters are used to identify the Centers.

Letter Center/Office

F Foods - CFSAN

D Drugs - Center for Drug Evaluation and Research (CDER)

Z Medical Devices & Radiological Health - CDRH

V Veterinary Medicine - Center for Veterinary Medicine (CVM)

B Biologics - Center for Biologics Evaluation and Research (CBER)

N Medical Devices (Voluntary Safety Alerts and Notifications)

A Audit Numbers issued by the District performing the recall, the Centers, Office of Enforcement (Division of Compliance Management and Operations [DCMO], or the Division of Field Investigations (DFI) to monitor recalls requiring audit checks.

7.1.1.7 - Medical Device Notification Order

An order issued by FDA requiring notification under section 518(a) of the FD & C Act [21 U.S.C. 360h (a)]. The directive issues when FDA determines a device in commercial distribution, and intended for human use, presents an unreasonable risk of substantial harm to the public health. The notification is necessary to eliminate the unreasonable risk of such harm, and no more practicable means is available under the provisions of the Act to eliminate such risk.

7.1.1.8 - Medical Device Notification

A communication issued by the manufacturer, distributor, or other responsible person in compliance with a Notification Order. It notifies health professionals and other appropriate persons of an unreasonable risk of substantial harm to the public health presented by a device in commercial distribution.

7.1.1.9 - Medical Device Safety Alert

This is a communication voluntarily issued by a manufacturer, distributor, or other responsible person (including FDA). It informs health professionals and other appropriate persons of a situation which may present an unreasonable risk to the public health by a device in commercial distribution.

NOTE: Medical Device Notifications and Safety Alerts as described in IOM 7.1.1.7, 7.1.1.8, and 7.1.1.9 are to be handled by the Districts as recalls. They will go through the stages of alert, recommendation, classification, field notification, firm notification letter, firm effectiveness checks and status reports, FDA audit checks, and termination recommendations.

SUBCHAPTER 7.2 - RECALL NOTIFICATION/INSPECTION

If FDA learns of a potentially violative product which may lead/has lead to a class I or significant class II recall, an inspection should be made to determine the root cause(s) of the problem(s). If the firm has failed to take appropriate preventive action, violations should be documented for possible regulatory action.

NOTE: In all discussions of violative or potentially violative products with the responsible firm, make it clear FDA is not requesting recall action. FDA requested recalls are authorized only by ORA, or by delegation of authority such as Drug Efficacy Study Implementation (DESI) recall requests.

When an investigation determines there is no evidence of manufacturing or distribution problems, but a firm has removed products from the market as a result of actual or alleged tampering with individual units, the action will be considered a Market Withdrawal. A market withdrawal means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.

7.2.1 - INSPECTION PROCEDURES

An important part of your job is to identify the root cause for the recall and assure the firm has implemented procedures to prevent it from reoccurring. In some cases, management will have conducted its own analysis and reached conclusions about the problem and its cause. The initial judgments about the problem are not always correct nor discriminating enough to identify the underlying causes. You need to verify the steps taken were sufficient in depth and scope and reflect the correct conclusions about both the problem and correction.

Determine if the firm conducted a failure analysis using techniques such as fault tree analysis or failure mode analyses. Did it consider things such as the length of time the product has been manufactured and sold, complaints or returns for the same or similar problems, any reworking

of product prior to release or distribution which may have been due to the same or similar problems and, process or personnel changes which occurred about the time the problem appeared.

For all recall inspections, in addition to verifying the identification of the root cause:

1. Issue a Notice of Inspection (FDA 482)
2. Discuss the suspected problem with management and review the firm's complaint file.
3. Investigate all areas, control points and/or circumstances which may have a bearing on the product's deficiency.
4. Fully develop individual responsibility for the problem.
5. Review batch records, processing logs and/or other types of records for violative lots and associated lots.
6. Review and obtain copies of the firm's quality control/analytical data.
7. Determine any actions the firm has taken, is taking, or has planned to take to prevent similar occurrences. If corrective action is not underway, determine the firm's timetable for achieving correction.
8. Determine what action the firm has taken or plans to take, and the time frames involved, regarding questionable product(s) remaining in commerce.

7.2.1.1 - Recall Decision Follow-up

If the firm has decided to recall, do the following:

1. Request that management obtain their FDA District's review of recall correspondence and any press releases before they are issued to prevent misunderstandings between the firm, its customers, and the FDA. This suggestion is voluntary on the part of the firm and is not required.
2. If the firm requests guidance in preparing recall communications, provide it in accordance with your District policy. See Chapter 7 of the RPM and IOM Exhibit 7-1 for an example of recall communications.
3. See RPM Chapter 7-10, Attachment B "Recommendation for Recall Classification" and 21 CFR 7.46a(1)-(9) for information to be obtained.
4. Obtain an Official Sample of the recalled product. (See IOM 7.2.6 for the collection of samples for electronic products or medical devices.)
5. Obtain a complete distribution list of all shipments of the suspect lot(s), including foreign distribution.
6. Obtain specimens or copies of all labels and labeling associated with the recalled product.
7. Obtain complete copies of all recall communications issued or planned including the text of phone conversations, and submit them to your District's recall coordinator. Look in the Blue Pages for a list of District Recall Coordinators.
8. Advise the firm on how the returned products should be handled. FDA must witness or otherwise verify the reconditioning or destruction of the products returned under the recall.
9. Take any other steps necessary in your judgment, or that your District requires.

NOTE: At this early stage there usually has not been a recall evaluation by the appropriate Center. In the absence of such an evaluation, avoid suggesting the firm extend its recall efforts.

7.2.2 - FOOD RECALLS

Experience with food recalls dictates specific information be obtained from firms which have used recalled material in the production of another product. This is necessary to decide if the recall must be extended to a new product(s). In those instances, the following are some areas to be covered:

1. Incoming ingredient quality control procedures.
2. Quality control over ingredients at the time of use, and the products in which the ingredients are used.
3. A detailed description of the methods used in preparation and packaging of the processed product.
4. How the finished product is stored and shipped.
5. Labeling of product, and any cooking instructions for consumer or purchaser.
6. Quality control testing of the finished product. Detail any test(s) performed by firm.
7. For products produced in USDA plants, determine if the USDA was notified of the suspect incoming ingredient? Did USDA determine what testing was done by the firm?

This information must be evaluated by CFSAN (HFS-607) prior to the initiation of any sub-recall.

7.2.2.1 - Interstate Milk Shippers

The FDA will not ordinarily be involved in the classification and auditing of Interstate Milk Shippers (IMS) product recalls where such actions have been, or are being, handled expeditiously and appropriately by the State(s). However, 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.

7.2.3 - MEDICAL DEVICE RECALLS

Medical device recalls may result from manufacturing defects, labeling deficiencies, failure to meet premarketing requirements [PMA, 510(k)], packaging defects or other nonconformance problems. How firms identify the causes of medical device recalls and corrective action activities is essential to the analysis of medical device failures and the determination of the effectiveness of the medical device GMP program. It is also useful in evaluating the medical device program, and for directing attention to problem areas during inspections. 21 CFR Part 806.1 requires device manufacturers and importers to report certain actions concerning device corrections and removals. They

must also maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA. (See 21 CFR Part 806.20). Failure to report as required by 21 CFR 806.10 is a violation and should be listed on the FDA-483, "Inspectional Observations." This may be included in a direct reference Warning Letter.

Each device manufacturer or importer must submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer, if one was initiated:

1. To reduce a risk to health posed by the device; or
2. To remedy a violation of the Act caused by the device which may present a risk to health, unless the information has been provided according to 21 CFR 806.10 (f), or the correction or removal action is exempt from the reporting requirements under 21 CFR 806.1(b).

Collection of complaint, PMA and 510(k) related information is necessary to determine compliance with the GMP requirements. During recall follow-up inspections, answers should be obtained to the questions below, in addition to routine recall information. For firms where it has been established a manufacturing defect led to the recall, conduct a complete GMP evaluation of the manufacturing operations. Report such inspections into FACTS as "qualifying" GMP inspections.

7.2.3.1 - Problem Identification

1. How did the firm identify the nonconformance which led to the recall, e.g., complaint, in-house data, etc.
2. If the recall was due to a device defect, did the firm conduct a documented failure analysis of the device, using such techniques as fault tree or failure mode analyses? If so, report whether these results were provided for review.
   a. Did the firm determine the failure mechanism, e.g., shorted component, incomplete weld, etc.?
   b. If not, how did firm determine the cause of the nonconformance?
   c. If not, what rationale does the firm have for not conducting a failure analysis?
3. Did the firm determine at what phase of the device life cycle the nonconformance occurred, i.e., design, manufacturing, storage, use, etc., and the actual cause of the nonconformance, for example, software design error, process out of specifications, employee error, user misuse, etc.? What evidence does the firm have to support the determination?
4. Did the firm determine if the nonconformance resulted in an injury or death?
5. If a component was responsible for the defect, determine if the same component was used in other devices manufactured by the firm. If so, has the firm conducted an analysis to assure the defect in the component will not have a deleterious effect on the operation of the other device(s)?
6. If a component was responsible for the device defect, what other device manufacturers use the same component (and especially the same lot number of the component)? Has the manufacturer of the recalled device notified the component manufacturer? Has the component manufacturer contacted its other customers about the problem?
7. Why was the component defective? Did the manufacturer of the component change the specifications without notifying the finished device manufacturer? Did the component fail to meet its release specifications?
   NOTE: A visit to the component manufacturer may be needed to adequately answer questions 5, 6 and 7. Before doing so, confirm with CDRH and your supervisor that the matter is egregious enough to warrant this "next step."
8. Did the finished device manufacturer have an incoming component/raw material sampling and testing procedure? If not, why not?
9. If the manufacturer recalled the device because the labeling was inaccurate, or the wrong labeling was applied to the device (label mix-up) determine the following:
   a. What quality system procedures should have been established to prevent the problem?
   b. If the label or instructions for use were inaccurate, was the inaccuracy introduced in the design stage, or was it due to a printing problem?
10. If the device has been on the market for a year or more, and the manufacturer claims the problem is the result of design:
    a. Why is the problem just now showing up? How many reports concerning the problem did the firm receive before deciding a recall was necessary? Does the firm have a procedure established for determining if a recall is necessary, and if so, did it follow the procedure? Obtain a copy of the procedure.
    b. If the firm doesn't provide rational answers to the above questions, determine if they explored other possible causes for the problem.
    c. Was the design feature which caused the problem included in the design of the device that was the subject of a premarket submission?
    d. If the design feature which caused the problem is part of the original design, did the manufacturer recall all products manufactured since the device was introduced to the market? If not, why not?
    e. If the problem was introduced via a design change, did the manufacturer follow established design change or change control procedures? If yes, are the procedures adequate? Was the nature of the problem such that it should have been anticipated, and the design verification/ validation study fashioned to detect the problem?
    f. Has the manufacturer recalled all products distributed since the design change was introduced? If not, why not?

7.2.3.2 - Corrective Action

1. Describe the corrective action taken to correct the immediate problem, e.g., redesign, modify SOP, process validation, etc.
2. Did the firm qualify/validate the corrective action?

3. Did the firm establish responsibility to assure that the corrective action would be implemented and satisfactorily completed?
4. What action did the firm take to prevent recurrence of the nonconformance, e.g., training, increased process monitoring, etc.
5. Was the nonconformance information provided to those responsible for the areas in which the nonconformance occurred?
6. Did the firm determine if the nonconformance extended to other devices?
7. Did the firm determine if changes were needed in procedures and, if so, did it validate and implement the changes?
8. Has the manufacturer taken appropriate corrective action?

7.2.3.3 - Complaint and Medical Device Reporting (MDR) Reporting

Determine if adequate complaint investigations were performed as required by 21 CFR 820.198(b). Also, determine if the investigation verified the complaint was a failure of the device to meet any or all of its specifications.

For complaints related to the recall, the firm should have made a determination whether the events are MDR reportable. Any event associated with a death or serious injury must be reported under MDR. Malfunctions likely to cause or contribute to a death or a serious injury are also reportable under MDR. Document the firm's explanations for the events they believe are nonreportable. Failure to submit required MDR reports are violations, and should be listed on the FDA-483 at the completion of the inspection.

Provide adequate documentation with the EIR to cross-reference complaints with associated MDRs.

Device Information - Obtain the 510(k) or PMA number for each device under recall. If there is no 510(k) or PMA, determine if the device is a pre-enactment device (i.e., in commercial distribution prior to May 26, 1976). If multiple devices are being recalled, obtain this information for each device model or catalog number under recall.

7.2.4 - DRUG RECALLS

7.2.4.1 - Recalls of Human Drug Products

If the recalled product is covered by a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA), determine if the defective product involves the type of problems shown under CFR 314.81(b)(1)(i) and (ii). Also note whether or not the firm reported the problem to the FDA district office that is responsible for the firm within 3 working days of its receipt of the information, as required by that section.

7.2.4.2 - Recalls of Veterinary Drug Products

Veterinary Drug Products Recalls are classified by and health hazard evaluations are obtained through CVM's Division of Compliance (HFV-230), Neal Bataller, Director. To inquire about specific veterinary drug product recalls or to obtain information on how to proceed, contact the Division at 240-276-9200 or contact Kathy Hemming-Thompson at 240-276-9216.

7.2.5 - HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE BASED PRODUCTS (HCT/PS) FOR IMPLANTATION, TRANSPLANTATION, INFUSION, OR TRANSFER

The agency may consider an order of retention, recall, destruction, or cessation of manufacturing when any of the conditions specified in 21 CFR 1271.440(a)(1) to (3) exist. The conditions include an agency finding that:

1. The HCT/P is infected or contaminated so as to be a source of dangerous infection to humans; or
2. An establishment is in violation of the regulations in this part and, therefore does not provide adequate protections against the risks of communicable disease transmission."

In addition to the conditions noted above, the agency may issue an order of cessation of manufacturing until compliance with the regulations has been achieved, as stated in 21 CFR 1271.440(a)(3), when the FDA determines there are reasonable grounds to believe there is a danger to health. An order to cease manufacturing would be issued where violations create an urgent situation involving a communicable disease, because an establishment is in violation of the regulations in Part 1271 and, therefore, does not provide adequate protections against the risks of communicable disease transmission. An order to cease manufacturing is a remedial action taken to put important protections in place to prevent communicable disease transmission.

NOTE: FDA will not issue an order for the destruction of reproductive HCT/Ps, nor will FDA carry out such destruction itself (21 CFR 1271.440(f)).

7.2.6 - SAMPLE COLLECTION

Collection of samples for regulatory consideration is at the discretion of District management. Consult your supervisor and/or compliance branch for guidance. If a sample is indicated, only collect documentary samples for electronic products or medical devices, unless otherwise instructed.

If, after consulting with the Centers, it is determined that a product must be examined physically for health hazard evaluation, ship an appropriate sample to the designated Center office by the most expeditious and practical means available. Notify the Center of the time and method you sent the product and its estimated time of arrival.

7.2.7 - RECALL ALERT

When a District learns of or confirms a recall situation exists or is planned, they will give the appropriate Center

Recall Office and OE/DCMO (HFC-210) a twenty-four hour alert. See RPM Chapter 7-10, Attachment A "Recall Alert Information."

7.2.8 - RECOMMENDATION FOR RECALL NUMBER

A memorandum should be prepared as soon as the recall number is available, and transmitted to your District's R&E Coordinator through your Supervisor. Do not wait for writing, typing and submission of the EIR. A copy of the memo may be attached to your EIR so the information need not be repeated in the body of the report. From the time the recall alert is sent to the appropriate Center, the district has five days to submit the Recall Recommendation (ten days if the recall is completed). See RPM Chapter 7-10, Attachment B "Recommendation for Recall Classification."

7.2.8.1 - Product

For each recalled product, provide: its name; type (e.g. tablet, sugar coated); strength; sizes; form; route of administration; shipping or unit package; and a brief description of the product and its use. If it is a drug product, indicate whether it is a prescription (Rx) or Over-the-Counter (OTC) product. 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 that information.

For each recalled product also provide: the brand name; name, address, and type of responsible firm on label; number and description of private labels. Complete copy of all labeling (including product inserts or information sheets). These must be sent to the appropriate Center by an expeditious method.

7.2.8.2 - Code

List all lot and/or serial numbers, catalog numbers, product numbers, packer or manufacturer numbers, etc., which appears on the product or its labeling.

7.2.8.3 - Recalling Firm/Manufacturer

Provide complete name and address of the recalling firm, and identify the type of firm, i.e., manufacturer, importer, broker, repacker, own label distributor. Provide complete name and address of the manufacturer, if different from the recalling firm. Also identify firms which processed or handled the product, or supplied components which might have been responsible for the problem. Indicate which firm(s) appear(s) responsible for the violation.

7.2.8.4 - Reason for Recall Recommendation

Provide detailed information as to how the product is defective and violates the FD&C Act or related statutes.

1. Include any analytical findings in qualitative and/or quantitative terms, whether from the firm or FDA analysis, and which laboratory was involved.
2. Provide inspectional (e.g., GMP) or other evidence, where appropriate.
3. List in chronological order any complaints, injuries, or associated problems with the product. Include any MDR's that have been submitted.

If firm management was advised of FDA findings, and the problem was discussed with them, report their reactions and plans. If the firm advised FDA of the problem, report and explain firm's own analytical results and how it learned of the need for a recall.

Explain all State involvement in the recall, including sample collection or analysis, recall agreement or initiation, recall monitoring, and product disposition.

For DESI related recalls, use the following terminology: "Federal Register Publication (date), Drug Efficacy Study Implementation."

In cases where a veterinary drug product is recalled due to subpotency prior to labeled expiration date provide the following information:

1. The firm's stability testing plan (including the 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.

Note if information regarding stability data on file with the firm, and the Quality Control (QC) procedures used by the firm to determine the potency of the active ingredients, is available in the EIR.

7.2.8.5 - Volume of Product in Commerce

Provide total volume of product(s) distributed. Provide estimate of amount and availability of stocks remaining on market, at all levels. (Indicate whether this is the firm's or FDA's estimates.) Include product expiration dates or shelf life expectancy.

NOTE: If recommendation is for an FDA Requested Recall, assure there is, in fact, product remaining in commerce.

7.2.8.6 - Distribution Pattern

Report the areas of distribution, the number of direct accounts, the approximate percentage of each type consignee, and the percentage of product sent to each type of consignee. List foreign countries and U.S. Government military and/or civil units/agencies to which

product(s) were distributed. If various labels are involved, describe any differences in distribution pattern.

Where there were any Defense Personnel Support Center (DPSC), Department of Veterans Affairs (DVA), or other government agency sales/distribution, the consignee list should be submitted separately through your District's R&E Coordinator to OE/DCMO. Show if these were direct or contract sales. If contract sales, report the contract number, contract date, and implementation date.

7.2.8.7 - Firm's Recall Strategy

Describe the firm's planned recall strategy. Comment on the adequacy of this strategy from your District's viewpoint, and evaluate the firm's ability to accomplish an effective recall. See Sections 7.42 and 7.46 of 21 CFR, Part 7, which set forth information to be obtained from the firm which will be evaluated by the Center. The firm's strategy should include the intended course of action when an account which distributed the recalled product is found out of business. Include the date the recall was initiated, if already underway.

7.2.8.8 - Firm Official

Report the name, title, location, and telephone number of the firm official who should be contacted concerning the recall. In case of potential Class I or FDA requested recalls, also provide this information for the firm's chief executive officer (CEO).

7.2.8.9 - District Audit Program

Report what actions have already been taken (FDA inspections, sample collections, etc.). Provide specific recommendations for the appropriate Center's action, where appropriate.

Provide details of any publicity issued or planned by FDA, the firm, the State, or local government.

Provide your District's proposed program for monitoring the recall. Include time table for reviewing the recall status and the level and type of audit checks which will verify the recall's effectiveness.

7.2.8.10 - Recommending Official

Name and title of your District's recommending official.

SUBCHAPTER 7.3 - MONITORING RECALLS

7.3.1 - INSPECTIONS TO MONITOR RECALL PROGRESS

It may be necessary to re-inspect the firm between the initiation and closeout of a recall to monitor its progress and verify the recalled product's disposition. These visits are limited inspections; issue an FDA-482, Notice of Inspection, at each one. Request recalling firms to submit periodic status reports to FDA. See 21 CFR 7.53.

7.3.2 - FDA RECALL AUDIT CHECKS

7.3.2.1 - Definition

A recall audit check is a personal visit, telephone call, letter, or a combination thereof, to a consignee of a recalling firm, or a user or consumer in the chain of distribution. It is made to verify all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action.

7.3.2.2 - Level of Audit Checks

Level A - 100% of the total number of consignees to be contacted.

Level B - Greater than 10% but less than 100% of the total number of consignees to be contacted.

Level C - 10% of the total number of consignees to be contacted.

Level D - 2% of the total number of consignees to be contacted.

Level E - No effectiveness checks.

NOTE: A statistical audit plan may be directed by the Center involved.

7.3.2.3 - Sub-Account Checks

If a recall strategy includes sub-recall by a firm's direct accounts, sub-recall checks will be made following the above levels, as instructed by the Center and your supervisor.

7.3.2.4 - Conducting the Check

Your assignment contains the necessary details of the recall, recall strategy, and a list of accounts to be checked. The Center will indicate how checks will be made, i.e., visit, phone calls, record checks, etc. Obtain at least the following information, plus any additional information requested by the monitoring district or your home District:

1. Name and title of person interviewed.
2. Was notification received, understood, and followed?
3. Date and method of notification.
4. Amount of recalled product on hand at time of notification.
5. Amount returned and the method of return.
6. Amount destroyed and method of destruction.
7. Amount presently on hand and its status (held for sale, awaiting return, etc.).
8. Date of anticipated return or destruction, and planned method (if applicable).

9. Was sub-recall conducted? (If so, obtain a list of consignees from which to select your sub-recall check locations).
10. Have injury reports or complaints been received? If so, report details.

When you conduct an audit check by visit, you should visit the storage sites for the recalled product and check the shelf stock to ensure all recalled product has been identified, removed from areas of use and properly quarantined. In firms where products are stored in multiple locations, a sufficient number should be checked to verify the consignee properly found and removed all product subject to the recall. This is especially important in Class I recalls and you should check each storage site.

7.3.2.5 - Audit Check Reporting

The narrative results of your audit check should be reported on an FDA 3177, "Recall Audit Check Report" form. See IOM Exhibit 7-2. Districts have the option of using computer generated audit check forms or hard copies. The FDA 3177 is a three-part form, which is basically self-explanatory. If necessary, instructions for completing it may be found in RPM, Chapter 7, Exhibit 7-12. It is distributed as follows:
Original - Monitoring district.
Yellow Copy - Accomplishing district files.
Pink Copy - District Use

Version 2 of FACTS allows you to enter the amount of time and other data information. When you complete Recall Audits, you should report your time using the "Miscellaneous Operations Accomplishment Hours" screen. You do not need to report the information on the 3177 unless your District SOP requires this. Until some other reporting procedure is developed, continue to report audit checks using the FD-3177 form or memorandum.

7.3.2.6 - Ineffective Recalls

If your audit check discloses recalled product being held for sale, or a requested sub-recall has not been initiated, document the responsibility for failure to follow recall instructions. This is particularly important if the account received the recall notice and ignored it. An Official Sample should be collected from these remaining products. If in doubt, contact your supervisor or R&E Coordinator. Encourage the consignee to follow the recalling firm's instructions. If a sub-recall is justified, obtain a commitment and details of the firm's sub-recall effort. Get distribution information for follow-up sub-account audit checks.

7.3.3 - RECALL TERMINATED/RECALL COMPLETED

7.3.3.1 - Definitions

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

Recall Completed - For monitoring purposes, the FDA classifies a recall action "Completed" when all outstanding product, which could reasonably be expected is recovered, impounded, or corrected.

7.3.3.2 - Closeout Inspection

The final monitoring step is a limited inspection made to verify recall closeout by the recalling firm. A memorandum or limited EIR should be prepared. See RPM Chapter 7, Attachments B1, “Recommendation for Recall Classification and Termination” and Attachment C, “Recall Termination or Recommendation for Termination” for the format. Portions of this format (i.e., Section II and certain items in Section III) will be completed by your supervisor, R&E Coordinator, or compliance officer, depending upon your District's policy.

During the closeout inspection, you should witness destruction or reconditioning of the recalled product when possible. If you are unable to witness the destruction or reconditioning, obtain written documentation from the firm and/or any state or local government agencies which may have witnessed or otherwise verified product disposition. The disposal of large amounts of contaminated or hazardous items may require the firm to file an Environmental Impact Statement (EIS), or pre-disposal processing to render the goods harmless. Do not agree to witness destruction without resolution of these issues. Obtain a "Letter of Voluntary Destruction" from the firm whenever you witness this operation. See IOM 2.6.4.1.

SUBCHAPTER 7.4 - SPECIAL RECALL SITUATIONS

7.4.1 - General

There are several special recall situations which may require you to deviate from the normal recall procedures. Seek your supervisor's or R&E Coordinator's guidance on these. Examples include:

1. Products in the possession of U.S. Defense Installations.
2. NDA and NADA withdrawals.
3. National Academy of Science (NAS)/Nuclear Regulatory Commission (NRC) (DESI) recalls of drugs judged ineffective.
4. Recalls involving jurisdiction of more than one Federal Agency (e.g., FDA/EPA, FDA/Consumer Product Safety Commission (CPSC), etc.).

MODEL DRUG RECALL LETTER

John Doe Laboratories
Somewhere, U.S.A. 12345

Control Division
Date _____

(red print) --URGENT: DRUG RECALL -- Nonsterile injectable

Re: List 1234, Cyanocobalamin Injection Lot No. 4321

Recent tests showed that the above lot number of this product is not sterile and therefore, represents a potential public health hazard. Consequently, we are recalling this lot from the market. Other lot numbers are not involved.

Please examine your stocks immediately to determine if you have any of Lot 4321 on hand. If so, discontinue dispensing the lot and promptly return via parcel post, to our New York City Plant; ATENTION RETURNED GOODS.

(NOTE: If a sub-recall is indicated in a particular situation, the following paragraph should be added:)

> "If you have distributed any of lot 4321, please immediately contact your accounts, advise them of the recall situation, and have them return their outstanding recalled stocks to you. Return these stocks as indicated above."

You will be reimbursed by check or credit memo for the returned goods and postage.

Please return the enclosed card immediately providing the requested information.

This recall is being made with the knowledge of the Food and Drug Administration. The FDA has classified this recall as class _____ (if classified).

We appreciate your assistance.

John Doe
President

PLEASE FILL OUT AND RETURN

We do not have any stock of List 1234, Cyanocobalamin

Injection Lot No. 4321 on hand

We have requested our accounts to return their stocks of this merchandise to us.

We are returning _____ bottles of List 1234, Lot No. 4321

Name _____

Address _____

First Class
Permit No. 2

BUSINESS REPLY MAIL

No Postage Stamp Necessary if mailed in U.S.A.

Postage will be paid by:

JOHN DOE LABORATORIES
Somewhere, U.S.A. 12345-0909

Henry Doe

JOHN DOE LABORATORIES *FIRST CLASS MAIL*

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

(red print) URGENT DRUG RECALL

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	d. OPERATION DATE (MM/DD/YY)
		17	

e. CENTRAL FILE NUMBER OF RECALLING ESTABLISHMENT

f. PAC CODE

g. EMPLOYEE			h. TYPE	# OF CHECKS	HOURS
HOME DIST.	POS. CLASS	NUMBER	VISITS		
			PHONE		

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 E.O.B. (HFC-162)

10. REMARKS *(Include action taken if product was still available for sale or use)*

SIGNATURE OF CSO/CSI

DISTRICT

DATE OF CHECK

TO:

DATE

SIGNATURE OF SCSO OR R&E COORDINATOR

ENDORSEMENT

FORM FDA 3177 (11/91) **RECALL AUDIT CHECK REPORT**
Circle Appropriate Copy: Home District (White) Accomplishing District DPU (Pink) Accomplishing District (Yellow)