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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 the FDA considers to be in violation of the laws it administers and against which it would initiate legal action (e.g., seizure). Market withdrawals and stock recoveries are not considered recalls. See the FDA's 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

Recall Classification is 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

Class I Recall is 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

Class II Recall is 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

Class III Recall is 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

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

#### 7.1.1.4 - Recall Strategy

Recall strategy is 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, which is known as the depth of recall.

### 7.1.1.6 - Recall Number

The recall number is assigned by the responsible Center, for each recalled product it classifies. This number comprises a letter designating the responsible Center (see Letter Codes below), a 3- or 4- digit sequential number indicating the number of recalls classified by that Center during the fiscal year, and a 4-digit number indicating the fiscal year the recall was classified. For example: F-100-2011 identifies the 100th recall classified by the Center for Food Safety and Applied Nutrition (CFSAN) in FY-2011. The following letters are used to identify the Centers.

#### Letter Center/Office

F	Foods and Cosmetics - (CFSAN)
D	Drugs - (CDER)
Z	Medical Devices & Radiological Health – (CDRH)
V	Veterinary Medicine and animal food/feed - (CVM)
B	Biologics - (CBER)
N	Medical Devices (Voluntary Safety Alerts and Notifications)
T	Tobacco Products – (CTP)

### 7.1.1.7 - Medical Device Notification Order

A medical device notification order is 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 such risk when a more practicable means is not available under the provisions of the Act.

### 7.1.1.8 - Medical Device Notification

A medical device notification is 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.

NOTE: Medical Device Notifications are to be handled by the divisions 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.

### 7.1.1.9 - Medical Device Safety Alert

A medical device safety alert is a notification to device users that, under certain circumstances, use of or exposure to the device may pose a risk of harm (the exposure mentioned in this definition excludes electronic product radiation exposure - see 21 CFR Subchapter J). CDRH will only consider a notification to be a safety alert if the device is not violative. The notification alerts users of the associated risk and steps to be taken to reduce or eliminate the risk.

#### Safety alerts will be entered in RES and processed accordingly. 7.1.1.10 Sub-Recall

A sub-recall is an action taken by a recalling firm's account to notify own-accounts/consignees of the recall where no changes were made to the recalled product.

If the recalling firm's account changes the recalled product ( e.g. used the product as a component of a new product, re-labeled the product to obscure the original product name and/or lot code, repackaged the product, etc.) the account will have created a new product which could warrant a new recall instead of a sub-recall.

### 7.1.1.11 Consignee

A consignee is anyone who received, purchased, or used the product being recalled.

### 7.1.1.12 Account

The account is the location where the audit check is being done.

### 7.1.1.13 Division Recall Coordinator

Each Division has at least one Division Recall Coordinator who enters and monitors recalls. A list of Division Recall Coordinators and their contact information is at <https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm>

### 7.1.1.14 Market Withdrawal

A market withdrawal is a firm's removal or correction of a distributed product for a minor violation that would not be subject to legal action by the FDA or that involves no violation (e.g. normal stock rotation practices, routine equipment adjustments, repairs, theft, etc.).

### 7.1.1.15 – Notification, Non-distribution, and Recall of Controlled Substances for Human or Animal Use Order

A controlled substance notification order is an order issued by FDA requiring non-distribution and the mandatory recall of controlled substances under section 569D of the Act [21 U.S.C. 360bbb-8d], as amended by section 3012 of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act ([SUPPORT ACT](#)). Refer to Chapter 7 of the [REGULATORY PROCEDURES MANUAL](#), 7-5-3 FDA Mandated Controlled and Ordered Recalls and Attachment K.

## SUBCHAPTER 7.2 - RECALL NOTIFICATION / INSPECTION

### 7.2.1 - RECALL SCENARIOS ENCOUNTERED DURING INSPECTIONS

The Division Recall Coordinator (DRC) or designee sends a recall alert within one working day of receiving necessary information to the appropriate Center Recall Unit (CRU) and OSPOP/DE/ROB (Office of Strategic Planning and Operational Policy Division of Enforcement Recall Operations Branch) through the Recall Enterprise System (RES) with basic information regarding the recall. See RPM Chapter 7-10, Attachment A for a list of information for the recall alert.

A recommendation for recall classification is submitted through RES by the DRC or designee within five working days after the recalling firm has provided the information (10 days if the recall has already been completed). See RPM Chapter 7-10, Attachment B for a list of information for the recall recommendation.

Due to the potential public health impact of recalls, when you find a recall during your inspection it is imperative to submit any information obtained to your DRC as soon as possible. The Division should not wait for writing, typing and submission of the EIR or memorandum when sharing recall documents with the DRC or submitting the recall alert or recommendation.

If the firm has decided to initiate a recall during an inspection or investigation, you should prioritize the removal of potentially hazardous product. Coordinate with your DRC and SCSO to ensure the following tasks are completed:

1. Provide firm management with your DRC's contact information and request that management obtain their FDA Division's review of recall correspondence and any press releases before they are issued to prevent misunderstandings between the firm, its customers, and the FDA. An updated list of contact information for FDA's DRCs can be found at <https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators>;

2. At the firm's request, provide guidance in preparing recall communications and obtain complete copies including the text of phone conversations to submit to your DRC. See Chapter 7 of the RPM, [Industry Guidance for Recalls](#), and IOM Exhibit 7-1 for an example of recall communications;
3. Obtain a complete distribution list of all shipments of the lot(s) involved, including foreign distribution;
4. Obtain copies of all labels and labeling associated with the recalled product(s) and any documentation of what led to the recall;
5. Advise the firm on how the returned products should be handled. Sometimes FDA will witness or otherwise verify the reconditioning or destruction of the products returned under the recall;
6. Obtain an Official Sample of the recalled product when necessary (See IOM 7.2.7);
7. Obtain as much information in the RPM Chapter 7, Attachment B as time allows; and
8. Take any other steps necessary in your judgment, or that your Division requires.

#### 7.2.1.1 – Firm Has Used Recalled Product to Manufacture New Product

If you are conducting an inspection or investigation at a firm who has received recalled product and used it in the production of a new product, or has relabeled recalled product, it may warrant the initiation of a new recall. Collect documentation on how the recalled product was manipulated, including finished product labels, to provide to your DRC immediately. If there is question about the potential hazard or violation of the new product, discuss the situation with your DRC and SCSO prior to discussing the initiation of a new recall with the firm.

##### 7.2.1.1.1 – Potential New Food Recalls

For potential new food recalls, 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; and
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?

##### 7.2.1.2 – Learning of Completed Recalls During Your Inspection

If you are conducting an inspection and learn that a recall has occurred, obtain the following from the firm to provide to your DRC:

1. Complete copies of recall communications including the text of phone conversations;
  2. Complete distribution list of all shipments of the recalled lot(s), including foreign distribution;
  3. Specimens or copies of all labels and labeling associated with the recalled product(s); and
  4. Take any other steps necessary in your judgment, or that your division requires.
6. Review and obtain copies of the firm's quality control/analytical data; and
  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.

This information should be shared immediately. Do not wait until the submission of the EIR to notify the DRC that a recall has taken place.

## 7.2.2 – ROOT CAUSE INSPECTIONS

If FDA learns of a potentially violative product that may cause or has caused a class I or significant class II recall, an inspection may be assigned to determine the root cause(s) of the problem(s). Deficiencies in the firm's corrective and preventive action should be documented as violations subject to possible regulatory action.

An important objective of the inspection is to identify the root cause for the recall and assure the firm has implemented effective corrective actions to eliminate its recurrence. In some cases, firm management will have conducted its own analysis and reached conclusions about the problem and its root cause. It is important to verify that the firm's conclusions and judgments, about the root cause of the problem that led to the recall, are discriminating enough to identify the true cause(s) and steps taken are sufficient in depth and scope. Without identifying the true root cause, it will be difficult for the firm to implement an effective corrective action.

Determine if the firm conducted a failure analysis using quality tools such as cause-and-effect diagrams (i.e. fishbone diagram or Ishikawa diagram), fault tree analysis (FTA), or failure mode and effects analysis (FMEA). Determine if the following variables were considered; 1) the length of time since the product had been manufactured and sold; 2) complaints or returns for the same or similar problems; 3) reworking of the product prior to release or distribution that may have been due to the same or similar problems; and 4) process or personnel changes which occurred about the time the problem appeared.

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;

### 7.2.2.1 - State Monitored Recalls

The FDA is not ordinarily involved in classifying and auditing Interstate Milk Shippers (IMS) and Interstate Shellfish Shippers (ISS) product recalls where such actions have been, or are being, handled expeditiously and appropriately by the State(s). However, the FDA Division office in which the recalling firm is located must be assured that all States involved in an IMS or ISS plant's recall are participating in ensuring removal of the product from commerce and that, when appropriate, the States issue warnings to protect the public health.

In the event that the FDA determines that the States are unable to effect the recall actions necessary, it will classify, publish, and audit the recall; it will issue 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](#) and failure to maintain records as required by [21 CFR 806.20](#) are violations and should be listed on the FDA-483, Inspectional Observations. You should collect documentation that will enable CDRH to evaluate the firm's compliance with [21 CFR Part 806](#).

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 806.10\(b\)](#).

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 (i.e., 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, at least partly, caused 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. Determine why the problem was not detected earlier. 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 that caused the problem included in the design of the device that was the subject of a premarket submission?
  - d. If the design feature that 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 Division 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 Drug Compliance. To inquire about specific veterinary drug product recalls or to obtain information on how to proceed, email CVM Recalls at [CVMRecalls@fda.hhs.gov](mailto:CVMRecalls@fda.hhs.gov).

### 7.2.5 - HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE BASED PRODUCTS (HCT/Ps) FOR IMPLANTATION, TRANS-PLANTATION, INFUSION, OR TRANSFER

The FDA 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 – TOBACCO PRODUCT RECALLS

When you become aware of, or obtain information about, a possible tobacco product recall, contact the Center for Tobacco, Office of Compliance and Enforcement, Division of Enforcement and Manufacturing. See CTP's intranet site for contact information.

<http://inside.fda.gov:9003/CTP/ucm249908.htm>

## 7.2.7 - SAMPLE COLLECTION

Collection of samples for regulatory consideration is at the discretion of Division 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 and Division Management it is determined that an official sample should be collected, ship an appropriate sample as directed by the Center and your Division. Keep the Center informed on the status of the shipment.

## SUBCHAPTER 7.3 - MONITORING RECALLS

### 7.3.1 - INSPECTIONS TO MONITOR RECALL PROGRESS

It may be necessary to inspect the firm between the recall initiation and the termination of a recall for several reasons including: to monitor the recall's progress, verify product disposition, or conduct a reconciliation of the distribution records for the recall. An inspection may also be assigned by your division if the Division Recall Coordinator requires assistance collecting necessary information from a firm,

and the recall is potentially class I or significant class II. These visits are limited inspections on an as-needed basis. Issue an FDA-482 Notice of Inspection and collect needed information. During these inspections, remind recalling firms to submit periodic status reports to FDA. See [21 CFR 7.53](#).

### 7.3.2 - FDA RECALL AUDIT CHECKS

NOTE: Do not conduct recall audit checks at DOD and VA facilities, as the FDA has a Memorandum of Understanding with them, and they have their own procedures for recalls.

#### 7.3.2.1 - Definition

A recall audit check is a personal visit, telephone call, letter, or a combination thereof, to an account of a recalling firm, or a user or consumer in the chain of distribution. It is conducted to verify 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

Conduct the number of audit checks requested in your assignment. If you are unable to do so, contact your supervisor for further instruction.

#### 7.3.2.3 - Conducting a Recall Audit Check

The purpose of a recall audit check is to confirm the account received the recall notification from the notifying firm and followed all instructions included in the notification. The notifying firm may be the recalling firm, or a downstream account that received the recalled product and is conducting a sub-recall (such as a distributor). Notifications sometimes come in through other means, for example an automated notification system sent to hospitals. These other means are not considered to be an official notification of the recall, as the recalling firm, or a downstream account, did not directly contact the consignee.

Prior to conducting a recall audit check, review the recall audit check assignment given to you. Your assignment will contain the necessary details of the recall, recall strategy, and a list of accounts to be audited (Please Note: The assignment may list specific accounts to be audited or may provide a list of accounts to choose from). Conduct the audit check by the due date provided in the assignment. Pay particular attention to the type of product recalled, the labeling of the product, and the recall notification attached to the assignment which the recalling firm sent to their accounts. Take note of the depth of the recall listed in the assignment (i.e. wholesale, retail, consumer level). Your responsibility is to verify the account received the same recall information, they followed the instructions in the recall notification, and that the recall has been carried out to the appropriate depth listed in the assignment. The assignment will include how checks will be conducted, i.e., visit, phone calls, email, etc. as well as detailed instructions specific to the recall. Do not conduct recall audit checks by visit at consumer

homes unless specifically directed in your assignment. If the assignment is for email audit checks, please use the email audit check template provided in the assignment.

During your review of the assignment, try to gain an understanding of the list of accounts, and whether those listed actually received or may have received the recalled lot. This information affects the endorsement for the audit check. If the list is specific to the recalled product lot, the account should have received it. If the list is not so specific, or the account you are auditing does not know or remember if they received the recalled lot, the account should still follow the instructions in the recall notification and initiate a sub-recall of the product, if needed. This information affects the endorsement of the recall (see section 7.3.2.6 Endorsing the Recall Audit Check). It is appropriate to challenge the account if the distribution list is included with the assignment includes them as a consignee for the specific recalled lot, and they say they never received the product.

When initiating a recall audit check, attempt to make contact with an individual at the account who has knowledge of the receipt of recall notifications and the disposition of recalled products. In hospitals, this responsibility may be held within the Risk Management or Safety departments. PLEASE NOTE: In the case of an audit check at the consumer level, attempt to verify you are speaking with the individual who was indicated as having received the product before disclosing the name of the recalled product and verifying they received notification of the recall.

If the account did not have any knowledge of the recall prior to your recall audit check, inform them of the recall, provide them with a copy of the press release (if available) and recall notification letter, encourage them to follow the recall instructions, and document that you did so. DO NOT give the account a copy of your recall assignment.

If your audit check discloses the account did not follow the recall instructions (for example, recalled product being held for sale, or a requested sub-recall has not been initiated), encourage the account to follow the recalling firm's instructions. If the account chooses not to follow the recall instructions, document the title/responsibility of the individual at the account who chose not to follow the recall instructions and reason.

When you conduct an audit check by visit, it is important to examine the storage sites where the recalled product is stored and check the shelf stock to ensure all recalled product has been identified, removed from areas of use, and properly quarantined or destroyed/corrected. This is especially important in Class I recalls.

For some recalls, the strategy may be a correction instead of a removal. Recall audit check assignments for field corrections may instruct you to verify that either the field correction has been completed, or to assess whether the recalling firm issued the initial instructions to discontinue and/or modify the use of the product, and the account followed those instructions. Detail the status of the

correction in the remarks section of your form FDA 3177.

If you encounter a refusal to permit entry or provide information during a recall audit check, document the name and title of the individual who refused, and the reason why they refused the audit check. Contact your supervisor for additional instruction.

FDA has a contract with a third party to conduct recall audit checks on behalf of the FDA. Any questions you or the firm may have regarding the third party contract should be directed to OSPOP/DE/ROB at [orarecalloe@fda.hhs.gov](mailto:orarecalloe@fda.hhs.gov). There are also other entities conducting audits (e.g. state investigators conducting audits as part of their state duties or on behalf of the FDA, private firms who conduct audits on the behalf of a recalling firm)

If during your audit check you find that the consignee used the FDA regulated product to manufacture USDA-regulated product, distributed product to a USDA facility, or the product was used in or procured for one of the USDA nutrition programs (i.e. National School Lunch Program), complete the recall audit check. Provide the information to your Division Recall Coordinator, who will forward it to OSPOP/DE/ROB, who will share it with the USDA. If during your audit check you find that the consignee is a DoD supplier and/or used the FDA regulated product to manufacture DoD products, complete the recall audit check. Provide the information to the FDA Liaison to DoD as per IOM section 3.2.3 – DEPARTMENT OF DEFENSE (DoD), 3.2.3.6.1 – DoD/FDA Liaisons; the FDA Liaison will forward it to the DoD Liaison and appropriate ORA/OSPOP/DE/ROB contact.

During your audit check, verify that the consignee has conducted a sub-recall to the level specified in the assignment. If the consignee is unsure if he or she handled the recalled product, then collect the distribution list. Inform the consignee that a sub-recall may be necessary. If an account has not conducted a sub-recall, follow the procedures outlined in "Exhibit 7-3, #7."

Conduct sub-recall audit checks to the level specified in the assignment. Sub-recall audit checks may be made by telephone for accounts in another division, in lieu of creating a separate recall audit check assignment for that division to conduct the sub-recall audit checks.

### 7.3.2.4 - Audit Check Reporting

The results of your audit check should be reported on a form FDA 3177, "Recall Audit Check Report" form. See IOM Exhibit 7-3. It is preferred that Divisions complete the form FDA 3177 electronically. Divisions have the option of completing the form FDA 3177 electronically or as a hard copy. Directions for completing the form FDA 3177 can be found in Exhibit 7-3. Conducting the Recall Audit Check. The form FDA 3177 will be routed through your supervisor to the recall coordinator at the division monitoring the recall, who will store the official signed form in the recall file.

Identified exhibits should be submitted with your FDA 3177. Identify each page or file with the following information:

- RES Event number (as listed in your assignment)

- Direct account name or sub-account name, whichever is applicable
- Investigator's initials and date of the audit check
- Exhibit and page numbers

FACTS allows you to enter the amount of time spent conducting your audit check. When you complete a recall audit check, you should report your time using the "Miscellaneous Operations Accomplishment Hours" screen using the code OP 17.

Submit one OP 17 per RES event. In the Assignees Accomplishment Hours block of the Miscellaneous Operations screen, enter the FEI of the recalling firm and for the "#Ops" enter the number of separate audit checks conducted.

### 7.3.2.5 - Ineffective Recalls

An audit check is considered ineffective if one of the following conditions were found:

- A. The account did not receive formal notification from the notifying firm. Note: in instances where the account was not formally notified but still took action based on information learned about the recall from a source other than the notifying firm, the audit check is still ineffective.
- B. The account did not follow the instructions provided by the notifying firm. If the account is not sure if they received the recalled lot(s), they should still follow the instructions in the notification.
- C. The account distributed the recalled product, but did not conduct a sub-recall, if applicable.
- D. The account received the type of product under recall, cannot determine whether they received the specific recalled lots, and did not conduct a sub recall. The account should still conduct a sub recall if there is any possibility that they received the recalled lot(s).

### 7.3.2.6 Endorsing the Recall Audit Check

Recall audit checks should be endorsed by the Supervisory Investigator based on the information collected during the audit check.

The audit check should be endorsed based on conditions found when the audit check was conducted and not based on the account's actions to correct ineffectiveness. Choose the endorsement that is best described by one of the scenarios below.

An audit check should be endorsed "Effective" if the account was notified of the recall by the appropriate notifying firm and followed, or is in the process of following, the instructions in the recall notification. Please note: If you selected "No" for question 5a or 6a on the 3177, you cannot endorse the 3177 as "Effective". If both 5a and 6a on the 3177 are "Yes", the 3177 should be endorsed as "Effective"

The following are examples of ineffective recall audit checks:

A. "Ineffective – Notifying Firm"

- The account did not receive formal notification from the notifying firm. Note: in instances where the account was not formally notified but still took action based on information learned about the recall from a source other than the notifying firm, the audit check is still ineffective.

B. "Ineffective – Consignee"

- The account did not follow the instructions provided by the notifying firm. If the account is not sure if they received the recalled lot(s), they should still follow the instructions in the notification.
- The account distributed the recalled product, but did not conduct a sub-recall, if applicable.
- The account received the type of product under recall, cannot determine whether they received the specific recalled lots, and did not conduct a sub recall. The account should still conduct a sub recall if there is any possibility that they received the recalled lot(s).

Your Division's Recall Coordinator can assist you if you need help evaluating if an account must conduct a sub-recall. In some instances, (e.g. field corrections) the effectiveness of the recall audit check may be determined by the assignment and discussion with the recall coordinator.

If the account assigned for a recall audit check is out of business, endorse the audit check as "Out of Business".

Endorse as "Other" on very rare occasions, such as if the account cannot remember whether or not they received the recall notification and does not carry the recalled product.

### 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 Division 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

Some recalls may require a limited inspection at the recalling firm as a final monitoring step to verify the recall has been completed. 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, Recall Coordinator, or compliance officer, depending upon your Division's policy.

During the closeout inspection, you should witness destruction or reconditioning of the recalled product when possible, when unable to do so, obtain written documentation from the firm and/or any state or local government agencies that 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 ANDA withdrawals;
3. National Academy of Science (NAS)/Nuclear Regulatory Commission (NRC) (DESI) recalls of drugs judged ineffective; and
4. Recalls involving jurisdiction of more than one Federal Agency (e.g., FDA/EPA, FDA/Consumer Product Safety Commission (CPSC), etc.).

**7-1 RECALL COMMUNICATIONS EXAMPLE**

## MODEL DRUG RECALL LETTER

[Company Letterhead]

**(in red print) URGENT: DRUG RECALL – Nonsterile injectable**

[Date]

[Contact name or Department]

[Firm Name]

[Address]

Dear [wholesaler, retailer, consumer]:

This is to inform you of a product recall involving: [Brand Name (generic) dosage form, strength, description and size of packaging, NDC or UPC codes, lot numbers]

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

This recall has been initiated due to [describe problem and how it was discovered]. [Use/Consumption] of this product may [describe any potential health hazard].

This product was shipped between [range of distribution dates] 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. [If this is a retail or user level recall, include the following] 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 should you choose to create a separate letter.]

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

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. If you have any questions, call [name] at [phone number] [days of week] between [start time] am to [end time] pm [state time zone].

This recall is being made with the knowledge of the U.S. 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

<b>JOHN DOE LABORATORIES</b>	<i>FIRST CLASS MAIL</i>
<b>A. B. C. Pharmacy Anywhere U. S. A.</b>	
<b>(red print) URGENT DRUG RECALL</b>	



## 7-3 Instructions for Completing the FDA 3177 Recall Audit Check Report

### Completing the FDA 3177 Recall Audit Check Report Form

Note: Obtain as much information as possible in order to successfully complete the FDA 3177 Recall Audit Check Report Form as follows:

#### 1. RECALL INFORMATION

- a. RES NUMBER – Enter the Recall Enterprise System (RES) number as listed in your assignment.
- b. RECALLING FIRM – Provide the name and address of the firm listed in your assignment as the recalling firm.
- c. RECALLED CODE(S) – Provide the lot, batch, or serial number indicated as the recalled product in your assignment. If there are more numbers than can fit in the space, state that there are numerous lots under recall and refer to the assignment.
- d. PRODUCT(S) – Provide the name of the recalled product as indicated in your assignment. If numerous products are involved, use a generic term (such as ice cream, dried fruit, etc.).

#### 2. PROGRAM DATA – Complete as per division policy.

- a. MONITORING DIVISION – Enter the monitoring division as listed in your assignment. The monitoring division is often the division where the recalling firm is located, and is responsible for evaluating the effectiveness of the entire recall.
- b. FEI NUMBER OF RECALLING FIRM – FEI number of the recalling firm as listed in your assignment.
- c. PAC CODE – PAC code given in your assignment.
- d. HOURS – has been removed from the 3177, but operational hours should still be entered into FACTS as instructed in IOM section 7.3.2.4.

#### 3. AUDIT ACCOUNTS

Do not add any text to the sub-account or tertiary account fields (3a and 3b) if you are not reporting audit check information for these downstream accounts. Adding text (such as N/A) to these fields impacts how RES reads the form.

- a. DIRECT – The name, address, and telephone number of the account that was listed in your assignment as receiving the product directly from the recalling establishment. This may or may not be the same account at which you are conducting your audit check.
- b. SUB-ACCOUNT (SECONDARY) – If the Direct account indicates the recalled product(s) were further distributed, complete this section for each sub-account audited as well as the DIRECT account section with the name, address, and telephone number of the applicable establishments.
- c. SUB-ACCOUNT (TERTIARY) – If the Secondary account indicates the recalled product(s) were further distributed, complete this section for each sub-account audited, the SUB-ACCOUNT (SECONDARY) section, and the DIRECT account section with the name, address, and telephone number of the applicable accounts.

#### 4. CONSIGNEE DATA

Contacted by: The method used to conduct the audit check (check the appropriate box).

a. NAME OF PERSON CONTACTED & TITLE – The name and title of the person at the account being audited who provided the most information during the audit check.

b. TYPE CONSIGNEE – The type of establishment at which you are conducting your audit check (check the appropriate box – if none, check “Other” and describe the type of establishment).

c. DOES/DIDTHE CONSIGNEE RECEIVE THE RECALLED PRODUCT? – If the account at which you are conducting the audit check never received the recalled product, indicate “No”. If the account received or may have received the recalled product, indicate “Yes”. This includes if the company is unsure they received the recalled lot.

## 5. NOTIFICATION DATA

a. FORMAL RECALL NOTICE RECEIVED? – Indicate if the account received formal notification of the recall (check the appropriate box). Formal notification may be received from the recalling firm, direct account or the secondary/tertiary firm. If notification is received informally e.g. press release, subscription service, or social media, indicate “No” and explain in Remarks how the account received notification. If there is some reason why you cannot determine if a notification was received (for example, it may have been discarded) indicate “Cannot be determined” and explain in Remarks.

b. RECALL NOTIFICATION RECEIVED FROM – The firm that formally notified the account at which you are conducting your audit check (check the appropriate box).

c. DATE NOTIFICATION RECEIVED – Date the account received the formal notification.

d. TYPE OF NOTICE RECEIVED – How the formal notification was received (letter, phone, e-mail, automated messaging system, etc.).

## 6. ACTION AND STATUS DATA

a. DID CONSIGNEE FOLLOW THE RECALL INSTRUCTIONS? – If the account followed or is following all of the recall instructions prior to your audit check, indicate “Yes”. If the account did not follow or has not begun to follow the recall instructions prior to your audit check, indicate “No”. Explain what was/was not done in Remarks, and if the account took action as a result of your audit check.

b. AMOUNT OF RECALLED PRODUCT ON HAND AT TIME OF NOTIFICATION – The amount of recalled product the account had at the time they received formal notification from the notifying firm.

c. CURRENT STATUS OF RECALLED ITEMS – Indicate the status of the recalled items at the account at the time of your audit check (check the appropriate box). If the recalled product is still being held for sale/use, or was being held for return/correction, ensure that the account properly quarantined the product (if applicable) and followed the recall instructions. In the case of a medical device recall with instructions that permit the device to remain in use awaiting correction or servicing of the device, mark “was still held for sale/use”. Include details of the product status in the Remarks

d. DATE AND METHOD OF DISPOSITION – Indicate the date and method the recalled product was destroyed/returned/corrected.

7. SUB-RECALL NEEDED? – If during the course of an audit check, you find the recalled product has been further distributed, and your audit check for the recall has not reached the depth indicated in your assignment, a sub-recall may be needed. For example, if your assignment indicates the recall depth is at the retail level, and you are auditing a wholesaler, the wholesaler should conduct a sub-recall to reach the retail level.

In the case of a sub-recall, collect distribution of the recalled product, the sub-recall notification, and any other pertinent information to attach to your form FDA 3177. Carry out the recall audit check to the depth indicated in the assignment. Determine if the consignee followed the instructions and conducted a sub-recall. If they did not, then inquire with the consignee about their willingness to continue the recall to the depth specified in the recall strategy and gather as much distribution information as possible. Indicate “Yes” in this section and add as much detail as possible in Remarks.

In some cases, if the consignee has re-labeled, repackaged, or remanufactured the recalled product, a new recall may be needed instead of a sub-recall. However, a new recall may not be needed, if the consignee has manipulated the recalled product in a way that corrects the initial reason for the recall (e.g. if the consignee re-labels the product so the labeling issue is no longer a concern, or if the consignee heat treats the product adequately to eliminate the hazard causing the original recall).

If you determine a new recall is needed, or are unsure, collect all relevant information, including labeling to be evaluated with the assistance of your division’s Recall Coordinator (refer to section 7.3.2.4 for labeling instructions of attachments).

Indicate “No” in this section if the product has not been further distributed and your evaluation finds that a sub-recall is not necessary.

8. AMOUNT OF RECALLED PRODUCT NOW ON HAND – The amount of recalled product still at the account during your audit check.

#### 9. INJURIES/COMPLAINTS

a. IS CONSIGNEE AWARE OF ANY INJURIES, ILLNESS, OR COMPLAINTS? – Ask the consignee if they have firsthand knowledge of any injuries, illness, or complaints pertaining to the recalled product. Collect relevant information and route per division procedures.

10. REMARKS – Use this section to provide details that could not be addressed in the previous sections, or to give additional information. If you need additional space for remarks or other information, attach a written document to the 3177 and reference the attachment in the remarks section.

CHECK – Place a handwritten or electronic signature, followed by your name and title printed or typed, the date your audit check completed, and your division.

ENDORSEMENT – Follow section 7.3.2.6 Endorsing the Audit Check. Please note: If you selected “No” for question 5a or 6a on the 3177, you cannot endorse the 3177 as “Effective”.

If changes need to be made after the document has been signed, the signer needs to clear the electronic signatures by right clicking on the signature and pressing “clear signature”. Then the form can be modified and re-signed.