Chapter 7 – Recall Activities

7.1 – Purpose of Recalls

A recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the FDA. Manufacturers and distributors voluntarily carry out recalls fulfilling their responsibility to protect public health and well-being from products that pose a risk of injury or gross deception or are otherwise defective.

7.1.1 - What is a Recall?

A recall is a firm's removal or correction of a marketed product that the FDA considers to be violative. (See 21 CFR Part 7.)

7.1.1.1 – What is a Correction?

A correction means a repair, modification, adjustment, relabeling, destruction, or inspection of a product (including patient monitoring) without its physical removal to some other location.

7.1.1.2 – What is a Removal?

A removal involves the physical removal of a product from commercial channels to the extent necessary to protect public health. For medical devices, a removal is the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

7.1.2 – Recall Strategy

Recall strategy is a firm's plan for carrying out a removal or correction. The strategy should detail all the following information, at a minimum:

- The types of notifications to be used (for example, email, phone, letter)
- The depth of the recall (for instance, at the wholesale, retail, consumer/user level)
- How the recalled product will be disposed of (if a public warning is needed)
- The firm's plan to conduct its own internal effectiveness checks to verify that its consignees have received notification and followed recall instructions

The agency's Division Recall Coordinator (DRC); Office of Field Regulatory Operations, Division of Field Enforcement, Field Recall Effectiveness Branch (OII/OFOR/OFRO/DFE/FREB; and relevant centers will review and, when necessary, recommend changes to recall strategies to make the recall as effective as possible.

7.1.2.1 - Depth of Recall

Depending on the product's degree of hazard and the extent of its distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend--wholesaler, retailer, or user/consumer. This is known as the depth of recall.

7.1.3 – What are the Recall Classifications?

The FDA is responsible for classifying recall events. Each recall is assigned one of three numerical designations: Class I, Class II, or Class III. The recall classification indicates the relative degree of health hazard presented by the recalled product, with Class I being the most serious.

- A 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.

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

7.1.4 – What is a Sub-Recall?

A sub-recall is when a recalling firm's consignee further notifies its downstream consignees that received the recalled product, in accordance with 21 CFR 7.49(d). In a sub-recall no changes are made to the recalled product.

If the recalling firm's consignee changes the recalled product (for example, used the product as a component of a new product, re-labeled the product to obscure the original product name and/or lot code, or repackaged the product) the consignee will have created a new product. As such, the new product could be subject to a new recall instead of a sub-recall. (See 7.3.2 for instructions when encountering a potential new recall situation.)

7.1.5 - What are other types of actions taken for FDA products?

7.1.5.1 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 (for instance, normal stock rotation practices, routine equipment adjustments, repairs, etc.). (See section 7.3.1.1 for instructions on market withdrawals encountered during inspections.)

7.1.5.2 -Stock Recovery

A stock recovery is a firm's removal or correction of a product that has not been marketed or that has not left direct control of the firm. The product is located on premises owned by the recovering firm and no portion of the lot has been released for sale or use. (See section 7.3.1.1 for instructions on market withdrawals encountered during inspections.)

7.1.5.3 - Medical Device Safety Alerts

A medical device safety alert is a notification to device users (consumers) that, under certain circumstances, use of, or exposure to, the device may pose a risk of harm (Exposure, for these purposes, does not include electronic product radiation exposure –for more see 21 CFR Chapter I Subchapter – Radiological Health). The notification alerts users of the associated risk and steps to be taken to reduce or eliminate the risk.

Note: Center for Devices and Radiological Health (CDRH) will only consider a notification to be a safety alert if the device is not violative. (Violative devices would undergo a recall.) (See section 7.3.1.1 for instructions on market withdrawals encountered during inspections.)

7.1.6 – What Governs FDA's Recall Process?

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. For all recall guidance for industry see Industry Guidance For Recalls.

7.1.6.1 – What is a Voluntary Recall?

A voluntary recall is an effective method for removing or correcting marketed products, their labeling, and/or promotional literature that violate the laws administered by the FDA. FDA-regulated firms may initiate a recall at any time to fulfill their responsibility to protect the public health from products that present a risk of injury or gross deception or are otherwise defective.

7.1.6.2 – What are FDA-Requested, -Mandated, and -Ordered Recalls?

FDA-requested recalls are ordinarily reserved for urgent situations where mandatory recall authority does not exist or is not appropriate. FDA recall requests are directed to the firm that has primary responsibility for the manufacture or marketing of the product when the firm does not undertake a product recall on its own initiative. FDA-requested recalls are most often classified as Class I. The Associate Commissioner for Inspections and Investigations (ACCI) approves all FDA requests for firms to conduct recalls. (For more on this, refer to the Regulatory Procedures Manual (RPM) Chapter 7-5-2, FDA Requested Recall.)

Various sections of the laws that the FDA enforces authorize the agency to order a firm to recall a product or mandate recall requirements. The FDA can order recalls for adulterated foods, devices, tobacco products, and controlled substances. There are also recall order authorities for biological products and human cells, tissues, and cellular and tissue-based products (HCT/Ps). Additionally, recalls may be ordered by a consent decree. The FDA can also mandate specific recall requirements for certain infant formulas and radiation-emitting electronic products. (For more on this, refer to RPM Chapter 7-5-3, FDA Mandated and Ordered Recalls.)

7.1.6.3 – What is a Medical Device Notification Order?

Section 518(a) of the FD&C Act [21 U.S.C. 360h(a)] authorizes the FDA to issue a medical device notification order if a device intended for human use was introduced to or delivered for introduction into interstate commerce for commercial distribution and presents an unreasonable risk of substantial harm to the public health, and notification is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of the act. A medical device notification order is issued by the agency to a medical device manufacturer, distributor, or other responsible individual requiring the establishment to notify all healthcare providers who prescribe or use the device and any other persons who should properly receive such notification to eliminate the unreasonable risk.

Medical device notifications ordered under section 518(a) are handled by the same divisions as medical device recalls. They go through the same process as voluntary recalls, including the assignment of recall audit checks when necessary.

7.1.6.4 - What is Notification, Non-Distribution and Recall of Controlled Substances for Human or Animal Use Order?

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), authorizes the FDA to issue a controlled substance notification order when there is a reasonable probability that a controlled substance would cause serious adverse health consequences or death. The order requires manufacturers, importers, distributors, and/or pharmacists, who distribute such controlled substance to immediately cease distribution and

conduct a mandatory recall of such controlled substances. The FDA may issue this order after providing the appropriate person with an opportunity to consult with the agency.

(For more see RPM sections 7-5-3 FDA Mandated Controlled and Ordered Recalls and Attachment K.)

7.1.7 – What are the different recall identifiers?

The Recall Enterprise System (RES) Event ID (also known as the RES Number) is a numeric identifier generated for each recall record entered in the RES. RES is the electronic data system used by FDA recall personnel to submit, update, classify, and terminate recalls. This recall event record details information for all the products included in the recall throughout the process and is the source of the reference number publicized in the Enforcement Report when a recall is classified.

A Recall Number, which is different from a RES Number and appears on the Form 3177, is assigned by the responsible center, for each recalled product it classifies. This number is comprised of a letter designating the responsible center (see letter codes below), followed by a 3- or 4-digit sequential number indicating the number of products classified by that center during the fiscal year, then a 4-digit number indicating the fiscal year in which the product was classified. For example: F-100-2024 identifies the 100th product classified by the Human Food Program (HFP)in FY-2024.

Letter	Center/Office
F	Foods and Cosmetics – HFP and OCS
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)

7.2 – Responsibilities during Recalls

A detailed list of the recall process, including responsibilities of involved parties, can be found in RPM Chapter 7.

7.2.1 – Recalling Firm Responsibilities

A manufacturer or distributor may voluntarily initiate a recall at any time. Any firm pursuing a recall, because it believes the product to be violative, is requested to immediately notify the appropriate DRC. The FDA will then review the removal or correction and determine if the firm's action adequately meets the definition of a recall. In such cases, the firm will be asked, at a minimum, to provide the DRC with the information outlined in RPM Attachment B-- OR the Device Correction Removal Report for Industry (806 reporting form), if the recall pertains to devices.

7.2.2 – Division Recall Coordinator (DRC) Responsibilities

The DRC or designee is responsible for sending a recall alert through RES to the appropriate Center Recall Unit (CRU) and Office of Field Regulatory Operations, Division of Field Enforcement, Field Recall

Effectiveness Branch (OII/OFOR/OFRO/DFE/FREB) within *one* working day of receiving the necessary information. (See RPM Chapter 7-10, Attachment A for a list of information for the recall alert.)

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

The DRC may also provide recall guidance to the recall firm. This includes reviewing and suggesting changes to the firm's recall strategy, recall communications including public warning (e.g. press releases and corrective actions).

Each division has at least one DRC who enters and monitors recalls. You can find a list of DRCs and their contact information at OII Recall Coordinators

7.2.3 – Center Responsibilities

Each center also has a recall unit that is responsible for assisting with reviewing recall classifications and strategies and making recommendations for changes to those as needed. The relevant center's recall unit will review the division's recall recommendation for classification to ensure it meets the criteria of a recall (and not some other regulatory action, for instance, like a market withdrawal). It will then adjust the classification if needed and issue the final classification. Once this classification is complete, the recall is posted publicly on FDA's Enforcement Report.

7.2.4 – Consumer Safety Officer (CSO) Responsibilities

There are many instances in which you may encounter potential or nonreported completed recalls:

- While inspecting a company
- While conducting a recall audit check
- While conducting a recall follow-up inspection, in which you must determine the adequacy of the firm's recall scope and product disposition, and ensure that its Corrective and Preventive Action (CAPA) is effective in preventing problems from recurring)

Other CSO responsibilities associated with recalls include, assisting the DRC with obtaining recall information as needed, assessing downstream accounts to determine if they received recall notification and have followed recall instructions, and providing DRC contact information to firms that initiate voluntary recalls because of an inspection. (See IOM 7.3.)

Finally, if a firm or individual ever asks for guidance related to recalls, you can direct them to your DRC and to FDA Industry Guidance For Recalls.

7.3 – Recalls and Inspections

As mentioned above, there are different scenarios where recalls and inspections can and will intersect. As a CSO, you may encounter potential recall situations because of observations made during an inspection or encounter completed recalls that have been initiated prior to an inspection. You may also need to conduct inspections because of a recall. (For more information as it relates to specific commodities, see IOM 7.3.6).

7.3.1 - Encountering Completed Recalls that FDA Was Not Notified About ("Silent Recalls")

All recalls monitored by the FDA are listed in the OII Online Search and Retrieval system (OSAR). If you are conducting an inspection and learn that a recall has occurred, check OSAR first to see if the recall is listed there. If the recall is not listed in OSAR, obtain RPM Attachment B information from the firm to provide to your DRC, including all the following:

- Complete copies of recall communications including scripts of phone conversations with consignees
- Complete distribution list of all shipments of the recalled lot(s), including any foreign distribution
- Labels and labeling associated with the recalled product(s)

Take any other steps necessary in your judgment, or that your division requires.

Share this information immediately, while still on-site at the firm, if possible. Do not wait until the submission of the EIR to notify the DRC that a recall has taken place. Evaluate the firm's recall procedures to ensure they include notification to the FDA and provide firm representatives with your DRC's contact information. Also review the firm's corrective actions as they relate to the cause of the recall, as well as the firm's efforts to prevent reoccurrence of the issue. (For commodity-specific information please see IOM 7.3.6.)

7.3.1.1 Encountering Unreported Market Withdrawals, Stock Recoveries, and Medical Device Safety Alerts

If, during an inspection, you identify that a market withdrawal has occurred and that the agency was not previously notified, you should collect Attachment B information and notify the DRC. The DRC can consult with the appropriate center recall unit to ensure that the firm's action is designated as a market withdrawal.

If, during an inspection, you identify that a stock recovery has occurred, you should document the reason for the stock recovery in the EIR and investigate if corrective actions are adequate to prevent reoccurrence.

You should also notify your DRC of any safety alerts you encounter prior to closing an inspection, as these should be entered in RES and processed accordingly.

7.3.2 - Observations Made During an Inspection Could Result in a Recall

Due to the potential public health impact of recalls, it is imperative that when a recall is initiated during an inspection you submit any information you've obtained to your DRC as soon as possible. Do not wait to write, type, and submit the EIR or memorandum before sharing documents with the DRC.

If a firm decides to initiate a recall during an inspection or investigation, you should prioritize the firm's initiation of a recall and removal of potentially contaminated product. This includes coordinating with your DRC and Supervisor to complete all the following tasks:

- Provide firm management with your DRC's contact information and request that they obtain their FDA Division's review of recall correspondence and any press releases before they are issued to ensure consistent messaging between the firm, its customers, and the FDA. For an updated list of these contacts, see FDA's DRCs.

- If the firm requests it, provide guidance in preparing recall communications and obtain complete copies including the content (scripts) 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.)
- Obtain a complete distribution list of all shipments of the lot(s) involved, including foreign distribution.
- Obtain copies of all labels and labeling associated with the recalled product(s).
- Obtain any documentation of what led to the recall.
- Advise the firm on how the returned products should be handled. Sometimes the FDA will witness or otherwise verify the reconditioning or destruction of the products returned under the recall.
- Obtain an Official Sample of the recalled product when directed.
- Obtain as much information as detailed in the RPM Chapter 7, Attachment B as time allows.
- Take any other steps necessary in your judgment, or that your division requires.

(For commodity-specific information, see IOM 7.3.6.)

7.3.3 – Inspections to Monitor a Recall's 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, and/or conduct a reconciliation of the distribution records for the recall. An inspection may also be assigned by your division if the DRC requires assistance collecting necessary information from a firm, and if the recall is potentially Class I or significant Class II. These visits are considered limited inspections done on an as-needed basis. Typically, you'll be asked to issue an FDA-482 Notice of Inspection and collect the needed information. You will also want to remind the recalling firm to submit periodic status reports to the FDA. (For more, see 21 CFR 7.53. For commodity-specific information see IOM 7.3.6.)

7.3.4 – Root Cause Inspections

If the FDA learns of a potentially violative product that may cause, or has caused, a Class I or a significant Class II recall, an inspection may be assigned to determine the root cause or causes of the problem(s). Any deficiencies in the firm's corrective and preventive actions 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 ensure that 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 for you 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 1. identify the true cause(s) and 2. validate the sufficiency of the corrective steps taken, in terms of both depth and scope. Accurately identifying the true root cause is essential to the firm's ability to implement an effective corrective action.

You'll also want to determine if the firm conducted a failure analysis in determining the root cause using quality tools such as: cause-and-effect diagrams (fishbone and Ishikawa diagrams), fault tree analysis (FTA), or failure mode and effects analysis (FMEA).

(See the agency's final guidance to industry on using these quality risk management tools in the : The International Council for Harmonization (ICH) Q9(R1) Quality Risk Management document (May 2023).)

You should also inquire to see if the firm considered the following variables in its analysis:

- The length of time since the product had been manufactured and sold
- Any complaints or returns relating to the same or similar problems
- Any reworking of the product prior to release or distribution that may have been due to the same or similar problems
- Any process or personnel changes which occurred about the time the problem appeared

In addition to verifying the identification of the root cause, you should be sure to complete the following:

- Issue a Notice of Inspection (FDA 482).
- Discuss the suspected problem with the firm's management and review the firm's complaint file.
- Investigate all areas, control points, and/or circumstances that may have contributed to the product's deficiency.
- Fully develop individual responsibility for the problem.
- Review batch records, processing logs, and/or other types of records for violative lots and associated lots.
- Review and obtain copies of the firm's quality control/analytical data.
- Determine any actions the firm has taken, is taking, or has planned to take to prevent similar occurrences. Evaluate the adequacy of the correction. If any issues are identified, consult your supervisor and the DRC. If corrective action is not underway, determine the firm's timetable for achieving correction.

You should also determine if the recalling firm did the following (as applicable):

- If the recalled product is a drug product with an existing drug application the firm must file a field alert with the Agency. The FAR regulations found in 21 CFR 314.81(b)(1) establish an early warning system to help the FDA fulfill its responsibility to protect patient health.
- If the recalled product is a drug or biologic product subject to MedWatch reporting, check that the firm reported the adverse event to the agency. The FD&C Act (21 U.S.C. 353b, 355, 360i, 360l, and 393) and the Public Health Service Act (42 U.S.C. 262) constitute the statutory authorities for the FDA to collect mandatory adverse event reports from regulated industry on medical products once approved for marketing to monitor the safety of drugs, biologics, medical devices, and dietary supplements.
- If the recalled product is a biologic product subject to biologic deviation reporting requirements, check that the firm filed the deviation report. Under 21 CFR 600.14, firms are required to report certain events associated with the manufacturing (to include testing, processing, packing, labeling, or storage) and with the holding or distribution of a licensed biological product, which may affect the safety, purity, or potency of a distributed licensed product.
- If the recalled product is a medical device subject to Medical Device Reporting (MDR), check that the firm filed an MDR. The MDR regulation (21 CFR Part 803) contains mandatory requirements for manufacturers, importers, and device-user facilities to report certain device-related adverse events and product problems to the FDA.
- If the recalled product is considered a low acid canned food (LACF) product with a filed process, check that the LACF processor(s) notifies the FDA of instances of spoilage, process deviation, or possible contamination with microorganisms, the nature of which indicates potential health

significance when any lot of such food, in whole or in part, has entered distribution in interstate commerce.

(For more commodity-specific information see IOM 7.3.6.)

7.3.5 – Sample Collection

Collection of samples during recall-related activities is at the discretion of division management. Consult your supervisor and/or center compliance office for guidance. If a sample is indicated for electronic products or medical devices, only collect documentary samples, unless otherwise instructed. Use the same procedures listed in IOM Chapter 4 for recall-related samples, unless your assignment indicates differently.

7.3.6 – Commodity Specific Recall Information

7.3.6.1 – Human and Animal Foods

7.3.6.1.1 - Potential New Food Product Recalls

For potential new food recalls, the following are areas you may want to cover:

- Incoming ingredient quality control procedures
- Quality control over ingredients at the time of use, and the products in which the ingredients are used
- Methods used in preparation and packaging of the processed product
- Treatment or kill-step applied during processing, including time, temperature, pH, and validation information
- Percentage of recalled product used in final product formula
- How the finished product was stored and shipped
- Labeling of product, and any cooking instructions for consumer or purchaser
- Quality control testing of the finished product (For this, detail any test(s) performed by the firm)
- For products produced in USDA plants, determine if the USDA was notified of the suspect incoming ingredient. Also determine if USDA found out what testing was done by the firm.

7.3.6.1.2 – State Monitored Recalls

The FDA does not ordinarily monitor recalls on products that were distributed within the state. However, if the FDA determines that the recall actions cannot be accomplished by the state(s), the FDA will monitor the recall, including issuing public warnings when indicated, and conducting recall audit checks.

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 recall are participating in ensuring the removal of the product from commerce and that, when appropriate, warnings to protect the public health are issued by the state(s). (For more see RPM 7-5-1.)

7.3.6.1.3 – Infant Formula

If the recalled product is an infant formula product, determine if the firm voluntarily reported any "positive" infant formula results. On March 8, 2023, the FDA issued a letter to the infant formula industry requesting that firms voluntarily notify the agency when a product sample is found positive for a pathogen, even if the affected product(s) have not been released in commerce.

7.3.6.2 – Medical Devices

7.3.6.2.1 – Medical Device Recalls

Medical device recalls may result from manufacturing defects, labeling deficiencies, failure to meet premarketing requirements [PMA, 510(k)], packaging defects, and/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. These findings are 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. Manufacturers and importers must also maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to the 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.

7.3.6.2.2 – Medical Device Recall Reporting (806)

Consider these questions as you collect the documentation, mentioned above, to enable the center to evaluate the firm's 806 compliance.

- What quality system procedures should have been established to prevent the problem?
- If the device label or instructions for use were inaccurate, was the inaccuracy introduced in the design stage, or was it due to a printing problem?
- If the device has been on the market for a year or more, and the manufacturer claims the problem is the result of design then:
    - Why was the problem 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, if applicable.)

If the firm doesn't provide rational answers to the above questions, determine if they have explored other possible causes for the problem by asking them the following questions:

- Was the design feature that caused the problem included in the design of the device that was the subject of a premarket submission?
- 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?

- 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?
- Has the manufacturer recalled all products distributed since the design change was introduced? If not, why not?

7.3.6.2.3 - Corrective Action

The following questions can assist you in describing the corrective action (for instance, a redesign, modified SOP, process validation, or other action) taken by the firm to correct the immediate problem.

- Did the firm qualify/validate the corrective action?
- Did the firm establish responsibility to ensure that the corrective action would be implemented and satisfactorily completed?
- What action did the firm take to prevent recurrence of the nonconformance, for instance, new training, increased process monitoring, etc.?
- Was the nonconformance information provided to those directly responsible for the areas in which the nonconformance occurred?
- Did the firm determine if the nonconformance extended to other devices?
- Did the firm determine if changes were needed in procedures and, if so, did it validate and implement the changes?
- Has the manufacturer taken appropriate corrective action?

7.3.6.2.4 - Complaint and Medical Device Reporting (MDR) Reporting

With regards to any complaints and MDR, you should determine if adequate complaint investigations were performed as required by 21 CFR 820.198(b). You should 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 a 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 so should be listed on the FDA-483 at the completion of the inspection.

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

Device Information - Obtain the 510(k) or PMA number for each device under recall as well as UDI information. 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.

7.3.6.3 – Human and Animal Drugs

7.3.6.3.1 - 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 the firm reported the problem to the FDA Division office responsible for the firm *within three working days* of its receipt of the information, as required by that section.

7.3.6.3.2 - 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 .

7.3.6.4 – 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 with regards to HCT/Ps when any of the conditions specified in 21 CFR 1271.440(a)(1) to (3) exist. The conditions include an agency finding that:

- The HCT/P is infected or contaminated such that it is a source of dangerous infection to humans; or
- An establishment is in violation of the regulations in this part and, therefore, does not provide adequate protections against the risks of communicable disease transmission.

If the FDA determines there are reasonable grounds to believe there is a danger to health, 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). An order to cease manufacturing is issued in instances where violations create an urgent situation involving a communicable disease, because an establishment is in violation of the regulations in 21 CFR 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)).

7.3.6.5 – 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.)

7.3.6.6 – Special Recall Situations

There are several special recall situations in which you will need to deviate from the normal recall procedures and seek your supervisor's or DRC's guidance. These scenarios include encounters with the following:

- Recalled products in the possession of U.S. defense installations
- NDA and ANDA withdrawals
- National Academy of Science (NAS)/Nuclear Regulatory Commission (NRC) (DESI) recalls of drugs judged ineffective
- Recalls involving jurisdiction of more than one federal agency (for instance, FDA/EPA, FDA/Consumer Product Safety Commission (CPSC), etc.)

7.4 – FDA's Recall Monitoring Activities

The FDA monitors recalls by reviewing a firm's recall documentation (for instance, status reports showing consignee responses and product disposition). It also conducts its own verification of recalls using audit checks.

7.4.1 – FDA Recall Audit Checks

7.4.1.1 – What is a recall audit check?

A recall audit check (RAC) is an in-person visit, telephone call, email, or a combination thereof, to an account of a recalling firm (see below for definition), or a user or consumer in the chain of distribution. It is conducted to verify that consignees (see below for definition), at the recall depth as specified by the strategy, have received notification about the recall and have taken appropriate action.

NOTE: RACs are not conducted at DOD and VA facilities, as the FDA has a separate process with these agencies for recalls.

7.4.1.2 – Preparing to Conduct a RAC

DRCs create RAC assignments and disperse them to the divisions using the recalling firm's distribution list for the recalled product(s). You should plan to review the RAC assignment before conducting the RAC, including securing and being aware of the following details: recalling firm information, recalled product names and coding, the reason for recall, how many RACs to conduct and how (visit, phone, email), the recall strategy, and any additional information that may need to be collected. Assignment should also have attachments, including copies of recall notifications, press releases (if issued), product labeling, the distribution list, and any other items helpful in conducting the RAC.

7.4.1.2.1 – What is the difference between a Consignee and an Account?

A consignee is anyone who received, purchased, or used the product being recalled. The account is the location where the audit check is being done. If the audit check verifies the account received the recalled product, they are confirmed as being a consignee.

7.4.1.2.2 – Why is the recall's strategy important?

The recall strategy tells you how the recalling firm notified their consignees. If the account cannot remember if they received notification of the recall, it may help you narrow down the date the email was sent, that the notice would have come in through the mail, etc. The recall strategy also includes the depth of the recall the firm is aiming to reach.

7.4.1.2.3 – Why do I need to know the recall depth?

You must conduct RACs until you reach the depth listed in the RAC assignment (e.g. wholesale, retail, consumer/user). If the consignee you are auditing has further distributed product, you must ensure they have notified their own consignees and conduct RACs at those sub-accounts until you reach the appropriate recall depth (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). This evaluates the effectiveness of the recall to the depth prescribed.

7.4.1.3 - Conducting a Recall Audit Check

Plan to conduct the audit check by the due date provided in the assignment. You will need to fulfill the following: determine if the account received the recalled product, verify the account received the recall notification, verify they followed the instructions in the recall notification, and that the recall has been carried out to the appropriate depth listed in the assignment.

7.4.1.3.1 - Contacting the Account

When conducting a recall audit check, attempt to contact 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 following departments: Biomedical Engineering and Supply Chain (for devices); Pharmacy Managers (for drugs); and/or Risk Management or Safety departments.

In the case of an audit check at the consumer level, attempt to verify that you are speaking with the individual who was indicated as having received the product before you disclose the name of the recalled product and verify, they received notification of the recall. Do not conduct recall audit checks by visits to 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.

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.

7.4.1.3.2 - How Did the Account Use the Recalled Product?

Make note of the type of account you are contacting and if they received the recalled product. If they received the recalled product, the following information should be reviewed:

- If the consignee repackaged/relabeled recalled product or used it to manufacture a new product, collect all relevant information and notify your DRC. A new recall may be necessary, and your DRC may request additional information to make this determination (for example, 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 the consignee further distributed the recalled product without any manipulation, they should conduct a sub-recall. In this case, collect the consignee's distribution lists, the sub-recall notification, and other information you find pertinent about their sub-recall. You will conduct additional RACs at the sub-accounts as necessary to the depth indicated in the assignment. Sub-recall audit checks may be conducted by telephone for accounts located in other divisions, in lieu of creating a separate recall audit check assignment.
- If the consignee has not initiated a sub-recall, 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.
- If the consignee did not alter or further distribute the product, no sub-recall or new recall is needed.

USDA potential involvement: If the consignee used the FDA-regulated product to manufacture a USDA-regulated product, distributed product to a USDA facility, or the product was used in or procured for one of the USDA nutrition programs (for instance, National School Lunch Program), complete the recall audit check. Provide the information to your DRC, who will forward it to Office of Field Regulatory Operations, Division of Field Enforcement, Field Recall Effectiveness Branch (OII/OFOR/OFRO/DFE/FREB) who will share it with the USDA.

DOD: 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 9.2.4 – DEPARTMENT OF DEFENSE (DOD), 3.2.3.6.1 – DOD/FDA Liaisons; the FDA Liaison will forward it to the DoD Liaison and appropriate OII/OFOR/OFRO/DFE/FREB contact.

If the consignee is unsure if he or she handled the recalled product, they should follow the recall instructions and conduct a sub-recall.

7.4.1.3.3 – Recall Notification

Determine if the account received the recall notification from the recalling firm or a downstream consignee (such as a distributor). Notifications sometimes come in through other means, too (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.

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 recall notification letter and press release (if available), encourage them to follow the recall instructions, and document that you did so. Do not give the account a copy of your recall assignment or other internal documents such as the RES details page.

7.4.1.3.5 – Consignee Action and Recalled Product Status

Determine if the consignee followed the recall instructions.

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 that the account followed those instructions. If the consignee was subject to a Field Service Engineer's update/correction to a device, obtain a copy of that service order to attach to your RAC. Additionally, if a consignee's in-house biomedical engineers were instructed to correct devices, obtain their response form,

when available, to demonstrate that recall actions were followed. Detail the status of the correction in the remarks section of your form FDA 3177.

7.4.1.3.4 – Injuries/Complaints

Determine if the consignee has received any reports of injury, illness, or complaints. If the consignee reports potential complaints for the product under recall, direct them to Report a Problem with the FDA. If the consignee reports potential complaints for products outside the recall (another lot code, or another product), direct them to report to the FDA. Then, collect any relevant information, document your findings, and route per division procedures.

7.4.1.4 - Audit Check Reporting

The results of your audit check should be reported on a form FDA 3177, "Recall Audit Check Report" form completed electronically within the Regulatory Operations Management System (ROMS). ROMS allows you to enter the amount of time spent conducting your audit check directly within the system. When you complete a recall audit check, you should report your accomplishment hours within the "report and recommendations" tab using the applicable PAC code.

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

- RES Event ID (as listed in your assignment)
- Direct account name or sub-account name, whichever is applicable
- Exhibit description (or the. distribution list)
- Abbreviation of Division Conducting the Check

Note: Urgent recall audit check assignments may request periodic audit check status updates to the monitoring division. In these cases, work with your supervisor to ensure you are submitting the necessary information at the appropriate frequencies.

7.4.1.5 - Endorsing the Recall Audit Check

Recall audit checks should be endorsed by the supervisor based on the information collected during the audit check. The ROMS system automatically determines the appropriate endorsement based on the assignee's responses in the FDA 3177.

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.

7.4.2 - Non-FDA Recall Audit Checks

There are instances where RACs are conducted by entities outside the FDA. For example, state investigators may conduct RACs as part of their duties or on behalf of FDA. Private firms may also conduct RACs as a recalling firm's verification of their recall's effectiveness.

FDA also has a contract with a third party to conduct recall audit checks on behalf of the FDA. Contractors are instructed to provide their identification to the accounts with an FDA Authorization Letter. Any questions you or a firm may have regarding the third-party contract should be directed to OII/OFOR/OFRO/DFE/FREB at oiirecalls@fda.hhs.gov.

7.5 - Recall Completion and Termination

7.5.1 - 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.

7.5.2 – 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.

The division should advise recalling firms that FDA will not terminate a recall until the firm has brought the product into compliance or disposed of it in an acceptable manner. DRC's will request and review product disposition records, which demonstrate the firm's actions to destroy, rework, or otherwise bring recalled product into compliance.

7.5.3 - Inspections to Witness Product Disposition

Some recalls may require a limited inspection at the recalling firm to verify the recall has been completed and to observe and document product disposition. 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".

During the inspection, you should witness destruction or reconditioning of the recalled product, when possible. If 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. Firms should be instructed to follow state and federal (Environmental Protection Agency) regulations for the destruction.

Prior to witnessing a voluntary destruction, obtain a statement on the firm's letterhead, or on an FDA 463a Affidavit, provide the information included in 3.9.3.1 - Documenting Voluntary Destruction.

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

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

7-2 – Form FDA 3177 Audit Check Report

1. RECALL INFORMATION

a. RES Number | b. Recalling Firm Name | c. Monitoring Division

d. Product(s) | e. Recalled Code(s)

2. AUDIT ACCOUNTS - DIRECT ACCOUNT

a. Firm Name | b. E-mail | c. Phone No.

d. Address | e. City | f. State | g. Postal Code

SUB-ACCOUNT (SECONDARY) *(Leave blank if none.)*

h. Firm Name | i. E-mail | j. Phone No.

k. Address | l. City | m. State | n. Postal Code

SUB-ACCOUNT (TERTIARY) *(Leave blank if none.)*

o. Firm Name | p. E-mail | q. Phone No.

r. Address | s. City | t. State | u. Postal Code

3. CONSIGNEE DATA

a. Were you able to make contact?

b. Name of Person Contacted and Title | c. Method of Contact:

d. Type of Consignee (if Other, please specify in the field provided) | Other *(Please Specify)*

e. Does (did) Consignee receive Recalled Product? *(If Yes, answer 3f & 3g)* | f. Does (did) Consignee repackage/relabel Recalled Product or use Recalled Product to manufacture a new product? *(If Yes, detail in Remarks, and notify DRC)*

g. Did Consignee further distribute the Recalled Product to any other accounts? *(If Yes, collect info, conduct RAC at sub-account(s) and/or provide details in "Remarks")*

4. NOTIFICATION DATA

a. Did the customer receive formal notification of the recall from the appropriate firm? (If answer is other than "Yes", explain in remarks and skip to 5c)

b. Recall Notification Received From ☐ Recalling Firm ☐ Direct Account ☐ Sub-Account ☐ Other *(Please Specify)*

c. Date Notification Received | d. Type of Notice Received *(e.g., letter, phone)*

5. CONSIGNEE ACTION AND RECALLED PRODUCT STATUS

a. Did the Consignee follow the recall instructions? *(If No, discuss in "Remarks" action taken as a result of audit check.)*

b. Amount (include units) of Recalled Product on hand at the time notification was Received.

c. Current Status of Recalled Products? (* = *Ensure Proper Quarantine/Action*)

d. Date of Disposition | e. Method of Disposition

f. Amount (include units) of Recalled Product **now** on hand during Recall Audit Check.

6. INJURIES/COMPLAINTS *If answer is other than "None", complete 6b and 6c, collect relevant information, document findings, and route per division procedures*

a. Is the Consignee aware of any injuries, illness or complaints?

b. Was information on how to file a complaint with FDA provided to the Consignee? *(If No, provide a reason in the remarks.)*

c. Was the complaint related to a lot code, date, etc. outside of the recall? *(If Yes, provide additional lots in the remarks.)*

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

AUDIT CHECK

Date of Audit Check | FDA Division | Printed Name and Title | Signature

FDA ENDORSEMENT *If No, is checked for 4a and/or 5a, "Effective" cannot be selected as an Endorsement.*

Select Endorsement Type *(If Other, please specify)* | Other *(Please Specify)*

Date of Endorsement | Printed Name and Title | Signature

FORM FDA 3177 (10/24) **RECALL AUDIT CHECK REPORT**

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

FDA 3177 Instruction Sheet

1. RECALL INFORMATION

a. RES Number - Enter the Recall Enterprise System (RES) number as listed in your assignment.
b. Recalling Firm Name - Provide the recalling firm name listed in your assignment.
c. Monitoring Division - Enter the monitoring division that requested the RAC assignment. Note: New recall division names are followed by the corresponding IB division names to aide in the selection.
d. Product(s) - Provide the name of the recalled product as indicated in your assignment. If numerous products are involved, use a generic term (e.g. numerous ice cream products, infusion pumps).
e. Recalled Code(s) - Provide the lot, batch, or serial number indicated as the recalled product in your assignment, or "numerous lot codes" if there are too many to list.

2. AUDIT ACCOUNTS

DIRECT ACCOUNT
a-g - Enter the Firm Name and contact information of the account that is indicated 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.
SUB-ACCOUNT (SECONDARY)
h-n - If the Direct account indicates the recalled product(s) were further distributed, enter the Firm Name and contact information for the sub-account audited as well as the Direct Account section. Do not add N/A to any fields.
SUB-ACCOUNT (TERTIARY)
o-u - If the Secondary account indicates the recalled product(s) were further distributed, enter the Firm Name and contact information for the tertiary sub-account audited as well as the Direct Account and Sub-Account (Secondary) section. Do not add N/A to any fields. For quaternary and further accounts, enter the account you are auditing as a Sub-Account (Tertiary), then include the preceding accounts names in the remarks section.

3. CONSIGNEE DATA

a. Were you able to make contact? - If you have trouble making contact, three attempts should be made. If this is the case, or if the account is OOB, skip to the remarks section and explain your attempts. Choose the corresponding endorsement.
b. Name of Person Contacted and Title - The name and title of the person at the account being audited who provided the most information during the audit check.
c. Method of Contact - Choose the method used to conduct the audit check.
d. Type of Consignee - Choose the type of establishment at which you are conducting your audit check.
e. Does (did) Consignee receive Recalled Product - Choose yes or no. If the person you are talking to is unsure, select unknown. If yes, complete questions f and g.
f. Does (did) Consignee repackage/relabel Recalled Product or use Recalled Product to manufacture a new product - Select yes or no. If Yes, enter details in Remarks, collect relevant information including labeling for evaluation, and send all information to your DRC).
g. Did Consignee further distribute the Recalled Product to any other accounts - Select yes or no. If yes, carry out the audit checks to the depth indicated in the assignment. Collect the distribution list for the recalled product, the sub-recall notification, and any other pertinent information to attach to your FDA 3177. If the account has not conducted a sub-recall, 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. Detail in remarks.

4. NOTIFICATION DATA

a. Did the customer receive formal notification of the recall from the appropriate firm - 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 - If 4a is yes, choose the firm that formally notified the account.
c. Date Notification Received - If 4a is yes, choose the first date the account received recall notification.
d. Type of Notice Received - How the formal notification was received (letter, phone, e-mail, automated messaging system, etc.).

5. CONSIGNEE ACTION AND RECALLED PRODUCT STATUS

a. Did the Consignee follow the recall instructions - If the consignee followed or is following all of the recall instructions prior to your audit check, choose "Yes". If the consignee did not follow or has not begun to follow the recall instructions prior to your audit check, choose "No". Explain what was/was not done to date, and if the consignee took action as a result of your audit check, in the Remarks section. If the consignee is not sure if action was taken, choose "UNK".
b. Amount (include units) of Recalled Product on hand at the time of notification - The amount of recalled product the consignee had at the time they received formal notification.
c. Current Status of Recalled Products - Choose the status of the recalled items at the account at the time of your audit check. 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, choose "Was Still Held for Sale/Use". Include details of the product status in the Remarks.
d. Date of Disposition - Enter the date the product was destroyed, corrected, etc. if applicable.
e. Method of Disposition - Enter specifics about the method of disposition completed or planned.
f. Amount (include units) of Recalled Product **now** on hand during Recall Audit Check - Enter how much product is on hand while you are conducting your RAC.

6. INJURIES/COMPLAINTS

a. Is the Consignee aware of any injuries, illness or complaints - Select the appropriate choice. If the answer is "None", skip 6b and 6c. If answer is other than "None", continue to 6b and 6c.
b-c. Determine if the complaint was related to the specific recalled product and codes. If the complaint is related to the specific recalled product, no additional action is necessary. If the complaint is related to a product or code not included in the recall, inform the firm about Report a Problem to the FDA, and collect relevant information, document findings, and route per division procedures. Answer 6b and 6c as appropriate.

7. 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. Note: In order for 3177 results to be seen in RES, the form will populate some other field results into the remarks section automatically. Please ignore this functionality.

AUDIT CHECK and ENDORSEMENT

Complete each field accordingly. If No, Cannot Be Determined, or Unknown is checked for 4a and/or 5a, then "Effective" cannot be selected as an Endorsement.

FORM FDA 3177 (10/24) RECALL AUDIT CHECK REPORT