CHAPTER 13
FOOD RECALLS

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1.0. PURPOSE

This chapter outlines and provides best practices for key areas of a recall strategy and can be used by regulatory agencies when developing their own recall processes and procedures.

2.0. SCOPE

This chapter is focused on foods that are involved in the FDA recalls, and are subject to FDA's jurisdiction, including dietary supplements, bottled water, food additives, infant formulas, and other food products (except some aspects of meat, poultry, and egg products).

3.0. RESPONSIBILITY

3.1. RRT (or investigatory team, in states without an RRT) Leadership

RRT leadership is responsible for ensuring that personnel assigned to perform tasks within a recall strategy have been provided with appropriate training.

3.2. RRT Members

RRT members are responsible for playing an active role in maintaining both their subject matter expertise and ability to work effectively in multidisciplinary and multi-agency response teams.

4.0. DEFINITIONS

- **Recall –** A firm's removal or correction (repair, modification, adjustment, relabeling, destruction, or inspection [including patient monitoring] without its physical removal to some other location) of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g. seizure. Recall does not include a market withdrawal or a stock recovery.
- **Sub-recall** – 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 products.
- **Recalling firm** – the firm that initiates a recall, or in the case of an FDA requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.
- **Recall strategy** – a planned 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.

- **Market Withdrawal –** A firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by FDA, or which involves no violation, e.g. normal stock rotation practices, routine equipment adjustments and repairs, etc.
- **Stock Recovery –** A firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e. the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.
- **Recall Classifications –** The numerical designation, i.e. I, II, or III, assigned by the FDA to a product recall to indicate the relative degree of health hazard presented by the product being recalled (Refer to Attachment A for examples).
    - **Class I** 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.
    - **Class II** 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.
    - **Class III** is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.
- **Consignee –** Anyone who received, purchased, distributed, or used the product being recalled.
- **Depth of Recall –** The level of product distribution to which the recall is to extend:
    - **Consumer or User level –** All end users of a product including households and all levels of distribution which can include hotels, restaurants, and other food service institutional consignees.
    - **Retail level –** This includes all retail sales of the recalled product.
    - **Wholesale level –** This is the distribution level between the manufacturer and the retailer. This level may not be encountered in every recall situation (e.g. the recalling firm may sell directly to the retail or consumer level).
- **Scope –** This defines the amount and kind of product in question. For example, all products of a specific lot number produced during a specific date range. Distribution of the product can also be a factor in determining the scope of the recall.
- **Correction –** The repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.
- **Product –** An article subject to the jurisdiction of the FDA, including any food intended for human or animal use.
- **Recall Effectiveness Check –** Effectiveness checks assist in the verification that all known, affected consignees have received notification about a recall

and have taken appropriate action. The firm has an obligation to conduct recall effectiveness checks as part of its recall strategy.

- **Audit Check –** A personal visit, telephone call, letter, or combination thereof, to a consignee of a recalling firm, or user or consumer in the chain of distribution made to verify all consignees at the recall depth specified by the firm's recall strategy have received notification about the recall and have taken appropriate action. Audit checks are selectively carried out by food regulatory agencies, separate from the effectiveness checks of the recalling firm, to assess the adequacy of a firm's recall efforts.

5.0. BACKGROUND

A food recall refers to a firm's removal or correction of marketed food products from commerce when there is sufficient public health concerns or evidence of a violation, such as products that are adulterated or misbranded under the provisions of applicable state and federal laws. Manufacturers and/or distributors may voluntarily initiate a recall at any time to fulfill their responsibility to protect human and animal health from products that present a risk of injury, gross deception, or are otherwise defective. Other firms in the supply chain may also initiate a new recall or sub-recall following notification of a problem by the FDA, a state agency, or other entity (suppliers, customers, foreign counterparts, USDA, etc.). Additionally, firms may initiate a recall in response to a formal or informal request by FDA or state agency, a mandatory recall statute, or an order issued by FDA or a state agency.

6.0. SAFETY

N/A

7.0. EQUIPMENT/MATERIALS

N/A

8.0. PROCESS DESCRIPTION

8.1. Product Recall Triggers

Issues that can trigger a product recall include:

- Laboratory results indicating that a product is adulterated and may be potentially hazardous
- Regulatory evidence obtained during a facility inspection
- Epidemiological evidence demonstrating that a product may be linked to an outbreak
- Industry monitoring and reporting (e.g. Reportable Food Registry (RFR))

- Consumer complaint investigations indicating that a product may be potentially hazardous.

8.2. Regulators' Roles and Authority

State regulatory agencies generally do not have the authority to order a recall. With the enactment of the Food Safety Modernization Act (FSMA), FDA was endowed with the authority to order a recall of a food where there is reasonable probability that the food (other than infant formula) is adulterated or misbranded and the use of or exposure to such food will cause Serious Adverse Health Consequences or Death to Humans or Animals (SAHCODHA). Recalls are typically voluntary actions carried out by the manufacturer or distributors of the food product.

In some cases, a company will discover one of its products is defective and conduct a recall entirely on its own volition. In other cases, the federal or state regulatory agency notifies a company that one of its products is defective and suggests, requests, or orders a recall. If the company does not recall the product, the regulatory agency may seek legal action, which may include seizure of the available product and public notification of risk associated with the product. State or Federal agencies may request assistance from local regulatory agencies in a recall investigation or response when the degree of risk to the public warrants widespread and immediate action to prevent further exposure to adulterated products in commerce.

Cooperation between industry and regulatory agencies has proven to be very effective and efficient in removing potentially dangerous products from the market. Both industry and regulatory agencies benefit when a potentially harmful product is prevented from reaching consumers. Maintaining "Recall Ready" is the fastest and most effective way for industry to remove violative products from the market, and the FDA Recall Ready Guidance, Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C, describes steps that firm should take to facilitate faster, more accurate recall actions to reduce market exposure time of recalled products.

During a recall, the recalling firm takes full responsibility for product recalls, including follow-up (effectiveness) checks to assure that recalls are successful. Regulatory agencies may assess the adequacy of the recall by conducting audit checks at a portion of the firms that received the recalled product. The need for and the number of audit checks to be conducted should be prioritized based on the level of health hazard, the remaining product that may exist in the marketplace, and the recall effectiveness data.

Federal Roles

The FDA has Recall Coordinators whose job is to serve as the primary contact for industry, other FDA Office of Inspections and Investigations (OII) staff, and the various FDA inspectorate divisions concerning recall activities. A listing of Recall

Coordinators is available at: https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators.

Recall Coordinators are aligned in compliance branches reporting to the Director of Compliance (DCB). Recall Coordinators specialize in the same programs as their DCB. They are typically the States' primary recall contact with the Agency. Any time a state or federal investigator identifies a potential recall situation, their Recall Coordinator should be notified immediately. If FDA requests state assistance to (or a state wishes to) conduct recall audit checks, all information will typically be funneled through the Recall Coordinator to FDA Commissioned officials in the state agency in accordance with applicable rules for FDA Commissioned Officers and FDA inspectorate divisions procedures.

FDA responsibilities are summarized below:

- **Initiation of a Recall**. FDA may request or mandate recalls under their authority as referenced above, however, most recalls can also be voluntary.
- **Classification and Strategy.** The FDA formalizes the recall action by reviewing the information, including the recall strategy provided by the firm, assessing the health hazard presented by the recalled product, and classifying the recall.
- **Notification and Public Warning.** For recalls that are mandated or formally requested by FDA, FDA will issue a written notification to the firm with the recall request or recall order. FDA notifies the firm that their action meets the definition of a recall and notifies the firm of the hazard level (classification) of each product under recall. FDA assesses the need for public notification, usually a press release, which may be issued by the recalling firm and/or by FDA. As appropriate, primarily for Class I recalls, and some Class II recalls, FDA posts these recall announcements on FDA's website. State-issued press releases announcing a firm's recall may also be posted. FDA requests that recalling firms provide an image of the recalled product to post with the recall announcement. All recalls of FDA regulated products are posted to the FDA Enforcement Report after the recall has been determined and classified. FDA also shares distribution information for recalled products, as needed and as per agreement, with other federal and state agencies and with foreign governments.
- **Monitoring and Auditing the Recall.** FDA may issue recall audit checks to verify the effectiveness of the recall. The FDA may take regulatory action or other measures when the firm fails to recall violative product or when a recall action fails. Additionally, FDA asks that firms submit periodic status reports to the FDA inspectorate division office monitoring the recall on a monthly, or more frequent basis. These status reports contain information on the progress of the firm's recall action

including the number of consignees responding to the recall notification and the number of products returned or corrected.

- **Termination and Completion of a Recall.** FDA determines when a recall should be terminated and, upon such determination, provides written notification of termination to the recalling firm. In some cases of Class I recalls and high-risk Class II recalls, a limited close-out inspection to verify recall completion and observe/document product disposition may be conducted at the discretion of the Recall Coordinator and/or FDA inspectorate divisions management.

State Roles

- **Initiation of a Recall:** Often done in collaboration with FDA inspectorate divisions. Includes voluntary, state requested, and state mandated (where state law allows the regulatory authority to mandate recalls within their jurisdiction).
- **Classification and Strategy:** If the state leads the government recall action by mutual decision with their federal counterparts, they may coordinate with FDA to classify the recall after assessing the health hazard presented by the recalled product. States without authority to mandate recalls in their jurisdiction must allow FDA to make the final determination of classification.
- **Notification and Public Warning:** The state may publish recalls on their website or through alternate means, such as social media. While it is the firm's responsibility to ensure distribution of the press release to the public and FDA, the state may assist the firm in formulating and distributing the message within its borders to the appropriate media channels.
- **Monitoring and Auditing the Recall:** States may elect to develop and implement a recall audit strategy to ensure that the recall action has been effective for the product distributed within their jurisdiction. Alternatively, the state may choose to assist FDA in conducting recall audit checks if resources are available, preferably using a reporting mechanism like the FDA 3177 form that will accurately collect the necessary information to insure the effectiveness of the recall.
- **Termination of a Recall:** The FDA determines when a recall should be terminated and, upon such determination, provides written notification of termination to the recalling firm. States with recall authority will work with FDA and industry to terminate a recall. States with the authority may work with industry partners to terminate recalls for products sold exclusively within that state's boundaries.

Local Roles

Local agencies typically have regulatory jurisdiction over food service establishments and have variable recall authorities. Recall activities are often done in collaboration with state and federal agencies when adulterated products originated from establishments under local jurisdiction.

- **Classification and Strategy:** State and federal authorities may depend on epidemiologic information collected by local agencies in their classification and review of a firms' recall strategy.
- **Notification and Public Warning**: Local agencies can play important roles in further disseminating recall information and answering questions from concerned citizens if recall information is shared with them in a timely manner.
- **Monitoring and Auditing the Recall.** Local agency involvement in recall audit checks often is dependent on the severity of the hazard and the availability of resources. Locals can conduct audit checks independently or in coordination with state and federal agencies to ensure that the recall action has been effective for the product distributed within their jurisdiction.
- **Termination of a Recall.** Local agencies may report their recall audit check findings to State and Federal authorities, which may be used in their determination of if a recall may be terminated.

8.3. General Principles of Immediate Risk Management Decisions

If the product is still on-site at the facility/firm, it can be controlled by:

Seizure of existing product
The FDA has the authority to seize food, but it is often more expedient to rely on states' authorities in this matter, because it may be done much more quickly and with fewer legal hurdles. States and the FDA inspectorate divisions should be aware of each other's authorities in this capacity and work collaboratively to ensure measures like seizures, embargos or other regulatory actions within the food chain are initiated as quickly as possible to control violative foods.

Limitation of future production
Regulatory agencies may have the authority to limit the products a firm may produce temporarily or permanently through license suspension/revocation or other means. If this authority is available, the FDA in coordination with the state (and local agencies when applicable) should determine if production limitation would be the most expedient control.

Control of product in distribution channels
If a product has not left the direct control of the firm, it is possible for the firm to control the product using procedures other than a recall by performing a stock recovery operation.
When a violative product is in commerce and has left the direct control of the firm, it is necessary to conduct a recall to regain control of the product. States and federal agencies should coordinate their actions to make best use of their respective authorities and resources in exercising appropriate regulatory controls over recalled products.

8.4. Recall Strategy

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. This is known as the "depth of recall". If the recall extends below the wholesaler depth, the recall strategy should ensure that wholesalers conduct sub-recalls of the product to the appropriate recall depth.

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

- Determine what the firm's quality control procedures are for incoming ingredients.
- Ascertain the quality control over ingredients at the time of use and obtain a list of the products in which the ingredients are used.
- Obtain a detailed description of the methods used in the preparation and packaging of the processed product.
- Determine how the finished product is stored and shipped.
- Obtain copies or photographs of the labeling of the product and any cooking instructions for consumer or purchaser.
- Determine what quality control testing is done on the finished product. Detail any test(s) performed by firm.
- For products produced in USDA plants, determine if the USDA was notified of the suspect incoming ingredient? If notification was provided, did USDA determine what testing was done by the firm?
- Determine the impact/effect of any additional manufacturing processes on adulterated ingredients. If the firm incorporated an adulterated ingredient into a new food, assess whether the manufacturing process of the new product mitigated the adulteration.
- If the ingredient was contaminated with a pathogen, was there a validated kill step for the pathogen during the manufacture of the new product?
- If the ingredient was adulterated with extraneous material, was there a step, like sifting, that could have eliminated the extraneous material.
- For those ingredients that are misbranded, is there labeling on the finished product that could mitigate the misbranding of the ingredient? The ingredient may be contaminated with peanut residue but if the finished product is meant to and labeled as containing peanuts, then the misbranding of the ingredient is mitigated.

Federal Roles

Federal agencies have established protocols for obtaining information necessary to both classify and determine the necessary depth of recall, need for public notification, etc. and may coordinate with state officials to collect it. The FDA may

notify the firm of the classification and necessary changes in its recall strategy, including the need for press releases for those recalls conducted voluntarily.

State Roles: Communications and Press Releases
The state, working in conjunction with FDA, may notify firms within their jurisdiction of the classification and the need for press releases for those recalls conducted voluntarily. The state may assist the firm with composing the press release language and may coordinate with FDA to ensure all parties have a clear understanding of the recall message and appropriate language has been incorporated. There are several ways to disseminate information during recall activities, including webpage postings, social media, listserv, and newsletters. Additionally, the state may issue a press release announcing the recall of the product in their state.

Intra and Inter-Agency Information Sharing
Local, state, and federal authorities should have 24/7 contact information for their own and each other's staff. Contact lists should be updated at least annually to ensure the appropriate information is available. Open, accurate, and rapid information sharing can be expedited between agencies that have a Memorandum of Understanding (MOU) with each other regarding commercially confidential information.

FDA also can share other investigatory and/or pre-decisional information with state and local officials who have signed 20.88 Confidentiality Commitment Agreements or are commissioned through the federal commissioning procedure. The current FDA commissioning policies and procedures were developed and refined over the years by FDA to grant specific authority in a specific program area in a designated state to state and local officials pursuant to the following laws: Section 702(a) of the Federal Food, Drug, and Cosmetic Act; Section 360 E(2) of the Public Health Service Act; and authority delegated to the Commissioner of Food and Drugs by the Secretary of Health and Human Services under 21 CFR 5.35.

The Partnership for Food Protection (PFP) Best Practices for Improving FDA and State Communication During Food Recalls provides best practices on communications between governmental agencies, and offers guidance on how to streamline information between different agencies for expeditious and effective food recalls.

Recommended practices:

- Key Information to share:
    - Any facts regarding epidemiological and/or lab information on health risk, product contamination and/or reported illnesses or injuries.
    - Preliminary product information linked to illnesses or injuries and any positive sample results or other problems warranting a recall.

    - Information regarding the company or companies involved, their contact information and location and the scope of the proposed recall, if known.
- Establish routine meetings between federal, state, and local personnel who are involved in recall coordination activities to share informational updates and maintain lines of communication. This could be accomplished through Food Safety Task Force Meetings or other routine meetings with RRT partners.

8.5. Initial Investigation/Data Gathering

FDA and state agency representatives should consider collaboration for investigation and data gathering at the firm if there is shared regulatory jurisdiction, or alternatively, determine which agency is in the best position regarding available resources to investigate at the firm. FDA or states should use Attachment F of this chapter, "ALERT TO RECALL and ATTACHMENT B GUIDANCE", refer to instructions in Chapter 7 of the FDA's Regulatory Procedures Manual (RPM) and Chapter 7 of the FDA's Investigations Operations Manual (IOM) for collection of necessary recall data.
In the case of recalls that have been classified as or appear to be Class I or significant Class II recalls, the situation should be evaluated to determine if an establishment inspection should be assigned to determine the root cause of the problem and document violations for possible regulatory action. See the IOM Chapter 7 – Recall Activities for information on how to conduct recall related inspections.

Prior to initiating an establishment inspection, regulatory authorities should determine whether similar complaints have been entered into the FDA's Field Accomplishments and Compliance Tracking System (FACTS) or a state database or record.

The establishment inspection should, in addition to other activities:

- Obtain the recalling firm's proposed recall strategy [21 CFR 7.46(a)], if not previously submitted by the firm.
- Collect copies of all labeling associated with the product.
- Obtain complete distribution of all shipments of the suspect lot(s), including complete names and addresses of all foreign consignees.
- Obtain supporting documentation that will assist the agency in identifying and evaluating the problem such as product complaints, product specifications and test results, including the methods used to obtain the results.
- Assess the root causes of the problem. Determine how and when the problem occurred and how and when it was discovered. Obtain the firm's corrective action to prevent future occurrences.
- Verbally apprise the firm's management that the Recall Coordinator and/or state regulatory authority should be consulted prior to the reconditioning or

destruction of any returned product. Management should also be advised that the FDA, state, or local regulatory authority should witness or otherwise verify product disposition.

8.6. Recall Enterprise System (RES) Data Needs

The Recall Coordinator should submit the recall alert through RES by completing the fields per the RPM Attachment A – Recall Alert Information. At a minimum, the following fields are required:

- Product(s) Description
- Codes
- Recalling Firm
- Short Reason for Recall
- Division Awareness Date
- Recall Initiation Date, with Type of Initial Firm Notification
- Recall Status
- Voluntary or FDA Mandated Pick Lists, with Date

The Recall Coordinator may submit any other information at the same time.

8.7. Industry Communication

A firm may identify a problem with a product and notify the FDA or a state regulatory agency. If a state is notified of an industry-initiated recall directly by the firm, media, etc., it should immediately notify the Recall Coordinator and the FDA inspectorate division.

Registered food facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States under section 415(a) of the FD&C Act (21 U.S.C. 350d) are required to report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals. This information is submitted through the RFR. The RFR applies to all FDA regulated categories of human and animal food, except dietary supplements and infant formula. It is important to note that a report filed through the RFR does not always result in a product recall.

8.8. Public Notification/Press Releases

The recalling firm has a responsibility to provide information when there is a need to alert the public to a serious hazard presented by exposure to the firm's product(s). Industry should work with FDA and/or state regulatory authorities to ensure that the public message clearly identifies the products, and the potential risk involved. Public notification is important, particularly in situations where the recalled product may pose a significant health hazard and may be in the hands of consumers. In such situations (often Class I and sometimes Class II recalls), prompt issuance of a press release should be a high priority. Unique situations will be handled on a case-by-

case basis. When public notification is necessary, state and FDA regulatory officials will work with firms initiating a recall to issue a press release as soon as the recall situations are identified. Alternative forms of communication, in addition to a press release, should be considered if feasible through licensees and other partners (e.g. to school licensees, hospitals, etc.). FDA, states, and locals may issue press releases in addition to those issued by the recalling firm.

8.9. Press Releases

Essential elements of a press release include the following:

- Establishment – The name and address of the firm with points of contact for recall information, as appropriate (e.g. Compliance/Recall Coordinator, Recall Management, Media Inquiries, Consumer Inquiries, website) and phone or fax number(s) including the days and times (with time zone) when the consumer information phones are answered.
- Product Recalled – Exact and complete description of the specific product(s) recalled including type of packaging and sizes.
- Production Dates/ID Codes – Specific identifying codes or marks on the packages; specific dates of production including plant codes, sell-by dates, expiration dates and location of codes on the package.
- Quantity Recalled – The quantity of product recalled.
- Recall Classification – Class I, II, or III if information is available; Note: Typically press releases are issued before the recall has been classified, so this information is often unavailable.
- Recall Notification Level – Wholesale, retail, or consumer.
- Problem/Reason for Recall – The problem with the product or the reason for the recall.
- Specific Nature of Potential Hazard – Examples: allergic reaction, infection.
- How and When Discovered – Details regarding the discovery of the hazard.
- Distribution – Geographic (international, nationwide, statewide, specific counties, and if possible, names of retail chains that carried the product).
- Media and Consumer Contacts and Instructions – Two different contacts are often given. Instructions to the public regarding typical symptoms of illness and what to do with the recalled product if they have it, including the name and telephone number of a company contact for consumers with any questions including the days and times (with time zone) when the consumer information phones are answered. Indicate if there have been any illnesses associated with the recalled product;
- Risk Information – Succinct information about specific steps consumers can take to reduce their risk of illness. An explanation of the risk involved in consuming the product including typical signs and symptoms of adverse health effects caused by the agent.
- Follow-up Activities – A statement regarding the status of the investigation and agencies involved, as appropriate (e.g. “the firm is cooperating with the

investigation by state and federal officials to identify the source of contamination").

See the following:

- Example Press Release (Attachment B)
- Example Customer Notification Letter (Attachment C)
- Examples of contamination or hazard warning language (Attachment D)

8.10. Recall Effectiveness

It is the recalling firm's responsibility to determine whether its recall is progressing satisfactorily. The firm has an obligation to conduct effectiveness checks as part of its recall strategy. Effectiveness checks assist in the verification that all known, affected consignees have received notification about a recall and have taken appropriate action.

In some instances, a recalling firm may be unable to check the effectiveness of its recall. This could occur when a recall extends to the consumer-user level, the confidential business records of a firm's customers are not accessible, wholesalers, distributors, or retailers do not cooperate, or, because the urgency of the situation requires an all-out effort. In such cases, FDA or state regulatory authorities may assist in this activity and, where necessary, seek assistance from cooperating state and local agencies.

Recall Audit Checks:

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

Level of Audit Checks (IOM 7.3.2.2)

- Level A – 100% of the total number of consignees to be contacted.
- Level B – Greater than 10% but less than 100% of the total number of consignees to be contacted.
- Level C – 10% of the total number of consignees to be contacted.
- Level D – 2% of the total number of consignees to be contacted.
- Level E – No audit checks.

Information that may be used to determine the level of audit check required can include:

- Recall Classification Level (I, II, or III)
- Depth of product distribution
- Likelihood that product is still in commerce

- Reports of confirmed illness linked to the product
- Target population group likely to consume the product

Conducting a Recall Audit Check

Recall audit checks may be conducted in various ways including in-person visits, phone calls, e-mails, record checks, etc. The information that should be obtained during an audit check includes:

- Name and title of person interviewed
- Verification that notification was received, understood, and followed
- Date and method of notification
- Amount of recalled product on hand at time of notification
- Amount returned and the method of return
- Amount destroyed and method of destruction
- Amount presently on hand and its status (held for sale, awaiting return, etc.)
- Date of anticipated return or destruction, and planned method (if applicable)
- Was sub-recall conducted? (If so, obtain a list of consignees from which to select your sub-recall check locations)
- Have injury reports or complaints been received? If so, report details.
- See: FDA Recall Audit Check Form 3177 (Attachment E)

Normally within 10 days of issuance of the firm's recall communication, the monitoring FDA inspectorate division office will issue audit check assignments at the appropriate level in the FDA audit program. FDA may request state assistance in conducting these audits, depending on available resources, severity of risk to the public or volume of distribution of the recalled products. A state may also determine the necessity of conducting its own recall audit checks and/or requesting assistance from local agencies based on distribution information it receives from FDA or the firm. It is strongly suggested that the State coordinate any independent audit check efforts with its FDA inspectorate division counterpart to avoid duplication of effort.

Exceptions to the ten-day time frame would be made for Class I situations when the recall is to the consumer/user level, and it is critical that the agency be certain that the products are off the market or that consumer/users have been notified of the recall action.

Upon receipt of completed audit check assignments from FDA, the Recall Coordinator reviews the FDA 3177 for completeness and determines whether the recall was effective or not. States having conducted independent audits using the FDA 3177 form should submit their completed, signed forms to the Recall Coordinator within an agreed-upon time frame. Local agencies should submit completed forms through their state partners to insure coordination of audit responses with federal authorities.

If a state uses its own recall audit data gathering mechanism, such as a web-based tool or spreadsheet, the data should be shared with the Recall Coordinator as soon as possible and a summary of how the data was gathered and how to interpret it should be provided.

Ineffective Recalls

If an audit check discloses recalled product being held for sale, or a requested sub-recall has not been initiated, the responsibility for failure to follow recall instructions should be documented. This is particularly important if the account received the recall notice and ignored it, or the consignee (downstream) failed to receive notification altogether. In these instances, products should always be removed from sale before the audit check is completed.

Completion and Termination of Recall

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

- **Recall Terminated**: A recall can be terminated when a state or federal regulatory authority 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. For recalls that FDA is coordinating, written notification that a recall is terminated will be issued by the appropriate FDA inspectorate division to the recalling firm.

- **Documenting Recall Procedure Effectiveness:** For large scale events, it may be helpful to include recall activities and issues in the After Action Report (AAR). This would provide a mechanism for documenting issues encountered with the recall procedure and provide opportunity to review and revise the procedures as needed.

9.0. DESIRED OUTCOMES (ACHIEVEMENT LEVELS)

Level	Description
1	Single Agency Basic – The Agency* has conducted a review of recall resources and guidance to identify applicable legal requirements/recommended practices and has basic procedures and contact lists for communicating recall information to consumers, other agencies, and relevant stakeholders.
2	Multi-Agency Basic – Appropriate individuals within the Agency have either signed a 20.88 Confidentiality Agreement with FDA or are commissioned so the agency can receive commercial confidential information from FDA to expedite removal of recalled product from commerce.
3	Single Agency Comprehensive – The Agency has developed and implemented comprehensive written recall procedures, which include 1) procedures for sharing of recall information; 2) procedures for prompt removal of recalled products; 3) procedures for audit checks; 4) adequate recordkeeping and a periodic review and revision process for the procedures.
4	Multi-Agency Comprehensive – The Agency regularly maintains and has implemented a communication and coordination process with recall partner agencies during emergency and non-emergency events to ensure recall procedures are revised as needed to increase the effectiveness of multi-agency recall activities. Routine communication could include incorporating recall activity discussions in Food Safety Task Force Meetings or other regularly scheduled meetings. Including recall activity discussion into AARs would provide a mechanism for documenting recall issues and provide an opportunity for revision of procedures as needed.

*Agency is defined as any agency participating in the Rapid Response Team

10.0. RELATED DOCUMENTS

Food Recall References, Regulatory Authorities, and Guidance

- **State**: Regulatory authority to mandate recalls varies from state to state. States may use their own or federal food recall references and regulations for guidance or procedures on how to monitor recalls effectively. If a state cannot mandate food recalls within their jurisdiction, they may have other authorities outlined in their respective state statutes that allow them to regulate foods that may be adulterated.
- **Federal:** This chapter is focused on food that is subject to FDA recall authority.

Related RRT Best Practices Manual Chapters, Topics, and References

- Traceback: If source of product or ingredients is unknown
- Environmental Assessment: To identify the root cause of the contamination
- Joint investigations

11.0. REFERENCES AND OTHER RESOURCES

- 21 CFR Part 7, Subpart C – Initiation of Voluntary Recalls, Guidance for Industry, and FDA Staff https://www.fda.gov/media/123664/download?utm_medium=email&utm_source=govdelivery
- 21 CFR Part 7, Subpart C – Recalls (7.41 to 7.59) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=7
- 21 CFR Part 107, Subpart E – Infant Formula Recalls (107.200 to 107.280) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=107
- Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm
- FDA Investigations Operations Manual, Chapter 7 – Recall Activities https://www.fda.gov/iceci/inspections/iom/default.htm
- FDA Regulatory Procedures Manual, Chapter 7 – Recall Activities https://www.fda.gov/ICECI/compliancemanuals/regulatoryproceduresmanual/default.htm
- United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) Recall information https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts
- Food Safety Modernization Act (FSMA) Mandatory Recall Authority https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247548.htm#SEC206
- FDA Form 3177 – Recall Audit Check Report https://www.fda.gov/media/75482/download
    - Instructions for Completing FDA Form 3177 (Exhibit 7-3) https://www.fda.gov/media/75263/download
- RPM Exhibit 7-4 Model Recall Letter (Exhibit 7-4) https://www.fda.gov/media/71814/download
- Model Recall Return Response Form (Exhibit 7-5) https://www.fda.gov/media/71814/download
- Index of FDA Model Press Releases:
    - Allergens (Allergy Alert)
    - Listeria monocytogenes
    - Clostridium botulinum
    - Salmonella (all serotypes)
    - E. coli 0157:H7
- Other Examples of Process Flow Diagrams –
    - FDA Food Recall/Action Initiation Process Flow/Timeline for Class I Human Food Recalls (SAHCODH) (Appendix A)
    - Mandatory Food Recall Process Flow Chart (Attachment J10 – page 99 of RPM Chapter 7)

12.0. ATTACHMENTS

- Attachment A – Examples of Recall Situations
- Attachment B – Example Press Releases
- Attachment C – Example of a Customer Notification Letter
- Attachment D –Wording for Specific Contaminant Signs and Symptoms
- Attachment E – Recall Audit Check Form 3177
- Attachment F – Alert to Recall and Attachment B Guidance
- Attachment G – Example of a Recall Flow Diagram

13.0. DOCUMENT HISTORY

Version #	Status*	Date	Author
1.0	I	10/26/2012	RRT Recalls WG (ATL-DO**, FDA OO/OEIO/DE, MA, MI, NC)
1.1	R	5/26/2017	ORA/OP
2.0	R	6/1/2023	ORA/OP-AFDO Compiled Revisions
3.0	R	12/1/2024	ODP-AFDO Compiled Revisions

*Status Options: Draft (D), Initial (I), Revision (R), or Cancel (C)
**Workgroup Lead

Change History
1.1 – Minor editorial revisions to formatting to align with overall 2017 RRT Manual Edition revision effort.
2.0 – AFDO compilation for 2023 Edition of RRT Manual
3.0 – AFDO compilation for 2025 Edition of RRT manual. Updated FDA program names resulting from the 10/2024 FDA reorganization

Attachment A – Examples of Recall Situations

Examples of Class I, II, and III Recall Situations
Recall classifications often occur on a case-by-case basis. Certain hazards may be classified as Class I, II, or III depending on circumstances and risk. Each unique situation cannot be captured in list format; therefore the following list is meant as a guide only. When the state is assisting with a recall, the FDA is consulted as appropriate to assure proper recall classification.

Note: *The following list represents the most common classifications for the hazards listed. Many factors are considered when assessing hazards associated with products such as the level of an adulterant in a product or the population most likely to use a product. Consult with your local FDA District RC regarding the specific circumstances involved with the product being considered for recall.*

Class I
Class I 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.

Examples

- *Listeria monocytogenes* in certain types of ready-to-eat food
- *Clostridium botulinum* toxin
- *Shiga toxin* producing *Escherichia coli* including *E. coli O157:H7* and *non-O157* Shiga toxin producing strains (STECs)
- *Salmonella sp.* in ready-to-eat food
- *Salmonella sp*. in pet food or pet treats
- Uneviscerated salt-cured, dried, or smoked fish products greater than 5” in length (FDA Compliance Policy Guide 540.650
- http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm124048.htm)
- Foods containing undeclared sulfites at a level greater than 10 mg per serving
- Foods containing an undeclared ingredient that contains protein derived from one of the following:
  - milk
  - egg
  - fish
  - Crustacean shellfish
  - tree nuts

- wheat
- peanuts
- soybeans
- sesame seeds

Note: *The hazard posed by these allergens in food may be mitigated in ways such as the presence of another labeled ingredient in the food derived from the same allergen, the obvious presence of the allergen in the food or further processing the ingredient to eliminate all or most of the allergenic protein. For more information on labeling of foods containing allergens, see the following guidance on FDA's website*

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergen-labeling-edition-5.

Class II
Class II 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.

Examples

- Certain undeclared coloring agents such as FD&C Yellow No. 5- See 31 CFR 101.22 (k) (3) for requirements specific to color declaration on butter, cheese and ice cream
- Undeclared wheat
- Certain situations where a pathogen risk in food is likely to be mitigated by a heat-kill/processing step performed by the consumer/user (for example, *Salmonella* in tea intended to be prepared using boiling water)
- Norovirus
- Adulteration with hard/sharp foreign objects such as glass or metal pieces
- Histamine in seafood

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

Examples

- Undeclared certified colors other than yellow 5. Refer to FDA Office of Microbiological Food Safety and FDA Federal Food, Drug and Cosmetic Act, section 721 (a).

- Decomposition (which does not result in health hazard such as histamine)
- Filth (which does not result in health hazard)
- Products which are unfit for food based on off-odor or off-taste but do not pose a hazard to health
- Minor labeling problems (e.g. format, undeclared ingredients that are not allergens)

Attachment B – Example Press Releases

Press Release Template

<COMPANY NAME>
<COMPANY ADDRESS>
<COMPANY CITY, STATE, ZIP>

FOR IMMEDIATE RELEASE <TODAY'S DATE>
COMPANY OFFICIAL NAME, TITLE, PHONE
DESCRIPTIVE TITLE OF RECALL

CITY <COMPANY NAME, ADDRESS>, is recalling its <SPECIFIC PRODUCT(S)> because they <SPECIFIC REASON FOR RECALL>.
INSERT PATHOGEN OR OTHER REASON FOR RECALL DESCRIPTION – HAZARD STATEMENT
(***Note: The phrase "potentially harmful" is not adequate to express the nature of a hazard for a Class I recall.)***

The recalled <PRODUCT> was distributed <DISTRIBUTION DESCRIPTION>.

SPECIFIC PRODUCT DESCRIPTION (UPC/ Lot Code, Packaging, location of coding on package)

Illnesses <HAVE/HAVE NOT> been reported to date in connection with this problem.

The contamination was noted after testing by <STATE/FEDERAL AGENCY NAME> revealed the presence of <PATHOGEN NAME> in some <DESCRIPTION OF PRODUCT>.

Production of the product has been suspended while <THE COMPANY, STATE AND FEDERAL OFFICIALS> continue their investigation as to the source of the problem.

Consumers who have purchased <DESCRIPTION OF PRODUCT> are urged to return them to the place of purchase for a full refund. Consumers with questions may contact <THE COMPANY and COMPANY CONTACT NUMBER>.

Pathogen Contamination Recall Press Release Example

ABC Produce
43234 Test Drive
Lansing, MI 48912

August 20, 2007
FOR IMMEDIATE RELEASE
John Smith, Communications Director, 517-444-2333

ABC Produce Announces the Recall of Cantaloupe Melons Due to Potential *Salmonella* Contamination

LANSING– ABC Produce, a wholesale importer of fresh fruit and vegetables, announced the recall of cantaloupes due to potential *Salmonella* contamination. The recalled product has been linked with a multi-state outbreak of *Salmonella*.

Healthy persons infected with *Salmonella* often experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare circumstances, infection with *Salmonella* can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (infected aneurysms), endocarditis and arthritis. The very young, the elderly, and people with compromised immune systems are the most susceptible to foodborne illness. People experiencing these problems should seek immediate medical attention.

Approximately 3,430 cantaloupes were distributed to retail stores in Ohio, Michigan, Indiana, and Wisconsin. The cantaloupes have a light green color skin on the exterior with orange flesh. The cantaloupes were distributed for sale in bulk in cardboard cartons, with 10-12 cantaloupes per carton. The recalled cartons are a natural brown color, with "Tropi-loupes de Costa Rica" printed on the side in green and white lettering.

On the bottom of each carton is a 10-digit code; the first three digits are between 099 and 135. Cantaloupes bear a "Tropi-loupe de Costa Rica" sticker, with a code of 09879.

The recalled product has been epidemiologically linked with a multi-state outbreak of *Salmonella*. Investigation is ongoing.

Consumers who have purchased the recalled cantaloupes are urged to return them to the place of purchase for a full refund. Consumers with questions may contact ABC Produce Monday – Saturday from 8 AM to 6 PM EST at 517-444-2333.

Allergen Recall Press Release Example

XYZ Company
P.O. Box 123
Lansing, MI 48912

August 20, 2007
FOR IMMEDIATE RELEASE
Mary Smith, Communications, 877-111-2222, ext. 12

XYZ COMPANY ISSUES ALLERGY ALERT ON UNDECLARED MILK AND EGG IN "XYZ CHOCOLATE CHIPPERS, CHOCOLATE CHIP COOKIES"

LANSING – XYZ Company of Lansing, MI is recalling 16-ounce packages of "XYZ Chocolate Chippers, Chocolate Chip Cookies" because they may contain undeclared milk.

People who have allergies to milk run the risk of serious or life-threatening reactions if they consume this product. The recall "XYZ Chocolate Chippers, Chocolate Chip Cookies" was distributed nationwide through retail stores.

The recalled product comes in a 16-ounce red package with gold writing, UPC code of 33333-49393. All date codes are included in this recall. The codes are located on the back label.

No illnesses have been reported to date in connection with the recalled product.
The recall was initiated after it was discovered that the milk containing product was distributed in packaging that did not reveal the presence of milk. Subsequent investigation indicates a malfunction in the labeling equipment. This has been corrected.

Consumers who have purchased 16-ounce packages of "XYZ Chocolate Chippers, Chocolate Chip Cookies" are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company Monday – Saturday from 8 AM to 6 PM EST at 877-111-2222, ext. 12.

Attachment C – Example of a Customer Notification Letter

Recalling firm:
NAME
ADDRESS
TELEPHONE NUMBER
TODAYS DATE

CUSTOMER FIRM NAME & ADDRESS
Attention: <CONTACT PERSON NAME & TITLE>
Re: Recall of <TYPE OF PRODUCT>

Dear Sir or Madam:

This letter is to confirm that <COMPANY NAME> is recalling the following product(s) because <SPECIFY REASON FOR RECALL>: <DESCRIBE THE PRODUCT(S), INCLUDING NAME, BRAND, CODE, PACKAGE SIZE AND TYPE, ESTABLISHMENT NUMBER, ETC.>

We request that you review your inventory records and discontinue selling your existing stock of this product. Please segregate the <PRODUCT(S)> and <INDICATE PROPER DISPOSITION> as soon as possible. We will credit your account for product returned.

We are undertaking this action in cooperation with the <REGULATORY AGENCY/AGENCIES>. State and federal officials may contact you to confirm that you have received this notice and are cooperating in this action.

Your prompt action will greatly assist <COMPANY NAME> in this action. If you have any questions, please do not hesitate to contact <COMPANY RECALL COORDINATOR at PHONE NUMBER>.

Thank you for your cooperation.

Sincerely,

<COMPANY OFFICIAL NAME AND TITLE>

Additional Content For Class I Recalls

In order to advise the <REGULATORY AUTHORITY> about the effectiveness of this recall, please inform us of the quantity of the above product on hand immediately after you received this recall letter.

Please sign and send or fax to <FAX NUMBER> this letter back to us as soon as possible.

Quantity on Hand: _____ Cases/Cans/Packages (Circle One)

_____ _____
(Store Owners Name) (Signature)

Example of In-Store Notification

Voluntary Recall Notice

We were notified on <DATE> that traces of <ADULTERANT> were present in <PRODUCT> produced on <DATE(S)> in our store. We believe this to be an isolated occurrence in this one batch. We have had no other reports of <ADULTERANT> to date and are cooperating fully with federal and state officials investigating this event.

If you have any <PRODUCT> at all with a packed-on date of <DATE> and sell by date of <DATE>, please return it for a full refund.

We appreciate your business and if you have any further questions, please feel free to call the store manager <NAME> at <PHONE NUMBER> or contact the store director <NAME> at <PHONE NUMBER>.

Thank You,

_____
(Store Owner's Name)

Attachment D – Wording for Specific Contaminant Signs and Symptoms

E. coli 0157:H7

E. coli 0157:H7 infections can cause watery diarrhea (bloody or non-bloody), dehydration, abdominal cramps, vomiting, and in severe cases a serious condition involving kidney failure called hemolytic uremic syndrome (HUS). The very young, the elderly, and people with compromised immune systems are the most susceptible to foodborne illness. People experiencing these problems should seek immediate medical attention. Onset time after ingesting = 1-3 days.

Listeria monocytogenes

Consumption of food contaminated with *Listeria monocytogenes* can cause listeriosis, an uncommon but potentially fatal disease. Listeriosis can cause high fever, severe headache, muscle aches, diarrhea, and nausea. Listeriosis can also cause miscarriages and stillbirths. The very young, the pregnant, the elderly, and people with compromised immune systems are the most susceptible to infection. People experiencing these problems should seek immediate medical attention. The onset time to serious forms of listeriosis is unknown but may range from a few days to three weeks.

Clostridium botulinum

Botulism, a potentially fatal form of food poisoning, can cause the following symptoms: general weakness, vomiting, diarrhea, dizziness, descending flaccid paralysis, double vision and trouble with speaking or swallowing. Difficulty in breathing, weakness of muscles, abdominal distension and constipation may also be common symptoms. The very young, the elderly, and people with compromised immune systems are the most susceptible to foodborne illness. People experiencing these problems should seek immediate medical attention. Onset time after ingesting = 12-72 hours.

Salmonella

Healthy persons infected with *Salmonella* often experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare circumstances, infection with *Salmonella* can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (infected aneurysms), endocarditis and arthritis. The very young, the elderly, and people with compromised immune systems are the most susceptible to foodborne illness. People experiencing these problems should seek immediate medical attention. Onset time after ingesting = 6-48 hours.

Allergens

People who have an allergy or severe sensitivity to specific type of allergen (e.g. peanuts, tree nuts {chestnuts, Brazil nuts, walnuts, hazelnuts, pecans, pine nuts, cashews}, eggs, sulfites) run the risk of serious or life-threatening allergic reaction if they consume these products. Onset - Most severe allergic reactions occur within seconds or minutes after exposure to the allergen. However, some reactions can occur after several hours, particularly if the allergen causes a reaction after it has been eaten. In very rare cases, reactions develop after 24 hours.

Attachment E – FDA Recall Audit Check Report Form 3177

1. RECALL INFORMATION

a. RES NUMBER	b. RECALLING FIRM	c. RECALLED CODE(S)	d. PRODUCT(S)

2. PROGRAM DATA *(FDA Users Only)*

a. MONITORING DIVISION

b. FEI NUMBER OF RECALLING FIRM

c. PAC CODE

3. AUDIT ACCOUNTS

a. DIRECT — PHONE NO.:

b. SUB-ACCOUNT (SECONDARY) *(Leave blank if none.)* — PHONE NO.:

c. SUB-ACCOUNT (TERTIARY) *(Leave blank if none.)* — PHONE NO.

4. CONSIGNEE DATA

Contacted by: ☐ Phone ☐ Visit ☐ Other

a. NAME OF PERSON CONTACTED & TITLE

b. TYPE CONSIGNEE

☐ Distributor ☐ Consumer ☐ Pharmacy
☐ Retailer ☐ Physician ☐ Restaurant
☐ Processor ☐ Hospital ☐ School
☐ Other: _____

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

☐ Yes ☐ No

5. NOTIFICATION DATA

a. FORMAL RECALL NOTICE RECEIVED? *(If answer is other than "Yes", explain in remarks and skip to Item 6c.)*

☐ Yes ☐ No ☐ Cannot be determined

b. RECALL NOTIFICATION RECEIVED FROM

☐ Recalling Firm ☐ Other *(Specify below)*
☐ Direct Account
☐ Sub-Account

c. DATE NOTIFICATION RECEIVED *(mm/dd/yyyy)*

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

6. ACTION AND STATUS DATA

a. DID CONSIGNEE FOLLOW THE RECALL INSTRUCTIONS? *(If "No", discuss in "Remarks" action taken as a result of audit check.)* ☐ Yes ☐ No

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

c. CURRENT STATUS OF RECALLED ITEMS

☐ Returned ☐ None on Hand
☐ Corrected ☐ Was Still Held for Sale/Use*
☐ Destroyed ☐ Held for Return/Correction*
* = Ensure Proper Quarantine/Action

d. DATE AND METHOD OF DISPOSITION

7. SUB-RECALL NEEDED? *Did consignee distribute to any other accounts? (If "Yes", collect information and/or provide details in "Remarks" or Memo.)* ☐ Yes ☐ No

8. AMOUNT OF RECALLED PRODUCT NOW ON HAND

9. INJURIES/COMPLAINTS

a. IS CONSIGNEE AWARE OF ANY INJURIES, ILLNESS, OR COMPLAINTS?

☐ Injury ☐ Complaint
☐ Illness ☐ None

If answer is other than "None", collect relevant information, document findings, and route per division procedures.

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

CHECK		FDA ENDORSEMENT	
Signature		Signature	☐ Effective ☐ Out of Business
Printed Name and Title		Printed Name and Title	☐ Ineffective *(Indicate level)* ☐ Notifying Firm ☐ Consignee
Date of Audit Check *(mm/dd/yyyy)*	FDA Division	Date of Endorsement *(mm/dd/yyyy)*	*If "No" is checked for 6a and/or 6b, "Effective" cannot be selected as an Endorsement.*
			☐ Other *(Specify)*: _____

FORM FDA 3177 (08/19) RECALL AUDIT CHECK REPORT Page 1 of 1

Instructions (Exhibit 7-3):

1. **Recall Information:**
   a. **RES/Recall Number** – Assigned by FDA--If available, enter the recall number assigned by the Center. If not available, leave it blank. If more than one number is involved, enter the lead number.

   b. **Recalling Establishment** – Provide the name and address of the firm responsible for issuing the recall notification. This must be filled in or audit will not be credited to appropriate recall.

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

   d. **Product(s)** Provide the name of the product under recall. If numerous products are involved, use generic terms, e.g., ice cream, dried fruit, etc.

2. **Program Data**: Only complete those items listed below. Most of the other fields in this section will be filled in by the FDA.
   a. **Hours** – record the on-site hours spent on-site conducting the audit check.

3. **Audit Accounts**: Note that not all audits will go all the way down to the tertiary level, based on distribution. Complete address and contact information for each account identified as part of the distribution to the consignee. As shown in the example below.
   a. ***Direct Account –*** This should be the information for the company that received the recalled product directly from the recalling company. (In the example above, it would be Sizzle Distributors, who received it from the recalling company, Bixby Darling Corporation)

   b. ***Secondary Account –*** The company receiving recalled products directly from the Direct Account listed in 3a. (e.g. Wilson Grocery Distribution Center, who received from Sizzle Distributors

   c. ***Tertiary Account –*** The company receiving recalled product directly from the Secondary Account in 3b. (e.g., Wilson Grocery #445, who received from Wilson Grocery Distribution Center)

1. RECALL INFORMATION

a. RES NUMBER	b. RECALLING FIRM	c. RECALLED CODE(S)	d. PRODUCT(S)
(this is assigned by FDA)	Bixby Darling Corporation 12234 Ninth Street Anytown, WI 59999	CsUPC 48859 49953; Lot 11123A (best if used by date 2/29/2012) UPC 48859 49950; Lot 11134B (best if used by date 2/29/2012)	Darling peanut butter, 10oz plastic jar Darling peanut butter, 32 oz plastic jar

2. PROGRAM DATA *(FDA Users Only)*

a. MONITORING DIVISION	b. FEI NUMBER OF RECALLING FIRM
HAFW1	2473386334

c. PAC CODE

3. AUDIT ACCOUNTS

a. DIRECT	b. SUB-ACCOUNT (SECONDARY) *(Leave blank if none.)*
Sizzle Distributors 33454 Johnson Mason, MI 48554	Wilson Grocery Distribution Center 32 Wilson Street Lansing, MI 48909
PHONE NO.: 517-676-5555	PHONE NO.: 517-992-5555

c. SUB-ACCOUNT (TERTIARY) *(Leave blank if none.)*	PHONE NO.
Wilson Grocery #445 423 Miner Rd Lansing, MI 48990	517-997-5111

4. CONSIGNEE DATA

Contacted by: ☐ Phone ☐ Visit ☐ Other

a. NAME OF PERSON CONTACTED & TITLE: Owen James, Store Manager

b. TYPE CONSIGNEE

☐ Distributor	☐ Consumer	☐ Pharmacy
■ Retailer	☐ Physician	☐ Restaurant
☐ Processor	☐ Hospital	☐ School

☐ Other: _____

c. DOES (DID) THE CONSIGNEE RECEIVE RECALLED PRODUCT? ■ Yes ☐ No

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

- A consignee may be a retail facility, distributor, food bank, etc.
- The consignee would be the last facility in the distribution chain listed on the audit.

In the example above, the Consignee would be the Tertiary Account, Wilson Grocery #445". The audit information being collected on the form would be for the Wilson Grocery #445.

If the audit check was being conducted at the Secondary Account facility, the Secondary Account facility would be considered the Consignee, and both the Direct Account and Secondary Account address and contact information should be shown on the audit form.

1. RECALL INFORMATION

a. RES NUMBER	b. RECALLING FIRM	c. RECALLED CODE(S)	d. PRODUCT(S)
(this is assigned by FDA)	Bixby Darling Corporation 12234 Ninth Street Anytown, WI 59999	CsUPC 48859 49953; Lot 11123A (best if used by date 2/29/2012) UPC 48859 49950; Lot 11134B (best if used by date 2/29/2012)	Darling peanut butter, 10oz plastic jar Darling peanut butter, 32 oz plastic jar

2. PROGRAM DATA *(FDA Users Only)*

a. MONITORING DIVISION	b. FEI NUMBER OF RECALLING FIRM
HAFW1	2473386334

c. PAC CODE

3. AUDIT ACCOUNTS

a. DIRECT	b. SUB-ACCOUNT (SECONDARY) *(Leave blank if none.)*
Sizzle Distributors 33454 Johnson Mason, MI 48554	Wilson Grocery Distribution Center 32 Wilson Street Lansing, MI 48909
PHONE NO.: 517-676-5555	PHONE NO.: 517-992-5555

c. SUB-ACCOUNT (TERTIARY) *(Leave blank if none.)*	PHONE NO.
Wilson Grocery #445 423 Miner Rd Lansing, MI 48990	517-997-5111

4. CONSIGNEE DATA

Contacted by: ☐ Phone ☐ Visit ☐ Other

a. NAME OF PERSON CONTACTED & TITLE

Owen James, Store Manager

b. TYPE CONSIGNEE

☐ Distributor ☐ Consumer ☐ Pharmacy
☒ Retailer ☐ Physician ☐ Restaurant
☐ Processor ☐ Hospital ☐ School
☐ Other: _____

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

☒ Yes ☐ No

In the example below, the Consignee being audited is the Direct account, Sizzle Distributors. Please note that there are no other sub-accounts are listed on the audit form.

1. RECALL INFORMATION

a. RES NUMBER	b. RECALLING FIRM	c. RECALLED CODE(S)	d. PRODUCT(S)
(this is assigned by FDA)	Bixby Darling Corporation 12234 Ninth Street Anytown, WI 59999	CsUPC 48859 49953; Lot 11123A (best if used by date 2/29/2012) UPC 48859 49950; Lot 11134B (best if used by date 2/29/2012)	Darling peanut butter, 10oz plastic jar Darling peanut butter, 32 oz plastic jar

2. PROGRAM DATA *(FDA Users Only)*

a. MONITORING DIVISION	b. FEI NUMBER OF RECALLING FIRM
HAFW1	2473386334

c. PAC CODE

3. AUDIT ACCOUNTS

a. DIRECT	b. SUB-ACCOUNT (SECONDARY) *(Leave blank if none.)*
Sizzle Distributors 33454 Johnson Mason, MI 48554	Wilson Grocery Distribution Center 32 Wilson Street Lansing, MI 48909
PHONE NO.: 517-676-5555	PHONE NO.: 517-992-5555

c. SUB-ACCOUNT (TERTIARY) *(Leave blank if none.)*	PHONE NO.
Wilson Grocery #445 423 Miner Rd Lansing, MI 48990	517-997-5111

4. CONSIGNEE DATA

Contacted by: ☐ Phone ☐ Visit ☐ Other

a. NAME OF PERSON CONTACTED & TITLE: Owen James, Store Manager

b. TYPE CONSIGNEE

☐ Distributor	☐ Consumer	☐ Pharmacy
■ Retailer	☐ Physician	☐ Restaurant
☐ Processor	☐ Hospital	☐ School

☐ Other: _____

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

■ Yes ☐ No

- The data requested is self-explanatory.
- If the consignee typically has/had the product in stock during the time frame covered by the recall (carried the product six months ago, and the recall is for product in commerce at that time), 4c would be marked 'yes'.
- If the consignee has further distributed product and a sub-recall is needed to reach the appropriate recall depth, obtain a copy of their distribution list for the recalled product.

5. **Notification Data**: Box 5, a-d, each section box must have a checkbox completed and the detail of how the firm was notified.

- Did consignee receive a specific written, verbal, or personal contact providing recall notification?
- From whom and when was notice received?
- If they only heard about it from the media, include this information

6. **Action and Status Data**:
   a. Did the consignee follow the directions they received from their supplier/recalling company regarding what to do with the product? If 'no', record the consignee explanation for not following the directions along with other findings in Block 10.

   b. Record the amount the consignee said they had when they received notification of the recall, NOT the amount they have when you contact them.

      NOTE: If firm does not remember how much they had, document 'not available'. If they didn't have any when they were notified, enter 'none'

   c. Record information for product both on-site at time of audit as well as product they may have disposed of or sent back to the supplier.

   d. Document what firm did to the best of their recollection.

7. **Sub-Recall Needed**: If consignee supplies/supplied product to other accounts, then they may need to do a sub-recall in order to meet the appropriate recall depth. The inspector should mark item 7 with "YES"

- If the firm needs to do a sub-recall, obtain a copy of the distribution list for all of the recalled products and describe firm's sub-recall procedures in Block 10 REMARKS
- The inspector may also be asked to complete Attachment B information if directed by the Regional supervisor, and submit all information collected.
- If firm has refused to sub-recall properly without justification, include your agency follow-up actions in Block 10 and give reason why firm states they refuse to conduct a sub-recall. Mark INEFFECTIVE in the Endorsement block in the lower right-hand corner.

8. **Amount of Recalled Product Now on hand:** If none on hand at time of audit, document 'none', do not leave blank.

9. **Injuries/Complaints:** Self-explanatory.

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

CHECK section (lower left corner of document):
- Signature of CSO/CSI: Inspector's name goes here, preferable to physically sign and scan document to send electronically, if possible.
- Date of Check needs to be completed
- District will be provided to inspector

ENDORSEMENT Section of Form (lower center and right corner of document):

- This section is left blank by the Consumer Safety Officer (CSO), Consumer Safety Inspector (CSI), or field inspector for completion by the supervisor.
- The endorsement box needs to be completed by the supervisor with their name, statement “effective” or “not effective”, and date of endorsement.

Examples:
"Not Effective": The audit check discloses recalled product being held for sale or a requested sub-recall has not been initiated, Document the responsibility for failure to follow recall instructions. This is particularly important if the account received the recall notice and ignored it. The audit check is also considered ineffective if the consignee did not receive notification from the firm (recalling firm or distributor) that sold the recalled product to the consignee.

"Effective" Recall notice was received from the firm (recalling firm or distributor) that sold the recalled product to the consignee and the consignee followed the instructions in the recall notification.

Attachment F – Alert to Recall and Attachment B Guidance

RECALL REPORTING INSTRUCTIONS
(Not intended for blood, blood products or tissue recalls)

The following instructions may be used to assist in gathering recall information and documents from a recalling firm. It is based on the instructions in Chapter 7 of the RPM and Chapter 7 of the IOM and is intended to be a more descriptive, easier to use format.

ALERT TO RECALL (also known as "24 Hour Alert"):

Provide to the Recall Coordinator (RC) within 24 hours of learning the recall is planned or underway.

When you encounter a voluntary recall situation at a firm that has not yet notified the FDA of the recall, contact the Recall Coordinator at the FDA inspectorate division to report the recall as soon as possible, preferably the day you discover the recall.

(1) PRODUCT (brand name and product name of the product(s) being recalled)
(2) CODE (all production and manufacturing code(s) involved)
(3) RECALLING FIRM/MANUFACTURER (name and address, FEI/CFN)
(4) REASON FOR RECALL (briefly explain reason(s) product is being recalled)
(5) AWARENESS DATE/ RECALL START DATE (date any FDA inspectorate division personnel first became aware of the recall, date firm sent notice to consignees, and date firm issued press release**, if any)**

ATTACHMENT B INFORMATION (PLEASE Do **NOT** hold this form until you complete your inspection report):

This information is due to the RC within 4 working days of when the Alert information was submitted (within 10 working days for a closed recall).
Please be sure to collect copies of the "Recall Documents":
Recall Documents:

(1) Product label(s): Labels and labeling for each product/size, if product is unlabeled, collect any other record that shows the name of the product. Digital pictures are excellent.
(2) Recall Letter(s): letters/faxes/bulletins/emails that communicate recall information to consignees, customers, and consumers.
(3) Distribution List: list of consignees with FULL ADDRESSES and phone number
(4) Product Catalog: if any
(5) Test Results: analytical work sheet, methodology used, if available. If done by contract lab, obtain full name and address of lab

(6) Press Release**:** news release, or allergy alert, if any
(7) Health Hazard Documents: health hazard evaluation, risk analysis, etc.
(8) Other Documents**:** documents that reflect corrective actions, such as SOP changes

Please provide an **electronic** copy of the following information with the Recall Documents

Date(s) of establishment inspection:
Date CSO/inspector became aware of firm's recall:

Provide detailed information regarding the recall **(please follow the number format below)**:

1. PRODUCT(S):

IF THE PRODUCT IS A **FOOD**, BEVERAGE, ETC., INCLUDE:

a. Name of product:
b. Brand name:
c. Unit size (1/2 gallon, 18 ounce, 2 lb. pkgs.):
d. Container description (in paper cartons, in glass jars):
e. Total package size (12 packages per case):
f. Distributed by and/or Manufactured by (name & address—quote from label):
g. Storage instructions, if any (frozen, refrigerate after opening etc.):
h. Shelf life and/or expiration date:

2. CODE(S):

List all batch numbers, lot numbers, UPCs, product numbers, packer or manufacturer or plant numbers, etc.

3. RECALLING FIRM/MANUFACTURER:

Provide complete name and address of the recalling firm, including FEI/CFN. Provide complete name and address of manufacturer, if different from recalling firm.

4. REASON FOR RECALL RECOMMENDATION:

a. State simply **WHY** the firm has decided to recall the product.
b. How did the firm **DISCOVER THE REASON** for recall?
c. What is the **ROOT CAUSE** for the reason for recall? Include any analytical finding in qualitative and/or quantitative terms, indicating whether firm's analysis or private laboratory was involved. Provide copies of test results/lab results analytical work sheets, and methodology used, copy of FDA-483, report narrative and coversheet (483, EIR and C/S may be forwarded when completed).

d. What type of ILLNESS **or INJURY** may be caused by the problem?
e. What is the TOTAL number of reports of **ILLNESS or INJURY COMPLAINTS** received regarding recall product? Collect copies of all complaints and complaint investigations. If that is too voluminous, collect summary documents and a few representative complaints.
f. What is the TOTAL number of reports of **PRODUCT DEFECT COMPLAINTS** received regarding recall product? Collect copies of all complaints and complaint investigations. If that is too voluminous, collect summary documents and a few representative complaints.
g. Has the firm done any **HEALTH HAZARD EVALUATIONS** and/or Health Risk Assessments associated with the recall product? Is so, summarize and include copies.
h. What action is the firm taking to **PREVENT A SIMILAR OCCURRENCE** of the problem? Collect verification of training or SOP changes, documents pertaining to product QA, design control, specifications, validation of software, etc., as appropriate to support firm's actions.

5. VOLUME OF PRODUCT IN COMMERCE:

a. What is the total amount of product that was manufactured?
b. What is the total amount of product distributed in commerce?
c. What is the amount of recalled product remaining at the firm?
d. What are the dates of distribution? (e.g., 12/3/10 to 4/14/12)
e. Provide an estimate (%) of the amount of product that may be recovered.

6. DISTRIBUTION PATTERN:

a. What is the TOTAL number of **consignees** (all customers) that received the recall product? (6b+6c+6d+6e, see below)
b. What is the TOTAL number of **wholesaler dealers** that received the recall product?
c. What is the TOTAL number of **distributors** that received the recall product?
d. What is the TOTAL number of **retailers** that received the recall product?
e. What is the TOTAL number of **consumers/users** that received the recall product?
f. Where is the recall product **distributed**? Indicate whether worldwide, nationwide, statewide. If foreign distribution, name the countries. Also **name the U.S. States,** e.g., MI, IN or provide a list of the **U.S consignees** with their FULL ADDRESSES with PHONE NUMBERS. For recalls with Class I potential we will usually need a complete list of consignees, foreign and domestic.
g. Were there any recalled products distributed to the Defense Supply Center, Veteran's Administration, or other Federal Government sales/distribution centers? For all recalls, regardless of class, provide List of **foreign/military/government consignees** with full addresses.

7. FIRM'S RECALL STRATEGY:

a. Include the **DATE** the decision was made to recall and the **DATE** of the first recall communication to consignees.
b. How does the firm plan to **NOTIFY** all consignees affected by this recall? By letter, press release, fax, telephone, e-mail, visit, etc.?
c. Does the recall strategy include a **SUB-RECALL (recall beyond direct accounts)**? If yes, provide details on how this will be accomplished. Will the direct accounts handle the sub-recall or will the recalling firm obtain distribution from the direct account and contact the sub-account themselves? Collect any additional letters, faxes, e-mails, etc. that are generated.
d. How does the firm plan to monitor the number of **CONSIGNEES NON-RESPONDING** to the recall communication? By response form mailed, certified mailing with return receipt, etc.?
e. How does the firm plan to do **EFFECTIVENESS CHECKS** of all the consignees? By response form mailed, certified mailing with return receipt, fax, telephone, e-mail, visit, follow-up letters, etc.?
f. How does the firm plan to **STORE** the recalled product?
NOTE: It is equally important to assure that all returned merchandise is promptly inventoried, handled, and stored in such a manner as to assure its separation from acceptable materials so it will not inadvertently be used or shipped. Our past experience in similar situations has shown that the longer a defective product is held between the initiation and termination of a recall, the greater the chance of its accidental misuse.
g. How does the firm plan to **DISPOSE** of the recalled products? (destroy, recondition, correct label, field correct by firm's personnel, etc.)
h. Comment on whether you consider the procedures to be used in the recall strategy are adequate.

The firm should be reminded that any destruction, reconditioning or diversion to alternate use of recalled items may require FDA supervision and therefore the firm must inform the FDA prior to undertaking such action.

8. FIRM'S OFFICIAL:

List name, title, business address, direct business phone of the primary contact at the firm responsible for overseeing the recall (include phone number, fax number and email address).

9. FIRM'S MOST RESPONSIBLE INDIVIDUAL

List name, title, business address, direct business phone of the most responsible individual of the firm. Include phone number, fax number and email address.

10. STATUS: State whether the recall is ongoing, completed or terminated:

A recall is ongoing when the goods are still being retrieved from the market, still being field corrected, etc.

A recall completed when the recall action reaches the point at which the firm has actually retrieved and impounded all outstanding product that could reasonably be expected to be recovered or has completed all product corrections.

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 FDA inspectorate division to the recalling firm.

Collect destruction certificates or other documentation of destruction.

11. SAMPLE(s) COLLECTED (if any)**:**

State the sample number(s), if collected and product name. Indicate if documentary or physical sample was collected and the date collected.

12. FDA PRODUCT CODE: http://www.accessdata.fda.gov/scripts/ora/pcb/pcb.cfm

Some examples:
Ginger Ale in glass: 29BCG04
Carmel coated popcorn: 33SGG03
Maple Syrup in cans: 36BEG05
Ice Cream: 13AFGO1

13. LEGAL ACTION (if any)**:**

State any legal action planned/recommended/underway by State or Federal Regulatory Agency.

Attachment G – Example of a Recall Flow Diagram