

**ORA/Office of Enforcement
Division of Compliance Management and Operations**

**GUIDANCE FOR INDUSTRY
Product Recalls, Including
Removals and Corrections**

This guidance document is intended to provide guidance and instructions to FDA regulated industry for obtaining information to help fulfill the Agency's plans regarding product recalls. It represents the agency's current thinking on product recalls. This guidance does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. To discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance. This guidance is available electronically to the public.

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INTRODUCTION:

This guidance is intended to assist those members of industry regulated by the Food and Drug Administration (FDA) in handling all aspects of a product recall, including all corrections and removals. The guidance includes a checklist of documentation and information that FDA utilizes to evaluate, classify, monitor and audit product recalls. Various statutory provisions and regulations, described below, authorize FDA to require recalls of certain products in particular circumstances. Additionally, Subpart C of Part 7 of FDA regulations (21 CFR 7.40-59) provides general guidance for the voluntary recall of products, including those recalls initiated by a firm on its own and at FDA's request. This guidance provides more specific recommendations and applies to both mandatory and voluntary recalls of all FDA-regulated products (i.e. food, including animal feed; drugs, including animal drugs; medical and radiological devices; cosmetics; human biological products including blood; and human tissue.)

This is a level 2 guidance document published for immediate implementation in accordance with FDA's good guidance practices (21 CFR 10.115). This guidance sets forth the agency's existing practices in the handling of recalls. Interested parties may submit comments on this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

Guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Certain statutory provisions authorize mandatory recalls of infant formula (21 USC § 350a(e)-(g)), medical devices (21 USC § 360h(e)), and human biological products (42 USC § 262). Additionally, FDA regulations set forth specific requirements for mandatory infant formula recalls (Subpart E of 21 CFR Part 107), medical device corrections and removals (21 CFR Part 806), and mandatory human tissue recalls (Subpart D of 21 CFR Part 1270). In addition to the requirements in these statutory provisions and regulations, the guidance's specific recommendations would also apply to these types of recalls. In the context of a mandatory recall, those conditions in the guidance that are already set forth in a statute and/or regulation would be requirements, rather than recommendations, under the applicable statute and/or regulation.

FDA believes the cooperation of manufacturers and distributors in expediting recall activities is vital because of the determination that a distributed product is potentially hazardous to the public or animals and/or is in violation of the Federal Food, Drug, and Cosmetic Act (the Act). Recalling firms are urged to notify the local FDA District Recall Coordinator as soon as a decision is made that a recall is appropriate and prior to the issuance of press or written notification to customers. For your local recall coordinator, please check the following website: http://www.fda.gov/ora/inspect_ref/iom/iomoradir_monitors.html#recall

It is recommended that you submit the information outlined in this guidance to your local FDA District Recall Coordinator as soon as possible after the decision to recall is made and the coordinator notified. It is recommended that you do not wait to submit this information until ALL applicable information is prepared and assembled prior to FDA notification. This "early" notification will allow FDA the opportunity to review and comment on your written notification and to offer guidance and assistance in your recall process.

A. Recall Submission to FDA

We recommend that you include the following information in your recall submission:

1. PRODUCT INFORMATION:

- Product name (include brand name and generic name)
- Model, catalogue, or product order number(s)
- Description of the product
 - Include if product is powder, liquid, tablet, capsule, etc.
 - Include the intended use or indications.
 - If the product is perishable, include the expected shelf life.
 - Include type of packaging (i.e. box, flexible plastic, glass).
 - **TWO COMPLETE SETS OF ALL labeling to your Local FDA District Recall Coordinator. Include:**
 - Product labeling (including ALL private labels)
 - Individual package label
 - Case label (photocopy acceptable)

- Package Inserts
- Directions for Use
- Promotional Material (if applicable)

Additional information for **Drug** recalls:

- NDA/ANDA/NADA Number
- NDC Number
- Indicate if prescription or OTC
- Strength
- Route of Administration

Additional information for **Medical Device** recalls:

- 510(k)/IDE/PMA number

Additional information for **Biological** recalls:

- License number
- Registration number

2. CODES (Production Identification Numbers):

- Lot/Unit Numbers

(NOTE: If "all lots" are involved or the product is not coded, explain how non-recalled, or reintroduced product may be distinguished from product subject to recall. Provide an explanation of your lot number coding system.)

- Expiration date(s) or Use by date(s) or Expected shelf life of product.
- Serial numbers (medical devices)
- UPC codes

3. RECALLING FIRM:

- Firm name, address, city, state, zip code
- Identify firm type (i.e. manufacturer, importer, broker, repacker, own-label distributor)

CONTACTS for Recalling Firm:

- Name/title/phone/fax number/e-mail address for RECALL contact
- Name/title/address/phone/fax number of the most responsible individual for the recalling firm
- Name/title/phone/fax number/e-mail address for public contact

4. MANUFACTURER:

- Firm name, address, city, state, zip code
- FDA registration number, if applicable

5. IDENTIFY FIRM RESPONSIBLE FOR THE VIOLATION/PROBLEM:

- Firm name, address, city, state, zip code

6. REASON FOR THE RECALL:

- Explain in detail how product is defective and/or violative.
- Explain how the defect affects the performance and safety of the product. (Also see #5, Health Hazard Assessment)
- If the recall is due to the presence of a foreign object, describe the foreign objects' size, composition, hardness, and sharpness.
- If the recall is due to the presence of a contaminant (cleaning fluid, machine oil, paint vapors), explain level of contaminant in the product. Provide labeling, a list of ingredients and the Material Safety Data Sheet for the contaminant.
- If the recall is due to failure of the product to meet product specifications, provide the specifications and report all test results. **Provide copies of any sample analysis.**
- If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s).
- Please explain how the problem occurred and the date(s) it occurred.
- Explain how the problem was discovered and the date discovered.
- Please explain if the problem/defect affects ALL units subject to recall, or just a portion of the units in the lots subject to recall.
- Explain why this problem affects only those products/lots subject to recall.
- Provide detailed information on complaints associated with the product/problem:
 - Date of complaint
 - Description of complaint -include details of any injury or illness
 - Lot Number/Serial Number involved
 - **Medical Device Complaints** - include copies of MedWatch-MDRs
- If a State agency is involved in this recall, identify Agency and contact.
- **Drug recalls (NDA/ANDA/NADA/ANADA products)** – provide details for any Field Alert submitted

7. HEALTH HAZARD ASSESSMENT:

- Please provide your assessment of the health risk associated with the deficiency.
- NOTE: A recall decision does not depend solely on the health risk of the product. Defective products and misbranded products where no health hazard exists are still in violation of the law and should be recalled.
- For recalls of products such as human tissue and biological products, including blood products, due to donor suitability/viral marker testing, provide copies of:
 - donor screening form
 - test results, including viral marker test results for implicated unit, viral marker test results for subsequent donations, and, if available, confirmatory test results.
 - SOPs that show the acceptance criteria for donor screening and/or viral marker testing, that was not met for the product(s) subject to recall.

8. VOLUME OF RECALLED PRODUCT:

- Total quantity produced
- Date(s) produced

- Quantity distributed
- Date(s) distributed
- Quantity on HOLD by Recalling firm and its distribution centers.
- Indicate how the product is being quarantined
- Estimate amount remaining in marketplace
 - distributor level
 - retail level
 - pharmacy or veterinary level (drugs)
 - user level (i.e. Medical Devices)
- Provide the status/disposition of marketed product, if known, (e.g. used, transfused, implanted, used in further manufacturing, or destroyed).

9. DISTRIBUTION PATTERN:

- Number of DIRECT accounts (customers you sell directly to) by type, for example:
 - wholesalers/distributors
 - repackers
 - manufacturers
 - retail/pharmacy/veterinarian
 - users (medical devices - hospitals, clinics, laboratories)
 - consumers (internet or catalog sales)
 - federal government consignees
 - foreign consignees (specify whether they are wholesale distributors, retailers or users)
- Geographic areas of distribution, including foreign countries.
- **Provide a consignee list (names/address/city/state/contact name/phone number) to the local District Recall Coordinator. Be sure to include any foreign (including Canadian) customers and federal government consignees (USDA agencies, Veterans Affairs, Department of Defense)**
- Indicate what the consignee list represents (i.e. all customers who were shipped recalled product; all customers who were *sold* recalled product; all customers who *may have* been shipped or sold recalled product because it was sold to them within the applicable time period.)
- Was product sold under a government contract? If yes, provide contract number, contract date and implementation date. If no, indicate so.
- Was product sold to any federal, state, or local agency involved in the *school lunch program*? If yes, list the consignees and provide quantity and sale and shipment date.

In addition, it is recommended that you notify both "ship to" and "bill to" customers of the recall so that

- "Ship to" customers retrieve the product from their location.
- "Bill to" customers, if responsible, initiate the subrecall.

10. RECALL STRATEGY:

- Indicate the level in the distribution chain to which you are extending the recall. (i.e. wholesale/retail/pharmacy/medical user)

If your recall only extends to the wholesale/distributor level, we recommend that you explain your rationale for not recalling to retail/pharmacy level.

- Indicate the method of notification (i.e. mail, phone, facsimile, e-mail). It is advisable to include a written notification so customers will have a record of the recall and your instructions.
- Indicate how letters will be sent to customers (e.g. overnight mail, first class mail, certified mail, facsimile)
- If initial notification is by phone, provide a copy of the phone script to FDA.
- If you have a web site, you should consider posting the recall notification on the web site as an additional method of recall notification. (Note: This is not recommended as a sole means of customer notification.)
- Report on what you have instructed customers to do with the recalled product.
- It is helpful for recalling firms to know the name and title of the Recall Contact for each of its consignees. Addressing a recall notification letter to a recall contact will expedite the recall process and reduce the potential for the notification letter to get misdirected.
- If product is to be returned, explain the mechanics of the process.
- Explain if this recall will create a market shortage that will impact on the consumer.
- Report on recall **effectiveness check** strategy. Include your actions for non- responders. See: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm>
- Determine and provide your course of action for out-of-business distributors.
- Provide a proposed method of destruction, if applicable.
- If the product is to be "reconditioned", explain how and where the reconditioning will take place. Please provide details of the reconditioning plan to your local FDA District Recall Coordinator before implementation. All reconditioning must be conducted under any applicable CGMPs.
- Describe how reconditioned product will be identified so it is not confused with recalled (pre-reconditioned) product.

In addition, we recommend that:

- You contact your local FDA District Recall Coordinator prior to product destruction. FDA will review your proposed method of destruction and may choose to witness the destruction.
- The recalling firm and customers keep adequate documentation of product destruction (and whether or not destruction was witnessed by an FDA investigator).
- Field corrections, (i.e. product relabeling), be performed by recalling firm representatives, or under their supervision and control. It is not recommended that a disinterested party such as a wholesaler or retailer be responsible for field corrections. For Drug Recalls: Misbranded drugs for re-labeling should be returned to the recalling firm.
- You contact your local District Recall Coordinator prior to release of reconditioned goods.

B. Public Notification

1. PRESS RELEASE:

In a situation where the product may pose a significant health hazard and recalled product is in the hands of consumers, a press release is usually appropriate. Issuance of a press release should be the highest priority and it should be issued **promptly**. Unique situations will be handled on a case-by-case basis.

- You should consult with your local District Recall Coordinator before issuance of a press release

whenever possible. A joint press release may benefit the firm and FDA by alerting the public to a serious health hazard or situations deemed to be in the public interest. Model Press Release Guidance is available on the FDA website at: http://www.fda.gov/ora/compliance_ref/recalls/recallpg.html

- To assure the broadest coverage, press releases should be issued through the Associated Press (AP). For local and/or regional recalled product distribution, you should contact the Associated Press offices in the States in which the product was distributed. Associated Press contacts can also be found on their website at: www.ap.org. Click on “Contact AP” at top of the home page. For recall press releases needing national media coverage (8 states or more), firms should call the Associated Press, Washington, DC Bureau at 202-776-9467 during business hours. After 5:00 p.m. Eastern time, contact the AP news desk at 202-776-9477. The facsimile number is 202-776-9570. **Your local District Recall Coordinator can offer guidance.**

NOTE: For those recalls where FDA believes a Press Release is warranted, the Agency will issue a Press Release if the firm has failed to do so, or if the firm-initiated press release is not adequate.

2. GUIDANCE FOR WRITTEN RECALL NOTIFICATION LETTERS: **Recall Notifications** should be flagged in large bold print "**URGENT: [insert "FOOD", "DRUG", "MEDICAL DEVICE", etc.] RECALL or CORRECTION**". Envelopes should be similarly flagged. FDA recommends that you include the following information in a recall notification:

a. PRODUCT IDENTIFICATION:

- Include an accurate and complete description of the product and any codes used to identify the product, e.g. lot/unit numbers, expiration date, serial numbers, catalog numbers, model numbers, and UPC codes.
- Consider including a copy of the product label with the recall notification. This could be helpful for wholesalers and retailers in identifying and removing the recalled product.

b. DESCRIPTION OF THE PROBLEM:

- Identify the problem **and** any potential health hazard(s) associated with it.

c. DEPTH OF THE RECALL:

- The recall notification should **clearly** identify the depth to which the recall is to extend (e.g. wholesale, retail, or user level). If the recall is to the **retail** level, a statement should read “This recall is to the retail level.”
- If the product could have been further distributed by your customers, then you should include instructions to subrecall. Subrecall instruction should also include the depth of the recall, e.g. “If you have further distributed this product, you should notify your customers to the retail level.”
- If your customers are instructed to conduct subrecalls, it is advisable to provide them with the date range that the recalled product was distributed. Wholesalers/ distributors may need this information in order to identify customers they shipped/sold recalled product to.

You should consider providing a subrecall letter with your notification package for your customers to further notify their sub accounts. You are then assuring that the information to sub accounts is accurate and complete.

d. INSTRUCTIONS TO CUSTOMERS:

- Your recall INSTRUCTIONS should be clear. For example:
 - Remove product from sale
 - Cease distribution
 - Subrecall (if appropriate)
 - Return product
 - Explain procedure for product correction
- Include a RETURN RESPONSE card/form. This return response card/form should include all instructions from your recall letter. Your customers should be required to indicate that they followed every instruction.

Provide examples of ALL recall communications (include letters, attachments, envelope) to your Local District Recall Coordinator.

IMPORTANT: All customers in the distribution chain should be **NOTIFIED** of the recall, preferably in writing. Here are some examples of why this is important.

1. In the case of a human drug recall, FDA does not believe it is appropriate for a salesman to visit a doctor's office and remove product without notifying the physician or responsible staff. Physicians may be treating patients that may suffer or have suffered some adverse effect from the drug subject to recall. With knowledge of the recall and the reason for the recall, the physician can better evaluate a patient's condition and provide appropriate patient care.
2. In the case of products sold at retail stores, FDA does not believe it is appropriate for a salesman or broker representatives to remove product from retail shelves without informing store management of the recall. Failure to inform store management of the recall could result in product that is in storage, in transit to the store, or returned by customers, being offered for sale. The salesmen or broker representatives may not have knowledge or access to the recalled products stored in back rooms. Recalled products that are in-transit to the store would then be sold to customers. Recalled products returned by customers may be placed back on store shelves.

C. Evaluation of the Recall

1. EFFECTIVENESS OF THE RECALL:

It is the recalling firm's responsibility to assure that the recall is effective. Therefore, we recommend that you consider effectiveness checks for every recall. The purpose of an effectiveness check is to verify your recall notification letter was received by the customer, that the customer read and understood the letter and followed the recall instructions. The effectiveness check should also verify your recall reached the appropriate level in the distribution chain.

The effectiveness check is your means of evaluating the effectiveness of your recall. If your effectiveness checks indicate that the recall notification was not received, read and/or instructions followed, then you should take necessary steps to make the recall effective. These steps may involve sending out a follow up notification that better identifies the product, better explains the problem and/or provides better instructions to customers.

Your District Recall Coordinator will provide a copy of a FDA document, "Methods for

Conducting Recall Effectiveness Checks.”

Note: In addition to the effectiveness checks conducted by recalling firms, FDA may also contact a percentage of your customers (referred to as audit checks) as a means of assuring the recalling firm and its consignees are carrying out their recall responsibilities. If FDA's audit checks determine the recall to be *ineffective*, the recalling firm (or sub recalling firm if such is the case) will then be asked by FDA to take appropriate actions, including re-issuing recall notifications.

2. RECALL STATUS REPORTS:

You will be asked to provide Recall Status Reports after initiating a recall (usually on a monthly basis but more frequently when indicated) to your local District Recall Coordinator. The reports requested will usually include the following information:

- Dates customers notified
- Number of customers notified
- Number of customers responding
- Quantity of RECALLED product returned or accounted for
- Details of your recall effectiveness checks

3. ROOT CAUSE OF THE PROBLEM THAT RESULTED IN THE RECALL:

We recommend that you provide this information to your local District Recall Coordinator once the root cause has been established. It is important to establish the root cause of the problem so that appropriate preventative measures can be taken.

4. CORRECTIVE ACTIONS TO PREVENT FUTURE OCCURRENCES OF THE PROBLEM:

We recommend that you explain the corrective actions planned or underway that will prevent a similar problem from occurring. We further recommend that you provide this information to your local District Recall Coordinator when it has been established.

5. TERMINATION OF THE RECALL:

We recommend that you evaluate your recall for termination when all possible customer responses have been received and it is reasonable to assume that the recalled product has been recovered, corrected, reconditioned, or destroyed. A final status report and documentation of recalled product disposition should be provided to your local District Recall Coordinator before FDA will consider formal termination of the recall action. See:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=7.55>

Note: Upon receipt of necessary termination information, the district's recall coordinator will prepare a recall termination document for Center and/or district management concurrence. When concurrence is obtained, the district office will notify the recalling firm that FDA considers the recall terminated.

Additional Guidance and/or Requirements:

- 21CFR Part 7, Subparts A and C - Recalls - General guidelines
- 21CFR Part 107, Subpart E - Mandatory recall of Infant Formula
- 21 CFR Part 1270 - Human Tissue
- PHS Act - 42 U.S.C. 262 - Mandatory recall of biological products
- 21 CFR Part 806 - Medical Device Corrections and Removals
- FD&C Act, 518(e) - Mandatory Device Recalls

FDA DISTRICT RECALL COORDINATORS

A current list of FDA recall coordinators can be found on FDA's website at:

http://www.fda.gov/ora/inspect_ref/iom/iomoradir_monitors.html#recall

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