Contains Nonbinding Recommendations

Draft-Not for Implementation

Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C

Guidance for Industry and FDA Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2018-D-2074.

For questions regarding this draft document contact the Office of Regulatory Affairs (ORA), Office of Strategic Planning and Operational Policy (OSPOP) at ORAPolicyStaffs@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Center for Device and Radiological Health
Center for Food Safety and Applied Nutrition
Center for Tobacco Products
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Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C

Guidance for Industry and FDA Staff[1]

This draft guidance, when finalized, will represent the current thinking of the U.S. Food and Drug Administration (FDA, we, or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

The purpose of this draft guidance is to clarify FDA's recommendations for industry and Agency staff regarding timely initiation of voluntary recalls under 21 CFR part 7, Subpart C – Recalls (Including Product Corrections) – Guidance on Policy, Procedures, and Industry Responsibilities. The draft guidance discusses what preparations firms in a distribution chain, including manufacturers and distributors, should consider making to establish recall initiation procedures; to ensure timely identification of, and response to, product problems that might lead to a recall; and to promptly issue recall communications and press releases or other public notices. It also discusses preparations firms in the distribution chain should consider making to ensure timely responses to a recall communication. Additionally, it discusses how FDA assists firms with carrying out their recall responsibilities to protect the public health from distributed

[1] This guidance has been prepared by the Office of Regulatory Affairs (ORA), in collaboration with the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), the Center for Device and Radiological Health (CDRH), the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Tobacco Products (CTP), and the Center for Veterinary Medicine (CVM) at the U.S. Food and Drug Administration.

products in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and other laws administered by FDA.

This draft guidance applies to voluntary recalls of products subject to FDA's jurisdiction, including any food, drug, and device intended for human or animal use, any cosmetic and biological product intended for human use, any tobacco product intended for human use, and any item subject to a quarantine regulation under 21 CFR part 1240. It does not apply to electronic products subject to 21 CFR parts 1003 and 1004, although it does apply to devices that are electronic products regulated as radiology devices subject to 21 CFR part 892.

FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific statutory or regulatory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. TERMINOLOGY

Consignee

Consignee means anyone who received, purchased, or used the product being recalled. (21 CFR 7.3(n)).

Direct Account

Direct Account, for the purpose of this document, means the first consignee in a recalling firm's distribution chain.

Initiation of a Recall

Initiation of a recall means a recalling firm's first communication about a voluntary recall, to its direct accounts or to the public.[2]

Recall

Recall means a firm's removal or correction of a marketed product that the Food and Drug Administration 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. (21 CFR 7.3(g)).

Recalling Firm

Recalling firm means the firm that initiates a recall or, in the case of a Food and Drug Administration-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled. (21 CFR 7.3(i)).

[2] Please note that initiating a recall in accordance with the provisions in 21 CFR Part 7 does not negate any regulatory requirements that might be applicable (e.g., the requirement to report the initiation of a correction or removal in accordance with 21 CFR 806.10).

III. DISCUSSION

A. How should a firm in a product distribution chain prepare to facilitate timely initiation of a voluntary recall?

It is critical for firms in a product distribution chain to be "recall ready," to help minimize public exposure to products that are in violation of the FD&C Act and other laws administered by FDA. As appropriate and applicable to its operations, FDA recommends that a firm make the following preparations:

1. General Preparations

- Identify appropriate personnel. Specific employees should, and sometimes must, be assigned recall-related responsibilities and possess the authority to take the steps needed to implement a product recall when necessary.[3] The need for identification of alternate employees should be considered. When a firm anticipates that its recall efforts would be complex or have other complicating factors (e.g., a large or multi-layered distribution chain), the establishment of a "recall team" may be appropriate. For example, for a recalling firm the recall team could include a designated recall coordinator, and an official or employee with decision-making authority to initiate a product recall.

- Train personnel on their responsibilities. Employees that have been identified to perform recall activities should be trained so they have a thorough understanding of the recall procedures they are being asked to perform. A firm that anticipates complex recalls may want to consider additional preparatory steps, such as mock recalls, to verify the firm's recall readiness. Mock recalls familiarize employees with the recall process and may improve the effectiveness of the firm's recall program. The firm should also consider establishing metrics appropriate to its recall plan and take corrective action (such as modifications to procedures or additional training for employees) if it is not satisfied with the results of a mock or actual recall.

- Establish a recall communications plan. Such a plan should address internal communications, communications with FDA, and communications to direct accounts or the public in the event that a recall is deemed necessary. The firm should consider identifying specific points-of-contact ahead of time, and should maintain draft templates that help it issue recall communications promptly, e.g., notification letters to direct accounts and draft press releases.[4]

- Identify any reporting requirements associated with your products. A significant problem with a distributed product may trigger a requirement to make a report to FDA, e.g., a

[3] *See, e.g.*, 21 CFR 507.38(a)(2) and 21 CFR 117.139(b).

[4] Model recall communications templates are available on the FDA website (visit https://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm).

report to the Reportable Food Registry,[5] an adverse event report for a dietary supplement,[6] a Field Alert Report for a distributed human drug product,[7] a Field Alert Report for a distributed animal drug product,[8] a report of a deviation in the manufacturing of certain biologics,[9] or an obligation to report in advance of a discontinuance or interruption in your firm or facility's production of a life-saving drug that is likely to lead to a meaningful disruption in your *own supply* of that drug.[10] A firm may also be required to submit a report to FDA if it conducts a product correction or removal, e.g., the correction or removal of certain medical devices[11] or when it recalls infant formula.[12] A firm should know in advance whether its product is associated with any legal or regulatory requirements to make a report to FDA, or to report a product removal or correction to FDA.

- Use adequate product coding. While many products have specific product coding requirements — e.g., human prescription drug products generally use a "product identifier,"[13] blood and blood components generally have container label requirements,[14] and medical devices generally have a unique device identifier (UDI) requirement[15] — whether required or not, firms should use sufficient coding of regulated products to make possible positive lot identification and to facilitate the effective recall of all violative lots. (21 CFR 7.59(b)). The coding used should allow for identification of the production and control data created for each lot, batch, or unit. Product coding may help a recalling firm accurately define and limit the scope of the recall effort; because product coding facilitates a correct accounting of affected product, it may reduce the need to further expand a recall. Additionally, product coding may allow consignees to separate violative product lots from unaffected lots. Product coding may also help the public, e.g., if a consumer recognizes an affected product in their possession.

- Maintain distribution records. While certain products have specific requirements related to the maintenance of distribution records, e.g., distribution requirements for finished medical devices,[16] product tracing requirements for certain human prescription drug

[5] *See* section 417 of the FD&C Act [21 U.S.C. 350f].
[6] *See* section 761 of the FD&C Act [21 U.S.C. 379aa-1].
[7] *See* 21 CFR 314.81(b)(1).
[8] *See* 21 CFR 514.80(b)(1).
[9] *See* 21 CFR 600.14; 21 CFR 606.171; *see also* 21 CFR 1271.350.
[10] *See* 80 FR 38915 and section 506C of the FD&C Act [21 U.S.C. 356c]. FDA requests that you immediately notify Drug Shortage Staff at drugshortages@fda.hhs.gov (for products regulated by CDER) or cbershortage@fda.hhs.gov (for products regulated by CBER).
[11] *See* 21 CFR 806.10. As used in this guidance, a firm in the medical device context under 21 CFR 806.10 means a device manufacturer or importer. *See* 21 CFR 806.10(a). Moreover, device user facilities, manufacturers, importers, and distributors are subject to the medical device reporting regulations under 21 CFR part 803.
[12] *See* 21 CFR 107.240(a).
[13] *See, e.g.*, section 582(b)(2) of the FD&C Act [21 U.S.C. 360eee–1].
[14] *See* 21 CFR 606.121.
[15] *See* 21 CFR Part 801, Subpart B and https://www.fda.gov/udi.
[16] *See* 21 CFR 820.160.

product transactions,[17] distribution and receipt records for blood and blood products,[18] distribution records for drug products for animals, medicated feed for animals, and Type A medicated articles,[19] whether required or not, distribution records should be maintained by the recalling firm to facilitate the location of products being recalled. These records should be retained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning records retention. (21 CFR 7.59(c)). Distribution records should include enough detail to identify the consignees that actually received the recalled product and must conform with any applicable requirements. Direct accounts that further distribute the product should also maintain records of their consignees that actually received the product, to ensure that the recalling firm's instructions are extended to all consignees in the distribution chain.

2. Specific Recall Initiation Procedures

In addition to these preparations, FDA recommends that firms consider preparing and maintaining written recall initiation procedures. This recommendation does not supersede any specific recall plan requirements, e.g., for human or animal food.[20] Written recall initiation procedures help to minimize delays created by uncertainty as to the appropriate actions to take when a decision is made to initiate a recall, help ensure that necessary actions are not overlooked, and may minimize the disruptive effect a recall can have on a firm's business. Such procedures should be considered as part of a more comprehensive "written contingency plan for use in initiating and effecting a recall in accordance with [21 CFR] §§7.40 through 7.49, 7.53, and 7.55." (21 CFR 7.59(a)).

For recalling firms, initiation procedures may help reduce the amount of time a violative product is on the market. For consignees of recalling firms, initiation procedures help extend the recall quickly throughout the distribution chain, in accordance with the instructions received from the recalling firm.

A firm's written recall initiation procedures should assign responsibility and describe the steps to perform all actions related to initiating a recall, including the following, as appropriate to the firm or facility:

- Ceasing distribution, shipment, and/or sales of affected product(s).

- Developing a recall strategy. In accordance with 21 CFR 7.42, a recall should be initiated according to a strategy developed by the recalling firm after considering various factors, including, but not limited to, the potential risk to those exposed to the product and the ease in identifying the product. The recall strategy should suit the individual

[17] *See, e.g.,* section 582(b)(1) of the FD&C Act [21 U.S.C. 360eee-1].
[18] *See* 21 CFR 606.165.
[19] *See* 21 CFR 211.196, 225.110, and 226.110, respectively.
[20] *See* 21 CFR 117.139 and 507.38 (unless otherwise exempt from the requirements of 21 CFR parts 117 and 507, for human or animal food with a hazard requiring a preventive control, a firm must establish a written recall plan for the food).

circumstances of the particular recall, and will help guide the recalling firm's decisions related to recall depth and the need for additional actions such as public warnings.

- Notifying direct accounts about the product being recalled, including what should be done with respect to the recalled product. Communication with appropriate points of contact at each direct account is the most effective way to ensure that direct accounts know the product is being recalled and is consistent with our general guidance on recall communications in 21 CFR 7.49(a). Notification letters allow the direct account to act quickly and effectively to implement the recall. Where appropriate, instructing the direct account to further notify its consignees about the recall is essential to extending the recall throughout the product distribution chain.

    - Providing response instructions to notified direct accounts. The recall notification should include instructions for the method (e.g., written response form or telephone call) that the direct account should use to respond to the notification, and should include points-of-contact for follow-up communication, via telephone or electronic mail, at the recalling firm.

    - Including instructions for appropriate disposition of recalled product. Direct accounts should be given clear instructions regarding appropriate disposition of recalled product—e.g., through return or destruction of the product. Instructions for appropriate disposition of recalled product help the recalling firm and consignees ensure that the product will not remain a risk to the public. Disposition instructions may be subject to federal, state and local requirements.

- When appropriate, notifying the public about a product that presents a health hazard.[21]

NOTE: Recall plans and initiation procedures should be specific to the firm or facility. Firms should consider writing additional plans or procedures as appropriate to their business operations, e.g., to address a complex distribution chain.

B. What should a firm do if there is an indication of a problem with a distributed product?

[21] *See also* FDA's final guidance entitled, "Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C; Guidance for Industry and FDA Staff", 83 FR 2758, which represents the current thinking of FDA on this topic.

Certain products have specific regulatory requirements related to identifying,[22] investigating[23] and reporting[24] product problems. While compliance with regulatory requirements is necessary, we also recommend that all firms:

Identify the problem. As appropriate, a firm should implement procedures to identify indicators that there may be a problem with a distributed product that suggests it is in violation of the FD&C Act and other laws administered by FDA. Examples of such indicators may include:

- An internal report of a product specification deviation.
- Out-of-specification testing results for a product.
- Consumer complaints about a product, including reports of adverse reactions.
- Inspectional observations related to a product, made by a regulatory authority and indicating noncompliance with applicable product regulations.
- Reports of disease, injury, or death associated with product use.

Investigate the problem. The firm's procedures should assign responsibility and describe the steps to investigate a potential problem with a distributed product, which may include:

- A timely investigation to determine whether a deviation in manufacturing occurred and, as applicable, whether the safety, purity, or potency of distributed products may have been affected.
- A prompt evaluation by a qualified person and following established criteria, to ensure that potential risks are consistently assessed and investigated for products potentially affected.

Make decisions and take action. The firm's procedures should assign responsibility and describe the steps to ensure that decisions are made to control defective and potentially harmful products in a timely manner. The procedures should address:

- Deciding whether to initiate a voluntary recall.
- The appropriate scope of the recall, e.g., the groups of units to be recalled as identified by product coding, or in instances where the product does not bear a code, a description of the units distributed within a specific date range or period of time. For guidance on adequate product coding, see Question A in section III of this document.
- The appropriate depth of the recall, i.e., depending on the product's degree of hazard and extent of distribution, the firm's recall strategy should specify the level in the distribution chain to which the recall is to extend. (21 CFR 7.42(b)(1)).

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[22] *See, e.g.,* requirements to review postmarketing reporting of adverse experiences for human drugs under 21 CFR 314.80(b); *see also* quality program requirements for human cell, tissue, and cellular and tissue-based products (HCT/P) under 21 CFR 1271.160(b)(2); *see also* preventive control management components for food for humans (21 CFR 117.140) and food for animals (21 CFR 507.39).

[23] *See, e.g.,* the requirement to maintain procedures for investigating the cause of medical device nonconformities under 21 CFR 820.100(a)(2)); *see also* the requirement to review drug product production records and investigate any failure or discrepancy under 21 CFR 211.192; *see also* verification requirements for transactions involving certain human prescription drugs in sections 582(b)(4), 582(c)(4), 582(d)(4) and 582(e)(4) of the FD&C Act [21 U.S.C. 360eee-1].

[24] *See* footnotes 5-12 and accompanying text.

- The need to discontinue production and distribution of affected product.

Consult with FDA about the problem. If a firm has questions about its examination of a product problem, we encourage the firm to consult with FDA while its own investigation is ongoing. To contact an FDA recall coordinator, please see:
https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm

C. How should a firm initiate a voluntary recall?

A firm should initiate a voluntary recall by promptly sending recall communications to each affected direct account, and by issuing a press release or other public notice, if appropriate. FDA considers the date of a firm's first communication about a recall, either to its direct accounts or to the public, to constitute the date of initiation.[25]

In addition to compliance with specific regulatory requirements, we generally recommend that the recalling firm follow the initiation procedures in its recall plan to implement the recall in accordance with 21 CFR 7.46 (firm-initiated recall). This includes executing its prepared recall communications plan. Among the information generally requested by the Agency under 21 CFR 7.46(a) are copies of the firm's issued or proposed recall communications. If provided, FDA will review the content of the proposed communications and recommend changes as appropriate.

A recalling firm need not delay initiation of a voluntary recall pending FDA's review of its recall strategy or recall communications. Section 7.49(c) of 21 CFR provides content guidelines for recall communications. A recalling firm should clearly identify the level in the distribution chain to which the recall is to extend and should provide instructions to direct accounts to extend the recall to their consignees if the product could have been further distributed. We have previously issued procedural guidance regarding press releases and written recall notification letters.[26] Nevertheless, and notwithstanding any requirements for firms to submit a report to FDA for certain products, a firm that initiates a recall because it believes the product to be violative is requested to notify FDA immediately. (21 CFR 7.46(a)).[27]

As appropriate, a recipient of a recall communication, i.e., a notified direct account or consignee, should implement its own recall initiation procedures to extend the recall promptly to its sub-accounts that may have received the product, in accordance with the instructions received from the recalling firm. (See 21 CFR 7.49(d)). If any consignee fails to respond to a recall communication, then the recalling firm should consider conducting follow-up communications. (See 21 CFR 7.49(c)(2)).

D. How does FDA work with a recalling firm to initiate a voluntary recall in a timely manner?

[25] *But see* footnote 2.
[26] https://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm (Industry Guidance For Recalls, Information on Recalls of FDA Regulated Products).
[27] *But see* footnote 28.

FDA is committed to working cooperatively with a recalling firm whenever possible to facilitate the orderly and prompt removal of, or correction to, a violative product in the marketplace, particularly when the product presents a danger to health. FDA recall coordinators organized by product type (e.g., food, drug, or medical device), and located throughout the country, act as agency points-of-contact for recalling firms and offer assistance. Recall coordinators provide a recalling firm with information about the recall process and are available to work closely with the firm throughout the course of the recall. For example, recall coordinators may assist the firm with determining whether the action is a recall as defined in 21 CFR 7.3(g), and if so, with developing an appropriate recall strategy; with reviewing the recalling firm's communications to direct accounts or to the public about the recall; and with monitoring the destruction, reconditioning, or disposition of the recalled product.

A recalling firm located in the United States should contact a Division Recall Coordinator within the FDA Office of Regulatory Affairs (ORA).[28] If the firm is located outside of the United States and is recalling a product exported to the United States, then the recalling firm should contact ORA Headquarters. For a comprehensive list of FDA Recall Coordinator contact information by product type and location, please visit:
https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm

FDA officials may conduct discussions with a firm about a product problem. When FDA determines that a distributed product violates the law, it may inform the firm and may recommend that it cease distribution and recall the product in accordance with 21 CFR part 7, Subpart C and Agency procedures. If the firm voluntarily decides under any circumstances to recall the product, then the action is considered a firm-initiated recall under 21 CFR 7.46.

Under certain circumstances, FDA may also request a firm to initiate a recall under 21 CFR 7.45. FDA-requested recall is generally pursued after conducting discussions with a firm. FDA must make all of the following determinations before requesting a recall under 21 CFR 7.45:

(1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception;
(2) That the firm has not initiated a recall of the product; and
(3) That an Agency action is necessary to protect the public health and welfare.

During an FDA-requested recall the recalling firm may be asked to provide FDA with any or all information listed in 21 CFR 7.46(a), including but not limited to the identity of the product involved, the reason for the removal or correction, and the date and circumstances under which the product deficiency or possible deficiency was discovered. If the firm agrees to recall the product based on FDA's request, then the action is still considered a voluntary recall.

[28] For recalls of biologics products that participate in CBER's Direct Recall Classification (DRC) program, the DRC program is the primary means by which firms communicate with FDA regarding the recall. The DRC program refers to the classification of biologics recalls directly by personnel in CBER. Further information on the DRC program may be found at:
https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm172970.htm.

In the event that a recalling firm's actions do not adequately protect the public from a violative product, i.e., the firm fails to initiate a recall effectively, FDA may consider taking other appropriate regulatory actions.

IV. REFERENCES

1. U.S. Food and Drug Administration. Guidance for Industry: Product Recalls, Including Removals and Corrections. Last updated 08/22/2014. https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm

2. U.S. Food and Drug Administration. "Industry Guidance for Recalls. Information on Recalls of FDA Regulated Products." Last updated 09/25/2018. http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm

3. U.S. Food and Drug Administration. "ORA Recall Coordinators." Last updated 11/09/2018. https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm