

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

## **Guidance for Industry and FDA Staff**

You may submit electronic or written comments regarding this guidance at any time. 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, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2018-D-2074.

For questions or information regarding this guidance, contact the Office of Regulatory Affairs (ORA), Office of Strategic Planning and Operational Policy (OSPOP), Food and Drug Administration at [ORAPolicyStaffs@fda.hhs.gov](mailto:ORAPolicyStaffs@fda.hhs.gov).

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**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 Devices and Radiological Health  
Center for Food Safety and Applied Nutrition  
Center for Tobacco Products  
Center for Veterinary Medicine**

**March 2022**

*Contains Nonbinding Recommendations*

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## **Guidance for Industry and FDA Staff**

*Additional copies are available from:  
Office of Strategic Planning and Operational Policy  
Office of Regulatory Affairs,  
Food and Drug Administration  
12420 Parklawn Drive, Element Building,  
Rockville, MD 20857*

**U.S. Department of Health and Human Services  
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Center for Food Safety and Applied Nutrition  
Center for Tobacco Products  
Center for Veterinary Medicine**

**March 2022**

**Recalls**

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

## **Guidance for Industry and FDA Staff<sup>1</sup>**

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

This guidance applies to voluntary recalls<sup>2</sup> 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. This guidance applies to devices that are electronic products regulated as radiology devices subject to 21 CFR part 892. It does not apply to electronic products subject to 21 CFR parts 1003 and 1004.

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<sup>1</sup> 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 Devices 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.

<sup>2</sup> This guidance could also inform actions by manufacturers and distributors to remove or correct a marketed product under circumstances that would not meet the definition of a recall, e.g., a market withdrawal.

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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)).

### *Correction*

Correction means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location. (21 CFR 7.3(h)).

### *Direct Account*

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

### *Initiation of a Recall*

Initiation of a recall, for the purpose of this guidance, means a recalling firm's first communication about a recall, to its direct accounts or to the public.<sup>3</sup>

### *Market Withdrawal*

Market withdrawal means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc. (21 CFR 7.3(j)).

### *Recall*

Recall means a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which 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 FDA-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled. (21 CFR 7.3(i)).

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<sup>3</sup> Initiating a recall in accordance with the provisions in 21 CFR part 7 does not negate any regulatory requirements that might be applicable with respect to the violative product (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.” FDA recommends that a firm make the following preparations as appropriate and applicable to its operations in advance of when a recall may be needed:<sup>4</sup>

##### 1. GENERAL PREPARATIONS

- Identify appropriate personnel. Specific personnel should, and sometimes must,<sup>5</sup> be assigned recall-related responsibilities and possess the authority to take the steps needed to implement a product recall when necessary. The need for identification of alternate personnel 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, a recalling firm could designate a team of employees that includes a recall coordinator and personnel with decision-making authority to initiate a product recall.
- Train personnel on their responsibilities. Personnel who have been identified to perform recall activities should be trained on a regular basis 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 personnel 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 consider taking actions to improve its recall plan, such as making modifications to procedures or training its personnel, 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 for each of these types of communications ahead of time, and should maintain draft templates that help the firm issue recall communications promptly, e.g., notification letters to direct accounts and draft press releases.<sup>6</sup> FDA encourages the use of electronic communications for conveying voluntary recall communications about FDA-regulated products.<sup>7</sup>

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<sup>4</sup> 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.

<sup>5</sup> See, e.g., 21 CFR 507.38(a)(2) and 21 CFR 117.139(b).

<sup>6</sup> Model recall communications templates are available on the FDA website (visit <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls>).

<sup>7</sup> See FDA’s guidance *Using Electronic Means to Distribute Certain Product Information*, which represents the current thinking of FDA on this topic. We update guidances periodically. For the most recent version of a

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- Identify any reporting requirements for distributed products. Certain problems with a distributed product may trigger a requirement to make a report to FDA. Examples of reporting requirements include but are not limited to:
  - A report to the Reportable Food Registry.<sup>8</sup>
  - An adverse event report for a dietary supplement.<sup>9</sup>
  - A Field Alert Report for a distributed human or animal drug product.<sup>10</sup>
  - A report of a product deviation associated with the manufacturing of certain biologics.<sup>11</sup>
  - A report in advance of a discontinuance or interruption in a 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.<sup>12</sup>

A firm may also be required to submit a report to FDA when it conducts a product correction or removal, e.g., the correction or removal of certain medical devices<sup>13</sup> or when it recalls infant formula.<sup>14</sup> A firm should know in advance whether its product is associated with any legal or regulatory requirements to make a report to FDA.

- Use adequate product coding. Certain products have specific product coding requirements. Examples of product coding requirements include but are not limited to:
  - Many human prescription drug products must use a “product identifier.”<sup>15</sup>
  - Blood and blood components generally have container label requirements.<sup>16</sup>
  - Many medical devices must bear a unique device identifier (UDI) on their labels and device packages.<sup>17</sup>

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

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guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

<sup>8</sup> See section 417 of the FD&C Act [21 U.S.C. 350f].

<sup>9</sup> See section 761 of the FD&C Act [21 U.S.C. 379aa-1].

<sup>10</sup> See 21 CFR 314.81(b)(1) (human drug regulation); 21 CFR 514.80(b)(1) (animal drug regulation).

<sup>11</sup> See 21 CFR 600.14; 21 CFR 606.171; see also 21 CFR 1271.350.

<sup>12</sup> 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](mailto:drugshortages@fda.hhs.gov) (for products regulated by CDER) or [cbershortage@fda.hhs.gov](mailto:cbershortage@fda.hhs.gov) (for products regulated by CBER).

<sup>13</sup> 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.

<sup>14</sup> See 21 CFR 107.240(a).

<sup>15</sup> See, e.g., section 582(b)(2) of the FD&C Act [21 U.S.C. 360eee-1].

<sup>16</sup> See 21 CFR 606.121.

<sup>17</sup> See 21 CFR part 801, subpart B and <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>. In some cases, the device itself must be directly marked with a UDI. 21 CFR 801.45.

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control data created for each lot,<sup>18</sup> batch, or unit. Product coding facilitates a correct accounting of affected product, so it may help a recalling firm accurately define and limit the scope of the recall. Additionally, product coding may allow consignees to separate violative product lots from unaffected lots. Product coding may also help the public, e.g., by helping consumers recognize an affected product in their possession.

- Maintain distribution records. Certain products have specific requirements related to the maintenance of distribution records. Examples of distribution records requirements include but are not limited to:<sup>19</sup>
  - Distribution requirements for finished medical devices.<sup>20</sup>
  - Product tracing requirements for certain human prescription drug product transactions.<sup>21</sup>
  - Distribution and receipt records for blood and blood products.<sup>22</sup>
  - Distribution records for drug products for animals, medicated feed for animals, and Type A medicated articles.<sup>23</sup>

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 identify the direct accounts that received the recalled product by name, physical address where the product was delivered, and a contact telephone number. Distribution records also must conform with any applicable requirements. Any direct accounts that further distribute the product should maintain records of their own direct accounts to ensure that the recalling firm's instructions are extended to all consignees in the distribution chain.

## **2. RECOMMENDED PROCEDURES FOR INITIATING A RECALL AND PERFORMING ACTIONS RELATED TO INITIATING A RECALL**

In addition to these preparations, FDA recommends that firms consider preparing, maintaining, and documenting written procedures (in paper or electronic format) for initiating a recall and

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<sup>18</sup> On Sept. 23, 2020, FDA issued the "Requirements for Additional Traceability Records for Certain Foods" proposed rule (85 FR 59984). If finalized as proposed, this rule would establish certain recordkeeping requirements for persons who manufacture, process, pack, or hold certain foods, including requirements related to establishing and maintaining traceability lot codes and linking the codes to other information identifying the food throughout the supply chain. Additional information is available at <https://www.fda.gov/food/food-safety-modernization-act-fsma/proposed-rule-food-traceability>.

<sup>19</sup> On Sept. 23, 2020, FDA issued the "Requirements for Additional Traceability Records for Certain Foods" proposed rule (85 FR 59984). If finalized as proposed, this rule would establish certain recordkeeping requirements for persons who manufacture, process, pack, or hold certain foods, including requirements related to maintaining distribution records. Additional information is available at <https://www.fda.gov/food/food-safety-modernization-act-fsma/proposed-rule-food-traceability>.

<sup>20</sup> See 21 CFR 820.160.

<sup>21</sup> See, e.g., section 582(b)(1) of the FD&C Act [21 U.S.C. 360eee-1].

<sup>22</sup> See 21 CFR 606.165.

<sup>23</sup> See 21 CFR 211.196, 225.110, and 226.110, respectively.

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performing actions related to initiating a recall. This recommendation does not supersede any specific recall plan requirements, e.g., for human or animal food.<sup>24</sup> Written recall procedures help to minimize delays created by uncertainty as to the appropriate actions to take when a decision is made to initiate a recall. In advance of when a recall may be needed, a firm should incorporate written recall procedures into its training for personnel to help ensure that necessary actions are carried out effectively and to minimize the disruptive effect a recall can have on the firm's business. Such procedures should be considered as part of a 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, having specific procedures for initiating a recall and performing actions related to initiating a recall may help reduce the amount of time a violative product is on the market. For consignees, having such procedures may help extend the recall throughout the distribution chain, in accordance with the instructions received from the recalling firm.

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

- Ceasing distribution, shipment, and/or sales of affected product(s).
- Developing a recall strategy. As set forth in 21 CFR 7.42, a recall should be initiated according to an approved 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. 21 CFR 7.42(b) states which elements a recall strategy will address, including the depth of the recall. In addition, FDA recommends that the recall strategy suit the individual circumstances of the particular recall and help guide the recalling firm's decisions related to recall depth and the need for additional actions such as public warnings. The recall strategy should take into account the possibility that the scope of the recall may expand should additional lots or products be shown to be affected.
- Notifying direct accounts about the product being recalled, including what should be done with respect to the recalled product. A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. (21 CFR 7.49(a)). Communication with appropriate points of contact at each direct account is the most effective way to ensure that direct accounts know the product in question is subject to a recall. Timely recall communications allow the direct account to act quickly and effectively to implement the recall. Where appropriate, instructing the direct account to further notify its own direct accounts about the recall is essential to extending the recall throughout the product distribution chain.

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<sup>24</sup> 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). See also the *Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food; Chapter 14: Recall Plan* (October 2019) (when final, this guidance will represent FDA's current thinking on this topic). We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

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As noted above, FDA encourages the use of electronic communications for conveying voluntary recall communications about FDA-regulated products. If your recall communications plan specifies that you will contact your direct account by telephone, we recommend that your recall communications plan also specify that you will confirm that telephone communication in writing (e.g., follow up the telephone call with a written or electronic communication) and/or document the telephone communication in an appropriate manner. (See 21 CFR 7.49(b)).

- Providing response instructions to notified direct accounts. The recall communication should include instructions for the method (e.g., written response form, telephone call or electronic communication) that the direct account can use to respond to the notification, and should include points of contact for follow-up communication 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 may be subject to federal, state, and local requirements.
- When appropriate, notifying the public about a product that presents a health hazard.<sup>25</sup>

### **B. WHAT SHOULD A FIRM DO IF THERE IS AN INDICATION OF A PROBLEM WITH A DISTRIBUTED PRODUCT?**

Certain products have specific regulatory requirements related to identifying,<sup>26</sup> investigating<sup>27</sup> and reporting<sup>28</sup> 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 may be in violation of the FD&C Act and other laws administered by FDA. Examples of such indicators may include but are not limited to:

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<sup>25</sup> See also FDA's final guidance *Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C; Guidance for Industry and FDA Staff*, which represents the current thinking of FDA on this topic. We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

<sup>26</sup> 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).

<sup>27</sup> See, e.g., the requirement to maintain procedures for investigating the cause of medical device product, processes and quality system 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].

<sup>28</sup> See *supra* footnotes 8-14 and accompanying text.

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- An internal report of a product specification deviation.
- Out-of-specification testing results for a product.
- Consumer complaints about a product.
- Inspectional observations or laboratory analytical results related to a product, communicated by a regulatory authority, and indicating noncompliance with applicable product regulations.
- Reports of adverse events, e.g., illness, injury, or death associated with product use.

Investigate the problem. The firm's procedures should assign responsibility and describe the steps to investigate a problem with a distributed product. These steps may include but are not limited to:

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

The recalling firm need not delay initiation of a voluntary recall pending completion of the investigation.

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)).
- 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. A comprehensive list of FDA Recall Coordinator contact information, organized by product type and location, is available on FDA's website.<sup>29</sup>

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<sup>29</sup> ORA Recall Coordinators, <https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators>

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### **C. HOW SHOULD A FIRM INITIATE A VOLUNTARY RECALL?**

A firm should initiate a voluntary recall by promptly notifying each of its affected direct accounts about the recall, 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.

We 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 FDA 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 general content guidelines for recall communications.<sup>30</sup>

In addition, 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 own direct accounts if the product could have been further distributed. We have previously issued procedural guidance regarding press releases and written recall notification letters.<sup>31</sup> 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)).<sup>32</sup>

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 direct accounts that may have received the affected product, in accordance with the instructions received from the recalling firm. (See 21 CFR 7.49(d)). Where necessary, follow-up communication should occur for any direct account that fails to respond to a recall communication to ensure the direct account has received and understands the recall communication. (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?**

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 public health. FDA recall coordinators organized by product type (e.g., a food, drug, medical device, or tobacco product) 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

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<sup>30</sup> See also *supra* footnote 6 and accompanying text.

<sup>31</sup> Information on Recalls of FDA Regulated Products,

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls>

<sup>32</sup> But see footnote 33.

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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. For certain products, FDA recall coordinators may assist by referring the firm to another regulatory body outside FDA with primary responsibility for monitoring the product recall (e.g., voluntary recalls of certain alcoholic beverages are monitored by the Alcohol and Tobacco Tax and Trade Bureau).

A recalling firm located in the United States should contact a Division Recall Coordinator within the FDA Office of Regulatory Affairs (ORA).<sup>33</sup> 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. A comprehensive list of FDA Recall Coordinator contact information, organized by product type and location, is available on FDA's website.<sup>34</sup>

FDA officials may initiate 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 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 that a firm initiate a recall under 21 CFR 7.45.<sup>35</sup> FDA-requested recall is generally pursued only after conducting discussions with the 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). This information includes, but is 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.

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 actions.

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<sup>33</sup> For recalls of CBER-regulated products included 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/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/direct-recall-classification-program>

<sup>34</sup> ORA Recall Coordinators, <https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators>

<sup>35</sup> For medical devices, where FDA finds that there is a reasonable probability that the device would cause serious, adverse health consequences or death, FDA may initiate a mandatory recall by following certain procedures under 21 CFR part 810.