WINSTON & STRAWN LLP

BLOG

FDA Issues Guidance to Clarify Recommendations Regarding Timely Initiation of Voluntary Recalls

MARCH 10, 2022

This blog was originally written as a client alert on March 10, 2022.

Earlier this month, the Food and Drug Administration ("FDA" or "the Agency") issued guidance to clarify how firms in a product distribution chain, including manufacturers and distributors, should establish voluntary-recall initiation procedures that ensure timely identification and notification of and responses to product problems. As described in the Agency's press release, "because recalls can affect the entire supply chain, including downstream suppliers, wholesalers or vendors, the FDA recommends that companies develop recall procedures to quickly inform their entire distribution chain, so consignees can rapidly identify affected lots and recall downstream products when necessary." This guidance applies to voluntary recalls of products subject to the FDA's jurisdiction, with the exception of electronic products subject to 21 CFR Parts 1003 and 1004. The FDA strongly encourages firms to prepare as appropriate to ensure that they are "recall ready" in advance of when a recall may be necessary.

See FDA's Guidance for Industry and FDA Staff: Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C, *available at* https://www.fda.gov/media/123664/download?utm_medium=email&utm_source=govdelivery.

BACKGROUND

A product recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the FDA. A voluntary recall takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. *See* 21 CFR 7.40.

The FDA's newly issued guidance describes preparations that firms can take to become "recall ready." It also explains how firms should initiate voluntary recalls. Generally, the FDA recommends that firms promptly notify each affected direct account and issue a press release or other public notice, if appropriate. Firms are encouraged to follow the initiation procedures in their recall plans, which should be in accordance with 21 CFR 7.46 (firm-initiated recall). The FDA's guidance also discusses how the FDA assists firms with their recall obligations in order to protect

the public health from distributed products that violate the Federal Food, Drug, and Cosmetic Act and other laws administered by the FDA.

PREPARATIONS FOR INDUSTRY: HOW TO BECOME "RECALL READY"

To facilitate timely initiation of a voluntary recall, the guidance recommends the following advance preparations:

- **Identify appropriate personnel**—specific personnel should be assigned to recall-related responsibilities and have the authority to take the necessary steps to implement a product recall when necessary. If recall efforts would be complex or complicated, assigning a recall team may be appropriate.
- **Train personnel on their responsibilities on a regular basis**—a firm may want to conduct mock recalls.
- **Establish a recall communications plan that addresses internal communications, communications with the FDA, communications to direct accounts, and communications to the public, if necessary**—the FDA advises maintaining draft templates of these communications and identifying specific points of contact for each of these types of communications ahead of time. It also encourages the use of electronic communications for disseminating voluntary recall communications.
- **Identify any reporting requirements for distributed products**—certain problems with a distributed product may trigger additional FDA reporting requirements (e.g., a Field Alert Report for a distributed human or animal drug product). Firms should know in advance whether their products are associated with any legal or FDA regulatory-reporting requirements.
- **Use adequate product coding**—whether required or not, firms should use product coding to identify lots and facilitate recall of all violative lots. The coding should allow for identification of the production and control data for each lot, batch, or unit.
- **Maintain distribution records**—whether required or not, firms should maintain distribution records to facilitate the location of products being recalled. These records should identify the direct accounts that received the recalled product by name, address of delivery, and a contact telephone number.

PROCEDURES FOR INITIATING A RECALL

The FDA also recommends that firms prepare, maintain, and document written procedures for initiating a recall with the aim of reducing the amount of time a violative product is on the market. Firms are encouraged to:

- Create appropriate procedures for ceasing distribution, shipment, and/or sales of affected products
- Develop a recall strategy
- Notify direct accounts about the product being recalled, including what should be done with respect to the recalled product
  - Provide response instructions to direct accounts, including instructions for appropriate disposition of recalled product
- Notify the public when a product presents a health hazard (when appropriate)

RESPONDING TO POTENTIAL PROBLEMS WITH A DISTRIBUTED PRODUCT

If there is an indication of a problem with a distributed product, the FDA recommends that firms comply with specific regulatory requirements for certain products and take the following steps:

- **Identify the problem**—firms should implement procedures to identify indicators that there may be a problem with a distributed product (e.g., consumer complaints, internal report of a product specification deviation, out-of-specification testing results for a product).
- **Investigate the problem**—procedures should assign responsibility and describe the steps to investigate the problem with the distributed product.
- **Make decisions and take action**—procedures should identify the scope and depth of a voluntary recall, the need to discontinue the affected product, and the person(s) responsible for deciding whether to initiate a voluntary recall.
- **Consult with the FDA about the problem.**

Judith McMeekin, PharmD, associate commissioner of regulatory affairs at the FDA, noted in the Agency's press release that "voluntary recalls continue to be the fastest, most effective way for a company to correct or remove violative and potentially harmful products from the market to help keep consumers safe. It is critical that all companies in the supply chain are 'recall ready' to ensure appropriate actions are taken swiftly across the distribution channels to best protect public health and the integrity of the supply chain. We will continue to work with companies to improve their recall procedures and minimize Americans' exposure to potentially harmful products."

4 Min Read

Author

Esthefania Rodriguez

Related Locations

Washington, DC

Related Topics

Health Care

FDA

Related Capabilities

Product Liability & Mass Torts

Health Care

Related Regions

North America

Related Professionals

Esthefania Rodriguez

This entry has been created for information and planning purposes. It is not intended to be, nor should it be substituted for, legal advice, which turns on specific facts.