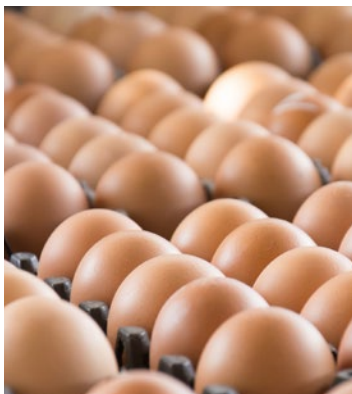


A Client's Guide to FDA Recalls



A Client's Guide to FDA RECALLS

Product recalls are critical events for firms that produce food and medical products. The lives and health of patients and consumers can be at stake. Companies risk enforcement action by the Food and Drug Administration (FDA), tort liability and damages to their reputations. Although the decision to initiate a recall is often voluntary, FDA oversees recalls and uses both formal compliance tools and public communications to ensure that recalls are properly completed. This client guide describes FDA recalls, including companies' responsibilities and FDA's authority.



Q. When does a recall occur?

A. A recall occurs when a firm removes or corrects a marketed product that violates Food and Drug Administration (FDA)-administered laws and regulations and would be subject to FDA legal action.¹ Recalls are intended to protect the public from products that are harmful, deceptive or defective.

In FY 2016, FDA oversaw 2,847 recall events involving 8,305 recorded recalled products.²

Q. Does every violation of the Federal Food, Drug, and Cosmetic Act lead to a recall?

A. No. Depending on the seriousness of the violation, risk to public health and other factors, FDA may use compliance and enforcement tools, rather than seek a recall, to ensure that a firm corrects the violation. As we explained in [A Client's Guide to FDA Inspections](#), these measures include judicial actions, warning letters, administrative detention, suspension of registration and import bans. These tools may affect a manufacturer's current inventory, how it would manufacture product in the future and product approvals, but they do not reach product that a manufacturer has already placed into the stream of commerce or that has been sold to a consumer or patient.

Q. Are there situations other than recalls where a firm may remove FDA-regulated products from the market?

A. Yes. One situation is a market withdrawal, which occurs when a firm chooses to remove or correct a distributed product from the marketplace that does not violate FDA-administered laws and regulations or involves a minor violation that would not warrant legal action

by FDA. For example, a manufacturer may withdraw a product from the market because of an incorrect address on its label, a relatively minor violation.³

There are two nonrecall situations specific to medical devices. One situation is a device enhancement, in which a firm makes a change to improve a device that is not made to remedy a violation of FDA law or regulations.⁴ The other situation is routine servicing, when a firm engages in regularly scheduled maintenance of a device.⁵

Q. How is a recall initiated?

A. There are four ways that a recall is initiated:

1. A firm may voluntarily initiate a recall through its own decision-making process, such as via an internal audit, safety or quality control programs, employee reporting or consumer feedback.
2. FDA may also recommend, through an informal discussion, that a firm initiate a voluntary recall based on information available to the agency, such as consumer complaints or results from an inspection, an outbreak investigation or laboratory tests.⁶
3. In urgent situations, FDA's Associate Commissioner for Regulatory Affairs may formally request voluntary recall action by a firm, providing the firm with a letter explaining the violation and associated health hazards, the need for an immediate recall and recommendations for a recall strategy.⁷

³ FDA, *Distinguishing Medical Device Recalls from Medical Device Enhancements*, 5 (2014), <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm418469.pdf>.

⁴ *Id.* at 4.

⁵ *Id.* at 5.

⁶ FDA, *Regulatory Procedures Manual*, §7-5-1 (2017).

⁷ *Id.* at §7-5-2.

¹ 21 C.F.R. § 7.3(g).

² FDA, *FDA Enforcement Statistics Summary Fiscal Year 2016* (2017), <https://www.fda.gov/downloads/ICECI/EnforcementActions/UCM540606.pdf>.

4. FDA also has mandatory recall authority for a variety of products, including FDA-regulated devices, certain biological products and food. FDA's mandatory recall authority does not extend to pharmaceuticals. FDA will use its mandatory recall authority when there is a serious public health risk and a firm has declined to initiate a voluntary recall. Because firms usually agree to an FDA request or recommendation for a recall, the agency has rarely used its mandatory recall authority. For example, though FDA gained the ability to mandate food recalls under the 2011 FDA Food Safety Modernization Act, it has used it only twice as of 2016.⁸

Q. Should a firm notify FDA if it is conducting a voluntary recall?

A. Yes. Although a firm's decision to initiate most recalls is voluntary, it is important to notify FDA of any recalls. Undeclared recall actions can result in agency and state investigations, administrative or judicial actions, or significant harm to a firm's reputation. Additionally, without FDA notification and input, FDA may decide that a firm-initiated recall was inadequate or ineffective.

For withdrawals of nonviolative products, it may still be advisable to alert FDA as to firm action to avoid misunderstandings or the appearance of impropriety.

Q. Whom should a firm contact at FDA when it decides to recall product?

A recalling firm should contact FDA's Office of Regulatory Affairs or the relevant FDA product center, depending on the nature of the recall.

⁸ Office of Inspector Gen., U.S. Dep't of Health and Human Services, *A-01-16-01502, The Food and Drug Administration's Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply*, 2 (Dec. 2017), <https://oig.hhs.gov/oas/reports/region1/11601502.pdf>.

Q. How should a firm respond if FDA requests or recommends a recall?

A. A firm should promptly consult with technical experts and legal counsel. It should also ask FDA questions in areas such as the scientific and public health basis for the recall; the scope of the recall (including areas of distribution, dates of manufacture and types of products); and the type of notice that FDA believes the firm should provide to wholesalers and retailers, medical professionals and the general public. The firm should be careful that the information it provides to FDA is truthful and complete.

Q. What if a firm declines to initiate an FDA-suggested recall?

A. Declining an FDA-suggested recall may significantly increase the risk of legal liability and harm a firm's reputation. Therefore, it is important that a firm have a strong legal and factual basis for declining any FDA-suggested recall.

If a firm declines to initiate an FDA-suggested recall, FDA may take several different actions. The agency may issue a press release warning the public that the agency believes that a product requires a recall but that the responsible firm, which it will name, has declined to take action. In areas where it has the authority, FDA may initiate a mandatory recall. It may also initiate administrative, judicial or enforcement actions such as detaining product, seizing product, suspending a firm's registration, banning a firm's imports, requesting an injunction, or pursuing criminal prosecution.⁹

Q. What are the steps of a recall after initiation?

A. Step one of a recall typically involves FDA review of all firm-provided background information regarding the

⁹ Office of Inspector Gen., U.S. Dep't of Health and Human Services, *OEI-02-14-00420, Challenges Remain in FDA's Inspections of Domestic Food Facilities*, 4 (Sept. 2017), <https://oig.hhs.gov/oei/reports/oei-02-14-00420.pdf>.





recall termination to the recalling firm and also publishes a status update indicating the recall's termination in its weekly Enforcement Report.

Throughout this process, it is important for a firm to consult with regulatory, legal and scientific experts to ensure that appropriate and timely decisions are made during a recall, minimizing risk to public health, limiting legal liability and protecting a firm's reputation.

Q. What are FDA recall "classifications"?

A. FDA classifies recalls into three categories based on the probability and severity of health consequences. These classifications determine how intensely FDA will audit a recall and what follow-up actions FDA will take after a recall.

A Class I recall occurs when there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. An example of a Class I recall is when food or medical product is contaminated with a dangerous pathogen.

A Class II recall occurs when use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. An example of a Class II recall would be an understrength drug that is not used to treat life-threatening conditions.¹⁴

A Class III recall occurs when the use of, or exposure to,

¹⁴ *FDA 101: Product Recalls*, FDA, <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm> (last updated Nov 9, 2017).

a violative product is not likely to cause adverse health consequences, such as a minor container defect.¹⁵

FDA's product centers classify recalls. They conduct health hazard evaluations, in which they look to past precedents and information about the current recall to evaluate the public health risk. FDA will perform intense audits of Class I recalls and will likely conduct inspections and product testing and initiate compliance and enforcement actions. Even Class II recalls may result in rigorous FDA follow-up activity. Class I and II recalls can also generate considerable media attention and congressional interest.

Q. What types of compliance and enforcement actions does FDA take during or after a recall?

A. FDA may initiate a variety of compliance and enforcement measures during or immediately following a recall. These actions include "for cause" facility inspections and warning letters, as well as administrative or judicial actions, such as import bans, injunctions, seizures and criminal prosecution. For recalls involving food, FDA may suspend a firm's registration of a food facility, immediately halting any food from leaving the facility for sale or distribution. A suspension continues until FDA believes that the relevant compliance problem has been resolved. For more information about FDA inspections and compliance and enforcement actions, see [A Client's Guide to FDA Inspections](#).

Q. What parts of FDA work on recalls?

A. Several parts of FDA work together during a recall. FDA's Office of Regulatory Affairs (ORA) is responsible

¹⁵ *Id.*

for inspecting and investigating firms, as well as enforcing FDA regulations. An ORA recall coordinator with appropriate expertise is assigned for every recall and works with other members of ORA's field force, such as investigators and compliance officers. ORA's Office of Enforcement and Import Operations provides advice and direction as needed. Each FDA product center has its own recall experts, who complete health hazard evaluations, classify recalls and finalize recall strategies. FDA's Office of Emergency Management coordinates response activities for recalls that accompany large outbreaks. The Office of the Chief Counsel provides legal advice, particularly when a firm and the agency disagree. The Office of the Associate Commissioner for Regulatory Affairs often plays a role when a firm declines an FDA suggestion to initiate a recall.

Q. Does FDA work with any other agencies during recalls?

Yes. FDA may work with a variety of state and federal agencies throughout the recall process, such as state departments of health, pharmacy and agriculture, as well as federal agencies, such as CDC and the U.S. Department of Agriculture. Collaboration with states most often occurs in recalls of human and animal food and compounded drugs. If a recalled product is sold outside the United States, FDA often collaborates with foreign regulators, who may choose to initiate recalls in their countries.

Q. How long does a recall take?

The length of a recall varies depending on the scope and complexity of the recall. Generally, both firms and FDA are motivated to initiate and complete a recall as soon as possible.

A recall's length may also be limited by a product's expiration date, or shelf life, as recalls target products remaining in commerce or still likely to be consumed.¹⁶ For example, a recall for fresh spinach may naturally have a shorter time frame than a recall for peanut butter or a medical device or over-the-counter drug.

Q. How should a firm be prepared for a recall?

FDA regulations covering most food and medical products mandate that firms have effective recall plans. A firm should have standard operating procedures in place for removing products from the market.

Generally, a plan should anticipate best methods for initiating and carrying out a recall based on the specific characteristics of the product (distribution supply chain, user base, shelf life, etc.). A firm should also have a plan for retaining technical experts and legal counsel in the event of any problems.

Firms should also maintain robust systems that comply with FDA's food safety and medical product safety and efficacy requirements, and should audit these systems. More robust preventive systems will make a recall much less likely.

¹⁶ See FDA, *Regulatory Procedures Manual*, §7-10, Attachment B; Attachment B1 (2017).





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