



A Client's Guide to FDA Recalls

Akin Gump
STRAUSS HAUER & FELD LLP

Recent FDA Recall Highlights & Developments

- The agency finalized Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C; Guidance for Industry and FDA Staff, providing recommendations regarding the use, content and circumstances for issuance of public warning and public notifications for recalls.
- FDA finalized Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff, providing answers to common questions regarding the agency's mandatory food recall authority.
- The agency gained the authority to issue a mandatory recall order for controlled substances under circumstances involving a reasonable probability of serious adverse health consequences or death.
- FDA increased recall information dissemination via social media, announcing a multi-state *Salmonella* outbreak on Twitter and Facebook.
- The agency issued its first mandatory food order of a food product under the agency's recall authority, which required the removal of *Salmonella*-contaminated kratom products from the market.

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.

When does a recall occur?

A recall occurs when a firm removes or corrects a marketed product that violates 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 fiscal year (FY) 2017, FDA oversaw 2,945 recall events involving 9,199 recorded recalled products.²

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

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.

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

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

How is a recall initiated?

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
4. FDA also has mandatory recall authority for a variety of products, including FDA-regulated devices, certain biological products and food. As of 2018, FDA's mandatory recall authority newly extends to controlled substances, but does not

¹ 21 C.F.R. § 7.3(g).

² FDA, *FDA Enforcement Statistics Summary Fiscal Year 2017* (2017), <https://www.fda.gov/downloads/ICECI/EnforcementActions/UCM592790.pdf>.

³ FDA, *Distinguishing Medical Device Recalls from Medical Device Enhancements; Guidance for Industry and Food and Drug Administration Staff*, 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 (2018).

⁷ *Id.* at §7-5-2.

include other pharmaceuticals.⁸ 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 ordered a mandatory recall only once as of 2018, with the agency initiating the process on two other occasions.⁹

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

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.

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 See 21 U.S.C. § 360bbb-8d(a).

⁹ FDA, *FDA Finalizes Guidance on Mandatory Recall Authority* (Nov. 2018), <https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm624443.htm>; 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>.

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

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.

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

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.¹⁰

What are the steps of a recall after initiation?

Step one of a recall typically involves FDA review of all firm-provided background information regarding the violative product. FDA uses this information to determine the scope of the recall and to recommend the best strategy for informing wholesalers, retailers, consumers and others that a product should be removed from the market and not consumed.

The scope of a recall is often defined by the type of product covered, when a product is made and where it is manufactured (for example, all sterile products, within expiry, manufactured at three facilities versus a single batch of one drug manufactured in one facility). As FDA receives new information, such as laboratory testing results and data from the Centers for Disease Control and Prevention (CDC), the scope of a recall may change.

¹⁰ 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>.

The recall communications strategy varies depending on the prevalence of the product, typical channels of distribution and the health hazard that the product poses to the public. A specialized product used by few consumers or patients may require more targeted notification, while a widely dispersed and high-volume product may require a broad communication strategy involving supply-chain distributor notification, as well as a public warning (a consumer-focused press release) [See additional explanation in our “Public Warnings Explained” section on page 6]. FDA may issue its own press release or work with the recalling firm to prepare a firm-issued press release. The precise wording of the press release is important for protecting the public and for preserving a firm’s reputation.

While not every recall requires media announcements, basic product information and event details on all recalls are published on a recall page on FDA’s website¹¹ and in FDA’s weekly Enforcement Report.¹² In a recent policy shift, FDA now publishes “not-yet-classified” recalls involving human drugs, foods and veterinary products in its Enforcement Report.¹³ This change is intended to shorten the time between recall initiation and public awareness of the recall effort.

For recalls involving food products, FDA may publicize lists of retail establishments that received or possess recalled products. The agency generally intends to take this action when the food is not easily identified for recall purposes based on its retail packaging and is likely available for consumption, though it may publicize the information under other appropriate circumstances as well.¹⁴

Step two of a recall involves monitoring by the firm and auditing by FDA. The recalling firm must ensure the satisfactory progress and effectiveness of a recall. The firm must reach out to affected persons and firms that have received, purchased or used the product subject to recall. Further, the firm is required to confirm that key affected persons and firms have received notification and taken appropriate action. The scope of the verification activities vary with the scope of a recall. The firm must also provide status updates to FDA regarding recall implementation.

FDA confirms recall progress through an audit program. This program is intended to review and verify firm reports, as well as to ensure that the recall is completed in a timely manner. FDA may place telephone calls or visit stores to confirm that violative products are off the market or that proper notifications have been completed. In some situations, FDA asks state regulators to assist in recall audits as well. If a recall is found to be ineffective, FDA will advise the recalling firm and review the firm’s plans for modification.

Finally, step three involves termination of the recall. When all recall activity by a firm has been completed and deemed effective (meaning that the product has been brought into compliance or disposed of appropriately), FDA will terminate the recall.¹⁵ FDA sends a notice of 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.

What are FDA recall “classifications”?

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.¹⁶

A Class III recall occurs when the use of or exposure to a violative product is not likely to cause adverse health consequences, such as a minor container defect.¹⁷

11 FDA, *Recalls, Market Withdrawals, & Safety Alerts*, <https://www.fda.gov/safety/recalls/default.htm> (Feb. 8, 2019)

12 *Enforcement Report Definitions*, FDA <https://www.fda.gov/Safety/Recalls/EnforcementReports/ucm181313.htm> (Oct. 4, 2018).

13 Douglas Stearn, *FDA to Expedite Release of Recall Information*, FDA (Jan. 18, 2018), <https://blogs.fda.gov/fdavoices/index.php/2018/01/fda-to-expedite-release-of-recall-information/>.

14 FDA, *Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls; Guidance for Industry and FDA Staff*, 4-5 (2015), <https://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM621668.pdf>.

15 FDA, *Regulatory Procedures Manual*, §7-9 (2018)

16 *FDA 101: Product Recalls*, FDA, <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm> (Sept. 10, 2018).

17 *Id.*

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.

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

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](#).

What parts of FDA work on recalls?

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

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.

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.¹⁸ 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.

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.

¹⁸ See FDA, *Regulatory Procedures Manual*, §7-10, Attachment B; Attachment B1 (2018).

Public Warnings Explained

What is a public warning?

A public warning is an alert issued by a firm or FDA to inform the public about a product presenting a serious health hazard, which is being recalled.¹⁹ The public warning can be disseminated through various methods, including the news media, trade press and online (e.g., FDA's website, a company website or social media).

When is a public warning appropriate?

A public warning is appropriate when a recalled product could have adverse public health consequences and a targeted communications strategy to prevent its use would be inadequate.²⁰ Further, a public warning may be necessary when a product has been widely distributed. FDA generally expects or requests public warnings for Class I recalls, or recalls with the potential for Class I classification. For example, FDA has suggested a public warning may be warranted for *Listeria monocytogenes* or *Salmonella*-contaminated food products, or malfunctioning medical devices delivering incorrect drug dosing.²¹ Other factors weighing in favor of a public warning include substantiated consumer reports of illness or injury, intended or likely use by vulnerable populations and substantial health impact.

In contrast, a public warning may not be appropriate in situations where it could cause confusion, particularly in the context of medical device recalls, which may necessitate consultation with a medical professional for adequate patient understanding.

What is the time frame of a public warning?

The time frame for issuing a public warning will vary depending on the individual circumstances of a recall. Generally, if a public warning is necessary, a draft version should be submitted to FDA for review as part of its recall strategy materials. FDA will comment on the draft public warning as needed and will provide a time frame for when the public warning should be issued. The agency expects that a firm

will issue a public warning within 24 hours of the agency's request. However, if an immediate warning is required, a firm may issue a public warning without FDA's prior review.

What information should be in a public warning?

A public warning should contain information allowing for identification of the recalled product by the public, such as pictures, serial numbers, packaging details, geographic distribution and dates of distribution.²² Additionally, a public warning should describe the reason for the recall, including details regarding the product defect or health hazard. Further, available information regarding the number and nature of illnesses, injuries and complaints stemming from the recalled product should be included. Contact information should be provided, as well as instructions for consumers or users. FDA cautions against overly lengthy public warnings or the inclusion of information or phrases that cloud or confuse consumers. A firm should consult with technical experts and legal counsel to evaluate the adequacy of its public warning.

What might make a public warning deficient?

FDA may consider a public warning deficient for a variety of reasons. Common issues include untimely or ineffective warnings, including a failure to adequately identify the recalled product, describe the health hazard posed or identify relevant product distribution information.²³ A public warning is also considered deficient if it fails to reach the correct target audience.

If FDA considers a public warning deficient, the agency may issue its own public warning or supplement a firm's public warning. Therefore, it is critical to maintain effective communication with FDA and meet agency expectations throughout the public-warning notification process.

¹⁹ FDA, *Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C; Guidance for Industry and FDA Staff*, 5 (2019), <https://www.fda.gov/downloads/Safety/Recalls/IndustryGuidance/UCM592851.pdf>.

²⁰ *Id.* at 6.

²¹ *Id.* at 7.

²² *Id.* at 9.

²³ *Id.*

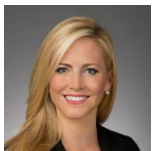
For more information, please contact:



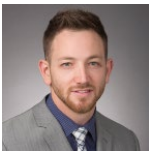
Nathan A. Brown
nabrown@akingump.com
202.887.4245



Howard R. Sklamberg
hsklamberg@akingump.com
202.887.4055



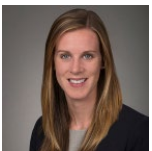
Christin Carey
chcarey@akingump.com
202.887.4257



Eli Z. Tomar
etomar@akingump.com
202.887.4209



Sudhana D. Bajracharya
sbajracharya@akingump.com
202.887.4258



Mallory A. Jones
jonesm@akingump.com
202.887.4259

Akin Gump

STRAUSS HAUER & FELD LLP

Akin Gump Strauss Hauer & Feld LLP is a leading global law firm providing innovative legal services and business solutions to individuals and institutions. Founded in 1945 by Richard Gump and Robert Strauss with the guiding vision that commitment, excellence and integrity would drive its success, the firm focuses on building lasting and mutually beneficial relationships with its clients. Our firm's clients range from individuals to corporations and nations. We offer clients a broad-spectrum approach, with over 85 practices that range from traditional strengths such as appellate, corporate and public policy to 21st century concentrations such as climate change, intellectual property litigation and national security.