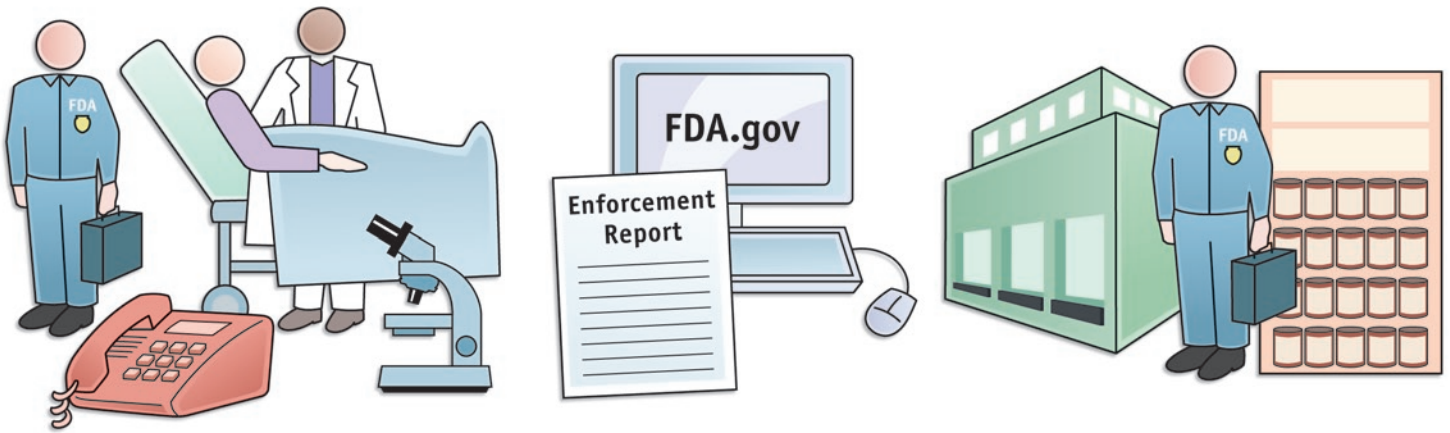


FDA 101: Product Recalls

From First Alert to Effectiveness Checks



First Alert

FDA hears about product problems through company notification, agency inspections and adverse event reports, and through CDC.

Alerting the Public

FDA posts regular updates about recalls to its Web site, and all recalls appear in the agency's weekly Enforcement Reports.

Effectiveness Checks

FDA reviews all of a company's corrective actions to determine when a recall is complete.

Once a product is in widespread use, unforeseen problems can sometimes lead to a recall. Contaminated spinach, for example, led to the recent recall of spinach products under multiple brand names. Contaminated peanut butter led to the recall of thousands of jars of two popular brands. In both cases, FDA responded immediately to minimize harm.

When an FDA-regulated product is either defective or potentially harmful, recalling that product—removing it from the market or correcting the problem—is the most effective means for protecting the public. In most cases, a recall results from an unintentional mistake by the company,

rather than from an intentional disregard for the law.

Recalls are almost always voluntary. Sometimes a company discovers a problem and recalls a product on its own. Other times a company recalls a product after FDA raises concerns. Only in rare cases will FDA request a

recall. But in every case, FDA's role is to oversee a company's strategy and assess the adequacy of the recall.

First Alert

FDA first hears about a problem product in several ways:

- A company discovers a problem and contacts FDA.
- FDA inspects a manufacturing facility and determines the potential for a recall.
- FDA receives reports of health problems through various reporting systems.
- The Centers for Disease Control and Prevention (CDC) contacts FDA.



RECALL CLASSIFICATIONS These guidelines categorize all recalls into one of three classes, according to the level of hazard involved:

- Class I** Dangerous or defective products that predictably could cause serious health problems or death. Examples include: food found to contain botulinum toxin, food with undeclared allergens, a label mix-up on a lifesaving drug, or a defective artificial heart valve.
- Class II** Products that might cause a temporary health problem, or pose only a slight threat of a serious nature. Example: a drug that is under-strength but that is not used to treat life-threatening situations.
- Class III** Products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing laws. Examples include: a minor container defect and lack of English labeling in a retail food.

When it comes to illnesses associated with food products, Dorothy J. Miller, Director of FDA's Office of Emergency Operations, says that FDA generally first hears of these kinds of problems from CDC.

"CDC hears about such problems from state health departments that have received and submitted illness reports," she says. "An ongoing outbreak means that we have an emergency, and when there's a public health crisis like this, you need to tell the public immediately."

Alerting the Public

FDA seeks publicity about a recall only when it believes the public needs to be alerted to a serious hazard. When a recalled product has been widely distributed, the news media is a very effective way to reach large numbers of people. FDA can hold press conferences, issue press releases, and post updates to its Web site regularly, to alert people.

"It's about being as transparent as possible," says Catherine McDermott, public affairs manager in the Division of Federal-State Relations in FDA's Office of Regulatory Affairs. "If we feel there is that much of a health risk, we will offer media updates every day to give new information,

FDA-regulated Products Subject to Recall

- human drugs
- animal drugs
- medical devices
- radiation-emitting products
- vaccines
- blood and blood products
- transplantable human tissue
- animal feed
- cosmetics
- about 80 percent of the foods eaten in the United States

and all that we know gets posted to FDA's Web site."

Not all recalls are announced in the media. But all recalls go into FDA's weekly Enforcement Report. This document lists each recall according to classification (see "Recall Classifications" box), with the specific action taken by the recalling firm.

Effectiveness Checks

FDA evaluates whether all reasonable efforts have been made to remove or correct a product. A recall is considered complete after all of the company's corrective actions are reviewed by FDA and deemed appropriate. After a recall is completed, FDA makes sure that the product is destroyed or suitably reconditioned, and investigates why the product was defective in the first place.

This article appears on FDA's Consumer Health Information Web page (www.fda.gov/consumer), which features the latest updates on FDA-regulated products. Sign up for free e-mail subscriptions at www.fda.gov/consumer/consumernews.html.

For More Information

Protect Your Health
Joint FDA/WebMD resource
www.webmd.com/fda

Recalls, Market Withdrawals, and Safety Alerts
www.fda.gov/opacom/7alerts.html

Weekly Enforcement Report Index
www.fda.gov/opacom/Enforce.html