

E-ALERT | Food & Drug

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RECALLS OF FDA-REGULATED PRODUCTS - WHAT YOU NEED TO KNOW

When faced with a potential recall, a company must act quickly to protect consumers, limit disruption to its supply chain, and avoid damage to its business and reputation. Decisions made in the early hours can determine whether a recall leads to major damage to the business and whether a wave of litigation follows. Poorly made decisions can lead to significant, even criminal, liability.

The safety of FDA-regulated products continues to be an issue in the spotlight, particularly as FDA has worked to implement the FDA Food Safety Modernization Act (FSMA) and has focused on compliance with current good manufacturing process (cGMP) requirements across the spectrum of FDA-regulated products. As FDA inspectors and downstream customers subject such products to increasing scrutiny, the number of recalls has continued to increase. This alert provides an overview of key issues that will arise during a recall: the need for a [recall plan](#), [evaluating the severity and scope of the recall](#), [notifications](#) to FDA, consumers, and the public, and securing [insurance coverage for potential losses and liabilities](#).

A Recall Plan - FDA proposed a rule in January of 2013 that would require food manufacturers to maintain a recall plan as part of the preventive controls requirements set forth in section 103 of the FSMA. FDA's current regulations at 21 C.F.R. §§ 7.40-7.59 provide valuable guidance for manufacturers of food and other FDA-regulated products, as does FDA's Guidance For Industry - Product Recalls, Including Removals and Corrections, available [here](#). If the manufacturer or distributor has no experience writing recall plans or conducting recalls, the plan should be reviewed by experienced regulatory counsel to make sure it is complete and appropriate. If the manufacturer produces food, infant formula, medical devices, or human biological products, the plan must address FDA's authority to mandate recalls of these products in certain cases.

Health Hazard Evaluation and Determining the Level and Depth of the Recall - The first step in determining how to address the potential recall issue requires the company to make a health hazard evaluation. That assessment will direct the classification of the recall and the overall approach both the company and FDA will take. FDA divides recalls into three classes:

1. **Class I** (in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death);
2. **Class II** (in which 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); and
3. **Class III** (in which use of or exposure to a violative product is not likely to cause adverse health consequences).

Therefore, a company must first perform the health hazard analysis before it can classify the recall. The class of the recall frequently dictates the depth of the recall, i.e., whether it is conducted back to the distributor/warehouse level, the retail level, or the consumer level.

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Notifications to FDA, Customers, and the Public - As part of the recall plan, a company will need to consider whether, when, and how to notify the public about the recall and whether and when to notify FDA. For foods, medical devices, and infant formulas, there are mandatory FDA reporting requirements in certain cases.

Several factors play a role in the decision of how to notify purchasers. For example, traditionally, in recalls of consumer products classified as Class I level recalls (i.e., those in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death), FDA requires that notification be provided directly to consumers. If the manufacturer can identify all consumers who purchased the product, notice can be given via letters or email. In the more typical case, however, manufacturers do not know the identities of consumers who purchased their products and notice is provided through a press release. The wording of the press release must be serious and specific enough to advise consumers of the severity of the problem and identify the particular products involved, but not so alarming that consumers will be discouraged from purchasing the manufacturer's products in the future. FDA prefers that press releases be issued through the Associated Press (AP). The agency also encourages the use of other media, such as websites of the company and of relevant consumer or patient advocacy groups.

The company also needs to decide whether and when to notify FDA regarding the recall. Under the Food and Drug Administration Amendments Act of 2007 (FDAAA), food and feed manufacturers who are "responsible parties" are required to report to FDA's "reportable food registry" within 24 hours of determining that a reportable situation exists, which is defined in exactly the same way as a Class I recall.¹ Therefore, if a manufacturer determines that a Class I recall situation exists with respect to a human or animal food, it must report that fact to FDA within 24 hours. Other than Class I recalls, notification to FDA that a company is voluntarily recalling a product is generally optional, although most companies opt to notify and work with FDA on Class II-level recalls as well. For medical devices, notification to FDA is required for Class I- and II-level recalls.

The FSMA granted FDA mandatory recall authority over food. When FDA determines "that there is a reasonable probability" that food is adulterated or fails to declare a major allergen and will cause "serious adverse health consequences or death to humans or animals," FDA may ask the responsible party to voluntarily recall the article. If the party refuses, FDA may issue a cease distribution order requiring that the party "immediately" cease distributing the item and notify recipients of the recall. The agency has stated that it anticipates using its new authority in "rare instances," but the fact that FDA now has this authority likely means that companies facing a questionable recall situation may err in favor of recalling the article rather than facing the threat of an FDA-mandated recall.

Insurance Coverage - Insurance can provide funding for many of the costs of a recall, potentially including direct losses of product and indirect losses from business interruption, loss of market share, and sometimes even brand rehabilitation.

A product recall can implicate several types of insurance coverage, including specialty product tampering or contamination insurance, sometimes described as "product recall coverage," if purchased by the company. This insurance may cover the costs of conducting the recall and may also cover:

¹ For our alert on the Reportable Food Registry, click [here](#).

- **Business interruption coverage.** Insurance may cover the company's business interruption resulting from a recall incident and the company's brand rehabilitation/reputation management costs.
- **Product liability coverage.** This insurance may cover third-party bodily injury or property damage claims and related defense costs arising out of contamination or other problems with the company's products. Defense coverage might be in addition to the policy's indemnity limits of liability.
- **First-party property insurance.** This insurance is designed to cover the loss of the company's own products and related business interruption losses.
- **Directors' and Officers' liability insurance.** In certain cases, contamination incidents and recalls can trigger claims that might be covered under these policies, which are payable to the directors and officers of a company (or to the company itself) for losses alleged to arise out of the actions of the company's directors and officers, and may include defense costs arising out of regulatory and criminal investigations.
- **Errors and omissions insurance.** Where the company is a processor or service provider, rather than a manufacturer, this insurance may cover losses arising out of errors that caused the product to be contaminated or damaged and subsequently recalled.

The company might also have rights under policies covering other parties in the distribution chain – for example, suppliers. It will need to preserve its rights under those policies as well as under its own policies.

Insurance companies do not always agree to pay, however, and one of their common defenses to coverage arises out of the “notice” condition in their policies. To avoid a battle on this front, the company should consult the notice provision of the policies and provide timely notice to insurers under all potentially implicated policies.

How We Can Help - Covington & Burling LLP's attorneys have extensive experience in successfully managing recalls involving FDA-regulated products, as well as related investigations, product liability, and insurance coverage claims. We have handled many high profile FDA-regulated product recalls, including matters related to recalls of nut products, pet food, and dietary supplements and related consumer and customer litigation and insurance coverage for these losses and liabilities. We can help you prepare for recalls generally and provide crucial advice early in the decision-making process to help reduce the impact on your customers and your business. Our product liability attorneys can assist with the product liability issues that often accompany recalls. Our insurance counsel can help you to tailor your coverage to your business before a problem arises and to carry out your obligations under insurance contracts to maximize your insurance coverage for the costs resulting from the recall and any third-party claims. Finally, Covington also has experienced white collar attorneys who can help plan and conduct any necessary internal investigations.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug and Insurance Practice Groups:

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