

# Food & Drug

## E-ALERT

February 9, 2009

### Recalls of FDA-Regulated Products - What You Need to Know

The current recall of peanut products due to potential salmonella contamination is poised to become the largest in history. Affecting over one hundred food manufacturers who sourced peanut-derived ingredients from the Peanut Corporation of America (PCA) and many hundreds of finished products, the recall likely will cost the food industry hundreds of millions of dollars. Federal authorities have begun a criminal investigation of PCA, and Congressional leaders and consumer advocacy groups are calling for greater oversight of the entities that manufacture and handle our food.

This latest crisis follows in the wake of an unprecedented spate of product recalls in the last few years. Hundreds of dog and cat food products were recalled due to melamine contamination, and over 21.7 million pounds of ground beef were recalled due to E. coli contamination, causing a 67-year-old meat processor to close its doors. Contamination of the drug heparin led to a major recall, and medical device manufacturers also have had to recall products due to reports of adverse events and device malfunctions.

These high-profile product recalls have highlighted the need for corporations to be prepared to deal with a recall situation before disaster strikes. The need to recall one or more products can and frequently does arise at the worst possible time, and when that happens, difficult decisions must be made quickly to reduce potential injury to consumers, disruption to the supply chain, and damage to the corporation's business and reputation. Decisions made in the early hours after a corporation learns it has a potential recall can determine whether a recall leads to major damage to the business and whether a wave of litigation follows. Poorly-made decisions at that point can lead to significant, even criminal, liability.

**A Recall Plan** - All manufacturers need to have a recall plan in place before the need for a recall arises. The regulations in 21 C.F.R. §§ 7.40-7.59 can provide valuable guidance, as can the United States Food and Drug Administration (FDA) Guidance For Industry - Product Recalls, Including Removals and Corrections, available at [http://www.fda.gov/ora/compliance\\_ref/recalls/ggp\\_recall.htm](http://www.fda.gov/ora/compliance_ref/recalls/ggp_recall.htm). 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 infant formula, medical devices or human biological products, the plan must address the fact that FDA has 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

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company and FDA will take. FDA divides recalls into three classes:

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);

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

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. Determining the level of the recall frequently will also dictate the depth of the recall, i.e., whether it is conducted back to the distributor/warehouse level, the retail level, or the consumer level.

**PR and Notifications** - 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 medical devices and infant formulas, there are mandatory FDA reporting requirements in certain cases. For other products, reporting to FDA is still voluntary, although that will change for food within the next few months, as described below.

A number of factors will go into 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 identity 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 decision also needs to be made as to whether and when to notify FDA regarding the recall. At this time, recalls of FDA-regulated products are usually voluntary. Although bills are pending in Congress to give FDA mandatory recall authority, currently the agency cannot require a company to recall a product, except in certain situations noted above. If a company is not cooperating to recall a product on its own initiative or at FDA request, FDA can apply pressure on the company to do so. For example, the agency can publish an unfavorable press release to pressure a company into launching a recall; and, if it obtains a court order, FDA can seize product a company refuses to recall. Notification to FDA that a company is recalling a product is usually optional, although most companies opt to notify and work with FDA on at least Class I and II-level recalls. For medical devices, notification to FDA is required for Class I and II-level recalls.

Under the Food and Drug Administration Amendments Act of 2007 (FDAAA), the agency was required to establish a "reportable food registry" by the end of September 2008. FDA did not meet that deadline, but the agency has advised that it will implement the registry by the spring of this year. "Responsible parties" under the FDAAA, which would include food and feed manufacturers, will be required to report to FDA within 24 hours of

determining that a reportable situation exists, which is defined in exactly the same way as a Class I recall. Therefore, once the registry is in place, if a manufacturer determines that a Class I recall situation exists with respect to a human or animal food, it will be required to report that fact to FDA within 24 hours.

**Internal Investigations and Government Enforcement Action** - Once a product issue has been identified and any associated recall launched, a firm must conduct an investigation to determine the source of the problem and the likelihood for recurrence. While making appropriate recall decisions can be the most important step in minimizing immediate impact both on consumers and on the corporation, the handling of the investigation can have much more far-reaching consequences. Investigations can raise personnel, manufacturing, and sourcing issues and improperly handled investigations can impact a firm in all of these areas.

In addition, recalls frequently trigger government enforcement inquiries from the FDA and, depending on the circumstances, potentially other government entities, such as the Department of Health and Human Services Office of Inspector General, the SEC, and the Department of Justice.

Once FDA learns of the recall, the agency may launch its own investigation. FDA inspectors and/or investigators can appear suddenly and without notice at the company's manufacturing facilities and it will need to be prepared to respond. The company must investigate what led to the recall and how the problem can be addressed before decisions can be made about how to respond to the agency on these issues. Having in place inspection standard operating procedures (SOPs) can be very helpful in dealing with these stressful situations, but the SOPs may not cover all possible contingencies and often crucial decisions must be made quickly. A company should have in place a consulting team it can call in immediately to help. The team should consist of regulatory, investigative and other counsel, any technical experts who may be helpful in reaching conclusions as to, for example, product contamination from external sources or from failure to follow appropriate current good manufacturing practices, and crisis managers to help handle communications in the case of a major recall and/or product liability issue. Having such a team already identified and the resulting ability to launch an immediate investigation will streamline the process of determining what steps to take in the early, crucial hours. Such an approach also can assist a company in positioning itself to defend against civil litigation that may result from the recall.

**Litigation** - To the extent that a recall also involves third-party claims for bodily injury or property damage, the company needs to brace itself for products liability litigation. In addition to defending such lawsuits, a company downstream from the original source of the recall also needs to consider whether to make its own claims against the source, as well as any intermediate suppliers. A multi-disciplinary team including attorneys with experience in products liability, regulatory compliance, insurance coverage, and even bankruptcy law would afford the company a comprehensive approach to the variety of interlocking issues that may arise in litigation.

**Insurance Coverage** - Insurance can provide funding for many of the costs of a recall, potentially including direct losses from returned product and product refunds, and the contingent losses associated with products liability issues and business interruption, including lost sales, if product cannot be replaced right away. Prolonged interruption of sales may occur when the product is imported, as FDA may hold up future shipments of products that had been the subject of recalls. Some specialty policies even cover costs incurred to regain market share and restore customer confidence.

A product recall can implicate several lines of insurance coverage. Relevant coverages may include:

- Product recall coverage, if purchased by the company.
- Product tampering or contamination insurance, which may afford coverage for business interruption resulting from a recall incident and for related crisis management costs.
- Products liability coverage for third-party bodily injury or property damage claims and related defense costs.
- First-party coverage for the loss of the company's own products and related business interruption losses.
- In certain cases, recalls can trigger claims that might be covered under directors' and officers' liability policies.

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. Insurers also often try to avoid their policies by arguing that notice was not given in strict compliance with the policy's requirements; therefore, it is prudent to review policy conditions and provide required information, assuming it is available, accordingly.

**How We Can Help** - Covington & Burling LLP's attorneys have extensive experience in managing recall issues involving FDA-regulated products. We have handled many high profile FDA-regulated product recalls, including matters related to this year's peanut products recall, 2007's pet food recall, and others. 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 products liability attorneys, who also specialize in regulatory matters, can assist with the products 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 the insurance contract in the event of a recall in order to maximize your insurance coverage for the costs resulting from the recall and any third-party claims. Finally, Covington also has experienced white collar criminal and investigative attorneys who specialize in regulatory matters and who can help plan and conduct any necessary internal investigations.

## Whom to Call

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