

November 6, 2007

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

In the early part of 2007, the United States witnessed an unprecedented spate of product recalls - and media and consumer attention to the quality of ingredients in and components of manufactured products. In the spring of 2007, hundreds of dog and cat food products were recalled and the United States Food and Drug Administration ("FDA") received a record number of consumer complaints and inquiries. Acute illnesses and deaths in cats and dogs were traced to the chemical melamine, which, along with some of its metabolites, was found in pet food ingredients imported from China. The pet food recalls caused government regulators to look at other products received from China and legislators to propose laws to deal with the weaknesses in our importation system. In October of this year, a 67-year-old meat processor closed its doors after recalling 21.7 million pounds of ground beef. Drug and medical device manufacturers have had to recall products due to reports of adverse events and device malfunctions.

On September 27, 2007, the President signed into law the Food and Drug Administration Amendment Act of 2007 (FDAAA), which contained a clause aimed at the safety of pet food and at enhancing recall procedures for all foods. These new procedures will change the way that companies in these industries must deal with product recalls.

The high-profile product recalls of this year 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 FDA Guidance For Industry - Product Recalls, Including Removals and Corrections, available at 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 company and FDA will take. FDA divides recalls into 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 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. Recalls of FDA-regulated products are usually voluntary. FDA cannot mandate that a company recall a product, except in certain situations involving medical devices. 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 recently enacted FDAAA, the agency is required to establish a "reportable food registry" by the end of September 2008. "Responsible parties" under that Act, 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, Government Enforcement Action, and Litigation - 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 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.

Insurance Coverage - Proper insurance coverage can help companies weather the storm created by negative publicity, 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. The latter scenario is particularly likely when the product is imported, as FDA may hold up future shipments of products that had been the subject of recalls. When a recall-triggering event occurs, it will be critical to make sure that timely notice is provided to the insurer and that it is given per the contract terms. It is also critical during the early hours of the decision-making process to verify that the company understands and fulfills its obligations under the policy.

A product recall can implicate several lines of insurance coverage. Relatively few companies purchase product recall coverage, although it is available in the market. The company must act promptly to comply fully with the terms of other potentially triggered policies, such as by providing prompt notice. This is the crucial first step in maximizing the coverage potentially available from the company's insurance assets. The relevant coverages may include:

- Product recall coverage, if purchased.
- Products liability coverage for third-party bodily injury or property damage claims and related defense costs which can be sustained.
- Product tampering or contamination insurance, which may afford coverage for business interruption resulting from a recall incident and for related crisis management costs.

How We Can Help - Covington & Burling LLP's attorneys have extensive experience in managing recall issues involving FDA-regulated products. We have handled many FDA-regulated product recalls, including a number of pet food and related recalls earlier this year. 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 navigate the maze of choosing an appropriate policy and

of making sure you fulfill your contractual obligations in the event of a recall-triggering issue to maximize your insurance coverage for the costs associated with the recall as well as for potential third-party liability. 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.

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