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REGULATORY ISSUES: HANDLING A RECALL

FDA's updated industry guidance document devotes several pages to the submission of recall-related information to the agency.

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The Food and Drug Administration (FDA) recently updated an industry guidance document on the handling of product recalls. Every food manufacturer, including manufacturers of ingredients and additives, should have internal guidelines to facilitate clear thinking and a quick response when confronted with the decision to recall a food.

The primary objective behind a food recall is to prevent consumers from being injured by something potentially harmful. Secondary objectives may include minimizing liability associated with an injury, keeping the manufacturer's reputation as undamaged as possible and avoiding too much regulatory scrutiny from FDA.

Under the Federal Food, Drug, and Cosmetic Act, FDA does not actually have authority to order a manufacturer to recall a food, other than infant formula. FDA does, however, play a role in food recalls. The agency has issued regulations and guidance indicating when a food recall should be undertaken.

Behind every "voluntary" food recall is an understanding that FDA has the authority to seize an unsafe food and publicize the danger associated with it in the absence of cooperation from the manufacturer. Given these alternatives, manufacturers generally prefer to be seen as partnering with FDA to remove the questionable food from the market.

Perhaps to enforce this understanding, FDA defines the term "recall" in its regulations to mean "a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure."

The bioterrorism factor

Today, the definition might be expanded to acknowledge that in addition to its seizure authority, FDA now has authority under the Bioterrorism Act to order an "administrative detention" of contaminated food. Under this authority, and without going to court, FDA can now effect the detention of an article of food upon "credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals."

FDA's expectations regarding recalls are set forth in a set of regulations appearing in 21 CFR Part 7. Note these regulations pertain to recalls involving not only food, but any FDA-regulated product. According to FDA's regulations, a recall is assigned a classification, Class I, Class II, or Class III, to indicate the seriousness of the health hazard associated with the product. These classifications are defined as follows:

* Class I is a situation 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 is a situation 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.

* Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Notice that as a threshold matter, the food in question is in violation of the Food, Drug, and Cosmetic Act, meaning it is adulterated or misbranded. Notice also the definition of "Class I" matches language in the Bioterrorism Act describing FDA's authority to detain food administratively. In other words, FDA now has authority to order the detention of any food that should be the subject of a Class I recall.

Class III seems to cover any instance in which a food is adulterated or misbranded in a way that does not present any danger to the consumer. These cases require some judgment in deciding whether a recall is necessary. For example, if a food is labeled as containing a color additive that is not actually present, the food is technically misbranded. But is a recall necessary? Probably not. A manufacturer facing that situation might sensibly decide to correct the problem without actually recalling any food that is already outside its control.

FDA's regulations tend to suggest Class III recalls may not be needed, as they state FDA will not request a recall unless the product in question "presents a risk of illness or injury or gross consumer deception." FDA's definition of the term "recall" also suggests Class III situations do not belong within its scope, as it pertains to products "against which the agency would initiate legal action."

Food recalls classified in Class III and included in FDA's Enforcement Reports are rare, but do exist. They almost always involve an incomplete ingredient statement, where the undeclared ingredients are not allergenic or otherwise harmful to sensitive individuals.

Class I recalls most likely do not require careful consideration of whether a recall is necessary. The most common types of Class I and Class II recalls are for food that contains an undeclared allergen or a pathogenic microorganism--such that a consumer of the food might experience a very serious adverse reaction or illness. Examples include food that contains undeclared sulfites or undeclared FD&C Yellow No. 5, both of which may be dangerous only to sensitive individuals.

FDA's weekly enforcement reports, made available on the agency's web site, list all food recalls

reported to or initiated by the agency. This is a good source of guidance for anyone considering whether a particular contamination or misbranding incident is of the type that would normally give rise to a recall. The enforcement reports generally indicate whether a recall was initiated by the manufacturer, was requested by FDA, or requested by a state agency.

In addition to defining the type of situations in which a recall is appropriate, FDA's guidance and regulations request manufacturers notify FDA whenever they initiate a food recall because the product violates the Food, Drug, and Cosmetic Act. (In theory, a manufacturer might recall a food because of quality reasons unrelated to the safety or regulatory status of the food, and in that case FDA does not wish to be notified of the recall.)

What FDA can and can't do

Notice that just as FDA cannot compel a manufacturer to conduct a recall, it also cannot compel a manufacturer to notify FDA of the recall. However, when a manufacturer, acting in its own best interest, decides to notify FDA of a recall, the agency requests a fairly detailed set of information including the reason for the recall, the volume of affected product, distribution information, the firm's recall communication or draft recall communication and the strategy for conducting the recall.

FDA's recent industry guidance document devotes several pages to the submission of recall-related information to the agency. Manufacturers are urged to notify FDA almost immediately upon deciding to conduct a recall, so FDA can offer guidance and assistance in the recall process. The guidance document also discusses the prompt issuance of a press release, particularly when a recalled product may pose a significant health hazard and is in the hands of consumers.

Manufacturers also are expected to evaluate the effectiveness of the recall; i.e., whether subsequent recipients of the food acted properly upon the recall notice, and all or most of the violative product was returned or destroyed. FDA will be interested in the root causes of the recall and the steps taken to prevent a recurrence.

After reviewing FDA's guidance, a manufacturer would be forgiven for thinking it might be nicer not to have FDA looking over its shoulder throughout a recall. Ultimately, the decision to involve FDA in a food recall probably will depend on factors such as the seriousness of the hazard, whether FDA is likely to learn about the recall in any event, and whether FDA's issuance of a press release would help mitigate the risk of harm to consumers.

However a manufacturer decides to handle a food recall, these questions should be given some thought in advance. Ideally, a set of internal procedures should be in place for the handling of a potential recall, including procedures for deciding whether a recall is needed and whether and when to notify FDA.

Thinking about how a recall would be handled also tends to reinforce the notion that it would be nicer to avoid food recalls in the first place. This is particularly true when the recall is caused by circumstances that are avoidable, such as the presence of an undeclared ingredient.

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