CLIENT ALERT

Draft Guidance for Industry on Mandatory Food Recalls Available for Public Comment

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On Wednesday, May 6, 2015, the U.S. Food and Drug Administration (FDA) published a draft guidance for industry on mandatory food recalls. Interested persons have 60 days—until **July 7, 2015**—to submit comments.

The guidance is part of FDA's continuing effort to implement the Food Safety and Modernization Act (FSMA), which President Obama signed in January 2011, and which granted FDA broad new powers over the U.S. food supply. Chief among those powers was the authority to order mandatory recalls of food that was adulterated or misbranded and the use of which could cause serious adverse health consequences or death to humans or animals.

Prior to the enactment of FSMA, FDA could only ask a responsible party to voluntarily recall food products. If the responsible party refused FDA's request, the agency's only option to remove the products from the marketplace was to direct the U.S. Marshals to seize it. Seizures, however, can be slow and cumbersome and are often ineffective at reaching products on store shelves nationwide.

FSMA gives FDA's recall requests more teeth, by enabling the agency to back up its requests with orders, and to enforce those orders with civil money penalties if they are ignored.

Before ordering a mandatory recall, FDA must still give notice to the responsible party and afford it the opportunity to initiate a voluntary recall. If the responsible party refuses to implement the voluntary recall or fails to institute a recall "within the time and the manner prescribed by the Secretary," FDA may order that distribution stop and require that all individuals "manufacturing, processing, packing, transporting, distributing, receiving, holding or importing and selling such article" be notified. Finally, in the event an order is issued, "[t]he Secretary shall provide the [firm] … with an opportunity for an informal hearing."

FDA's mandatory recall authority became effective with the enactment of FSMA. With the draft guidance issued this week, FDA has taken the opportunity, through a series of "Questions and Answers Regarding Mandatory Food Recalls," to articulate in greater detail its interpretation of that authority. In particular, the guidance includes discussions of evidence FDA may consider before moving forward with a mandatory recall, and the collection of user fees to cover food recall penalties.

Evidence Considered by FDA

> When deciding whether to move forward with a mandatory food recall FDA may consider all relevant evidence to determine if there is a reasonable probability that the article of food is mislabeled or adulterated and the exposure will cause serious adverse health consequences or death to humans or animals. The draft guidance explains that, in making this assessment, FDA may rely on evidence such as: observations made during inspections, results from sample analyses, epidemiological data, reportable food registry data; and complaints.

User Fees to Cover Food Recall Penalties

> The Food, Drug, and Cosmetic Act authorizes FDA to collect fees from a responsible party from a domestic facility and an importer that does not comply with a food recall order. Noncompliance may include: (1) failing to issue a recall ordered by FDA; (2) failing to conduct the recall in the manner prescribed by the recall order; or (3) failing to provide FDA with information requested regarding the recall. User fees are intended to cover the time spent by FDA conducting the mandatory recall, and a notice of fees for non-compliance is published in the Federal Registrar within 60 days before the start of each fiscal year.

Use of Mandatory Recall Authority

To date, FDA, has made only light use of its mandatory recall authority. In a recent report to congress, FDA cited just two cases where it had exercised this authority: in February 2013 it took action against Kasel Associations Industries, Inc. for certain lots of the firm's pet treats; and in November 2013, it ordered a recall of OxyElite Pro Dietary supplements after linking the use of the supplements to numerous cases of liver damage. In both cases, letters were issued informing the respective firms that if they did not voluntarily cease distribution of the adulterated products, FDA may, by order, require them to cease distribution and give notice to other parties. In response to the notification letters, both firms announced voluntary recalls of the products. By offering new draft guidance on recalls, however, FDA may be signaling its intent to more aggressively exercise this authority.

Additional FDA Enforcement Tools: Suspension of Registration and Administrative Detention

In addition to the mandatory recall authority, it is important to bear in mind the other tools that FSMA provided to FDA to deal with food products the agency suspects are adulterated or misbranded.

- **Expanded Administrative Detention:** FSMA authorizes FDA to detain an article of food for which there is information that the food presents a threat to the health of humans and animals. Detention may occur if "the officer or qualified employee has reason to believe that the article of food is adulterated or misbranded."
- **Suspension of Registration:** FSMA requires any facility engaged "in manufacturing, processing, packing, or holding food for consumption in the United States" to register with FDA. FDA may suspend a registration, however, if it determines "that food manufactured, processed, packed, received, or held by [the facility] has a reasonable probability of causing serious adverse health consequences or death to humans or animals," and the facility: (1) "Created, caused, or was otherwise responsible for such reasonable probability;" or (2) "Knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food." A facility that is under suspension is prohibited from distributing food.

This most recent guidance on the mandatory recall authority is likely just the beginning of what will be a busy year for food safety regulation. On April 23, FDA held a "FSMA Kickoff Meeting" in Washington, D.C. and declared that this is "the year of FSMA." FDA is moving closer to finalizing various pending rules implementing FSMA and further guidance explaining the new statutory and regulatory requirements is expected as well. Attorneys at Crowell & Moring are actively tracking new developments.

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