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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

New Food Recall Guidance May Signal Tougher FDA

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John Fuson

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

The guidance is part of the FDA's continuing effort to implement the Food Safety and Modernization Act (FSMA), which President Obama signed in January 2011 and which granted the 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 the FSMA, the FDA could only ask a responsible party to voluntarily recall food products. If the responsible party refused the 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.

The FSMA gives the 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, the 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," the 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."

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 With the draft guidance issued this week, the FDA has taken the opportunity, through a series of "Questions and Answers Regarding Mandatory Food Recalls," to articulate in greater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

Evidence Considered by the FDA

When deciding whether to move forward with a mandatory food recall the 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, the FDA may rely on evidence such as: observations made during inspections, results from sample analysis, epidemiological data, reportable food registry data; and complaints.

User Fees to Cover Food Recall Penalties

The Food, Drug and Cosmetic Act authorizes the 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 the FDA; (2) failing to conduct the recall in the manner prescribed by the recall order; or (3) failing to provide the FDA with information requested regarding the recall. User fees are intended to cover the time spent by the FDA conducting the mandatory recall, and a notice of fees for noncompliance is published in the Federal Registrar within 60 days before the start of each fiscal year.

Use of Mandatory Recall Authority

To date, the FDA has made only light use of its mandatory recall authority. In a recent report to congress, the 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, the 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, the 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 the FSMA provided to the FDA to deal with food products the agency suspects are adulterated or misbranded.

- **Expanded Administrative Detention**: The FSMA authorizes the 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**: The FSMA requires any facility engaged "in manufacturing, processing, packing or holding food for consumption in the United States" to register with the

FDA. The 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, the FDA held a "FSMA Kickoff Meeting" in Washington, D.C., and declared that this is "the year of the FSMA." The FDA is moving closer to finalizing various pending rules implementing the FSMA and further guidance explaining the new statutory and regulatory requirements is expected as well.

—By John Fuson and Chalana N. Williams, Crowell & Moring LLP

John Fuson is a partner in Crowell's Washington, D.C., office and was previously associate chief counsel at the FDA.

Chalana Williams is an associate in Crowell's Washington office.