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Regulatory Alert: FDA Releases Draft Guidance on FSMA Mandatory Recall Authority

May 7, 2015

On May 6, 2015, the U.S. Food and Drug Administration (FDA) released draft guidance for industry regarding the agency's authority to order a recall under the Food Safety Modernization Act (FSMA). Section 206 of FSMA (section 423 of the Federal Food, Drug and Cosmetic Act (FD&C Act)) granted FDA mandatory recall authority. Previously, FDA did not have authority to require firms to recall foods (other than infant formula). The draft guidance is in the form of questions and answers. This document summarizes the key points:

What foods are subject to FDA's mandatory recall authority?

Articles of food (excluding infant formula) that are manufactured, processed, packed or held at a food facility that is required to register with the agency under the Bioterrorism Act (i.e. a registered food facility). "Food" includes: (1) food and beverages for humans and animals; (2) chewing gum; and (3) components (e.g. ingredients) of such items. Dietary supplements are considered food.

What is a responsible party under section 423 of the FD&C Act?

The responsible party is the person who is responsible for implementing and assuring that a recall is performed. The responsible party is the owner, operator or agent in charge of a facility who is responsible for submitting the food facility registration. It is the same person who is a responsible party under the Reportable Food Registry requirements (Section 417 of the FD&C Act).

When do the mandatory recall provisions go into effect?

The provisions became effective the day President Obama signed FSMA into law—January 4, 2011. FDA has used this authority already.

Under what circumstances can FDA use its authority?

FDA must make the determination that:

1. There is a reasonable probability that the article of food is adulterated or misbranded with respect to allergen labeling; and
2. There is a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals.

How does the mandatory recall process work?

1. FDA must first provide the responsible party with an opportunity to voluntary cease distribution and recall the article of food. FDA will provide the opportunity in written form using an expeditious method.
2. If the responsible party refuses or does not voluntarily cease distribution and recall the article of food within the time and manner prescribed by FDA, the agency may: order the responsible party to cease distributing the article of food, order the responsible party to give notice to certain other persons to cease distributing the article of food, and give the responsible party an opportunity for an informal hearing.
3. After these steps are completed FDA may order a recall if it is determined that the removal of the article from commerce is necessary.

What evidence will FDA consider when deciding to move forward with a mandatory recall?

Evidence may include:

- Observations made during inspections (of the responsible party or others)
- Results from sample analyses
- Epidemiological data
- Reportable Food Registry data; and
- Consumer and trade complaints

How will FDA publicize information about a recall?

FDA will ensure that a press release is published, and alerts and public notices (as appropriate), to provide notification to affected consumers and retailers. Note that FSMA requires retailers to notify consumers of recalls, please contact us for additional information about this requirement.

When would user fees be assessed? Who would FDA assess and for what activities? Are civil money penalties applicable? Are criminal penalties applicable?

FDA may collect fees from a responsible party for a domestic facility, and an importer, who does not comply with a recall order (for food or infant formula). The fees would cover time spent by FDA conducting food recall activities, including technical assistance, follow-up effectiveness checks, and public notifications. FDA states that noncompliance may include: (1) not initiating a recall as ordered by FDA; (2) not conducting the recall in the manner specified by FDA in the recall order; or (3) not providing FDA with requested information regarding the recall.

User fees for fiscal year 2015 are $217/hour if domestic travel is required and $305/hour if foreign travel is required.

FDA may assess civil penalties on any person who does not comply with a recall order. Failure or refusal to follow a recall order is punishable with criminal penalties.

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