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Food, Drug & Device Law Alert - FDA Issues Draft Guidance On Mandatory Food Recalls Under The Food Safety Modernization Act

May 27, 2015 | Atlanta | Chicago | Columbus | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

The Food and Drug Administration (FDA) recently issued a draft guidance titled, "Questions and Answers Regarding Mandatory Food Recalls." FDA was given general mandatory food recall authority by the Food Safety Modernization Act (FSMA). The guidance is notable for its brevity, coming in at a total of seven pages including the cover. Although much of the content will be familiar to those with experience in food recalls, the guidance does discuss the procedure for FDA to order a mandatory food recall and the assessment of user fees for those subject to such a recall.

With respect to the procedure, the guidance states after FDA finds that the criteria for a mandatory recall have been met, it must first provide the responsible party with an opportunity to perform a voluntary recall of the food. FDA will provide this opportunity in writing using an expeditious method. If the responsible party does not voluntarily cease distribution and recall the food within the time and manner prescribed by FDA, FDA 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. After these steps are completed, FDA may order a recall if it determines that the removal of the food from commerce is necessary. Only the FDA Commissioner has the authority to order a recall.

As to user fees, the guidance observes that the FDA has the authority to collect fees from a responsible party for a domestic facility and an importer who does not comply with a food recall order. The fees would cover time spent by FDA conducting food recall activities, including technical assistance, follow-up effectiveness checks, and public notifications. FDA defines noncompliance to 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, as ordered by FDA. FDA publishes a Federal Register notice of fees for non-compliance with a Recall Order no later than 60 days before the start of each fiscal year.

Given that most parties will voluntarily recall food when the statutory conditions are satisfied to avoid a public relations disaster and harsh FDA action, it seems unlikely that FDA will have to resort often to the exercise of its mandatory recall authority or assessment of fees. The fact that FDA has this authority, however, helps ensure FDA will not have to exercise it.

A copy of the draft guidance document can be found here.

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