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The Hammer Revealed: Mandatory Recall Authority Under The Food Safety Modernization Act

by Michael Droke and Mark R. Kaster

The Food Safety Modernization Act (FSMA) overhauled the nation's food safety systems for the first time in over a generation. Among other changes, the food safety law gave the Federal Food and Drug Administration (FDA) mandatory recall authority for foods if there is a reasonable probability that the food is adulterated or misbranded, and that the food could cause serious illnesses or death. Put another way, the FDA was given authority to force a recall even if the retailer, supplier, or producer wanted to avoid it. The FDA must allow the responsible party to conduct a voluntary recall before ordering a mandatory recall. Prior to the FSMA, the FDA could only rely on manufacturers to voluntarily recall certain potentially harmful food products.

The FDA just released its final guidance regarding the agency's mandatory recall authority under FSMA. While this guidance is neither binding nor legal precedent, it outlines the process and legal standard that the FDA is likely to follow before issuing a mandatory recall order. This final guidance follows a draft made available for public comment in 2015, and provides additional clarity including modifications based on comments received. The guidance provides questions and answers on FDA's mandatory recall process, explains what FDA considers when moving forward with a mandatory recall, and more.

The FDA issued its first mandatory recall order in April 2018, in which it ordered Triangle Pharmanaturals, LLC to recall a powdered kratom product which contained *salmonella*, after the company purportedly failed to respond to a voluntary recall request.

The FDA's mandatory recall authority applies to all foods (other than infant formula) that are manufactured, processed, packed, or held at a food facility subject to the Food, Drug and Cosmetics Act. It applies to all food for humans, animals and the ingredients that go into that food. Infant formula has its own recall requirements under a different law.

Before the FDA can use its mandatory recall authority, the FDA must make a determination that there is a reasonable probability that the food is adulterated or

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misbranded. The FDA must also make a determination that there is a reasonable probability that using or exposure to such food will cause serious adverse health consequences or death to humans or animals (in a tongue twister, referred to a "SAHCODHA" hazard).

Once the FDA has determined that the criteria for a mandatory recall have been met, the FDA must provide the responsible party with an opportunity to voluntarily cease distribution and issue a voluntary recall. The FDA will notify the responsible party of this opportunity in writing. If the responsible party refuses or does not voluntarily cease distribution and recall the article of food within the time and manner prescribed by the FDA, the FDA may order the recall. The FDA must also allow the responsible party to request an informal hearing to be held within two (2) days after the order is issued.

The FSMA mandatory recall authority gives teeth to the FDA's enforcement right. This agency's guidance helps employers understand when that authority will be used, and will encourage companies to voluntary recall products to avoid a mandatory sanction. Food and ingredient companies should prepare in advance for the need to recall their products to minimize the risk of a mandatory order.

A complete copy of the guidance is at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM445437.pdf.