FDA issues draft guidance for mandatory recall authority

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USA June 8 2015

On Thursday, May 7, 2015, the FDA released draft guidance on the implementation of its mandatory recall authority. The guidance itself is not binding on food companies, but provides more information about the FDA's recall authority. Comments received on the draft guidance by July 6, 2015, will be reviewed as the FDA works to finalize the draft guidance.

Among other things, the Food Safety Modernization Act (FSMA) gives the FDA the authority to order a food recall under certain circumstances. Prior to the FSMA, the FDA could only request, but not require, that a food company recall its food products.

Under the FSMA, FDA-registered food facilities are subject to its mandatory recall authority. In order to issue a mandatory recall, the FDA must find that two conditions exist: (1) the FDA must determine that there is a reasonable probability that the food products in question are adulterated or misbranded; and (2) the FDA must determine that there is a reasonable probability that the use of or exposure to those food products will result in severe adverse health consequences or death to humans or animals.

Once those conditions are met, the FDA must give the responsible party (i.e., the food company) a chance to voluntarily recall those food products. This written notice must be promptly delivered. If the responsible party does not voluntarily recall the food products in question, the FDA may order the responsible party to stop distributing the food products, require the responsible party to notify others to stop distributing the food products, and provide the responsible party with an opportunity for an informal hearing. After completing those steps, the FDA may order a recall of the food products if it determines that it is necessary to remove those food products from the stream of commerce.

In determining whether to issue a mandatory recall, the FDA will use "all applicable evidence," including:

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

The draft guidance describes the criteria the FDA uses to determine if a food is adulterated and misbranded; how FDA will publicize information about the mandatory recall; and when user fees will be assessed.

Finally, the draft guidance reminds industry that the FSMA also gave the FDA the authority to assess civil money penalties to any person/food company that does not comply with a recall order.

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Article found at: http://www.lexology.com/library/detail.aspx?g=c86c59e9-9818-42d5-996e-893af8783ffa