

## FDA Issues Final Guidance On Public Warnings And Notification Of Recalls

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Earlier this month, the U.S. Food and Drug Administration (FDA) issued its final guidance associated with recall-related notifications and warnings. The guidance, entitled *Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C* (Guidance), relates to voluntary recalls of products subject to the FDA's jurisdiction, including food intended for human or animal use.

In conjunction with issuing the Guidance, the FDA's commissioner, Scott Gottlieb, M.D. issued a statement. As Commissioner Gottlieb explained, although most companies collaborate with the FDA with respect to issuing voluntary recalls, there are situations where the FDA may need to provide safety advice to the marketplace in order to protect consumers.

The Guidance outlines the circumstances under which a company should issue a public warning about its voluntary recall and "describes the general timeframe for companies to issue a warning, discusses what information should be included in a public warning, and describes situations where the FDA may take action to issue its own public warning." As noted by Commissioner Gottlieb, the FDA has already started implementing the recommendations noted in the Guidance. In fact, based on the draft version of the Guidance, the FDA issued alerts or consumer warnings related to numerous products, including romaine lettuce and other vegetables.

In light of the FDA's improved detection, tracking and tracing technologies and the FDA's greater involvement with respect to providing public notices and warnings, going forward, manufacturers and entities involved in the distribution chain for FDA-regulated products should expect to see more frequent communications on public health risks. Thus, entities involved in the recall process should carefully review the Guidance and work together with the FDA to develop appropriate and timely public warnings and notifications related to recalls. Although the Guidance does not establish legally enforceable responsibilities, it describes the agencies current thinking on the topic and, thus, should provide helpful insights for entities engaging in a voluntary recall.

If you have questions or would like more information, please contact Bill Doerler ([doerlerw@whiteandwilliams.com](mailto:doerlerw@whiteandwilliams.com); 215.864.6383) or another member of the Food and Beverage Group.

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