

ALERTS

Food, Drug & Device Law Alert - FDA Issues Advance Notice Of Proposed Rulemaking Seeking Further Input On Grocery Store Notices Of Food Recalls

March 27, 2014 Atlanta | Chicago | Columbus | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

Food Safety Modernization Act (FSMA), enacted in January 2011, amended the Food, Drug & Cosmetic Act by adding new provisions to the Reportable Food Registry (among many other things, of course). FDA recently issued an advance notice of proposed rulemaking (ANPRM) to seek further public input on several questions arising out of the new provisions.

Under the new provisions, FDA may require a responsible party to also submit to FDA "consumer-oriented" information to enable a consumer to accurately identify whether the consumer is in possession of a reportable food. FDA must prepare and publish on FDA's website a one-page summary of the consumer-oriented information that can be easily printed by a grocery store to notify consumers. A grocery store that sold a reportable food, that is the subject of an FDA one-page summary and that is part of a chain of establishments with 15 or more physical locations, is required to display the FDA one-page summary prominently, or the information from the summary, within 24 hours after the one-page summary is published on FDA's website, through a method to be identified by FDA.

By the ANPRM, FDA is seeking input on many specific questions related to the following general topics:

- The content of the consumer-oriented information to be required by FDA, when it will be required, and how will updates be handled
- How "grocery store" will be defined for this purpose
- How a grocery store can post the notification at the required locations and information to quantify the various burdens the rule will impose on grocery stores
- Whether consumer notifications should disclose that certain food categories are not subject to the notifications
- Should FDA publish the consumer-oriented information (if known) and require grocery stores to post a notification where the responsible party fails to report the problem

Electronic or written comments on Docket No. FDA-2013-N-0590 are due on or before June 9, 2014. The ANPRM may be found here.

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