



May 15, 2015

Michael Taylor, Deputy Commissioner for Foods
Food and Drug Administration
7519 Standish Pl.
Rockville, MD 20855

Dear Mr. Taylor:

The Food and Drug Administration (FDA) has unduly delayed issuing guidance to implement a recall notification system beyond the statutory deadlines in Section 211 of the Food Safety Modernization Act (FSMA). This is an important health and safety issue for consumers who would be protected by in-store notices about recalled food products. The Center for Science in the Public Interest (CSPI) calls on the agency to come into compliance with FSMA's deadlines by immediately issuing guidance to implement the recall notification system as required by Section 211.

CSPI is a nonprofit consumer advocacy and education organization focused on health, nutrition, and food safety issues. It is supported principally by its membership, the subscribers to *Nutrition Action HealthLetter*, individual donors, and private foundation grants.

Section 211 set two deadlines for action by FDA. Within one year of FSMA's enactment, FDA was to identify conspicuous locations and manners for posting recall notices in grocery stores that operate in 15 or more locations. By July 4, 2012, FDA was to specify for food facilities the consumer-oriented, critical information they must provide to FDA. The structure of the statute clearly dictates that July 2012 was also the deadline by which FDA was to start preparing notices and for such notices to begin appearing in grocery stores. To date, the agency has failed to meet each deadline and continues to delay implementation of a recall notification system required by law and crucial for consumer safety.

Implementation of the recall notification system is an important tool for protecting the public from contaminated food products that may cause serious adverse health consequences or death. For that reason, we have repeatedly urged the agency to comply with the Section 211 deadlines. In a letter dated July 12, 2012, CSPI chastised the agency for missing the statutory deadline for implementing the recall notification system. On June 9, 2014, CSPI filed comments in response to the advanced notice of rulemaking published by FDA. That comment reiterated our concern that FDA had missed the statutory deadlines. CSPI has also raised this issue formally and informally at public hearings and in meetings with FDA officials.

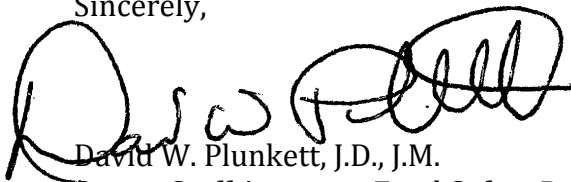
This is an issue of highest importance to our members. In 2014, CSPI surveyed its members and found strong – indeed, nearly unanimous – support for posting recall notices in grocery stores. CSPI found that only 12 percent of participants in the survey heard about recalls

from their grocery store even though 82 percent routinely shop in the same store. Nearly all respondents (98 percent) expressed support for stores notifying their customers of recalls.

This and other surveys point to serious gaps in how consumers receive information about food recalls. The current method of posting notices on FDA's website and issuing press releases only reach those few consumers who actively look for them. A Food Policy Institute poll found only 15 percent of the public visited government websites for recall information.¹ Section 211 addresses a second problem caused by grocery stores not receiving timely notices of recalls through their national headquarters. The 2009 Inspector General report "Review of the Food and Drug Administration's Monitoring of Pet Food Recalls" found that one large national chain had failed to notify its stores of the pet food recall almost four weeks after recalls began. As a result, recalled product remained on the shelf and available to consumers. By requiring grocery stores to regularly check FDA's Website and print recall notices, Section 211 overcomes delays caused by ineffective store procedures. It also speeds up notification by providing stores with formatted, consumer-friendly information that can be posted without further preparation by the store. In store notification would fill in these serious gaps in current methods for alerting consumers that food has been recalled.

Recent recalls highlight the high cost for public health when consumers lack information, and demonstrate why FDA must act quickly to improve food safety by issuing a list of conspicuous locations and manners for posting notices in grocery stores and revising guidance on the Reportable Food Registry as required by Section 211. Further delay harms consumers, leaving them exposed to recalled products because of inadequate notification. Issuing the guidance is also a simple matter which should not unduly tax agency resources. CSPI again urges the agency to prioritize implementation of the recall notification system in Section 211 and to bring its actions into compliance with the statutory deadlines provided by Congress.

Sincerely,



David W. Plunkett, J.D., J.M.

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Center for Science in the Public Interest

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Enclosures (2)

¹ William K. Hallman, Cara L. Cuite & Neal H. Hooker, *Consumer Responses to Food Recalls: 2008 National Survey Report*, Food Policy Institute, Apr. 14, 2009.