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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA-2013-N-0590]

RIN 0910-AG97

Implementation of the Food and Drug Administration Food Safety Modernization Act Amendments to the Reportable Food Registry Provisions of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to solicit comments, data, and information to assist the Agency in implementing the FDA Food Safety Modernization Act (FSMA), which added new provisions to the Reportable Food Registry (RFR) requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Under the new provisions, FDA may require a responsible party to also submit to FDA "consumer-oriented" information regarding certain reportable foods, including information necessary 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 Internet Web site a one-page summary of the consumer-oriented information that can be easily printed by a grocery store for the purposes of consumer notification. 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 prominently display the FDA one-page summary, or

the information from the summary, within 24 hours after the one-page summary is published on FDA's Web site, through a method identified by FDA. FDA is seeking input on topics including consumer-oriented information submissions, consumer notifications, posting consumer notifications in grocery stores, and grocery stores subject to the new requirements.

DATES: Submit either electronic or written comments by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. FDA-2013-N-0590 or Regulatory Information Number (RIN) number 0910-AG97, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

  Instructions: All submissions received must include the Agency name and Docket No. FDA-2013-N-0590 and RIN 0910-AG97 for this advance notice of proposed rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ted Elkin, Center for Food Safety and Applied Nutrition (HFS-008), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2428; or April Hodges, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9237.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Reportable Food Registry

Section 1005 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-085) amended the FD&C Act by creating section 417 entitled "Reportable Food Registry" (21 U.S.C. 350(f)). Under section 1005 of FDAAA, FDA established the RFR, an electronic portal that is used to submit mandatory and voluntary reports to FDA regarding "reportable foods." A “reportable food" is an article of food (other than dietary supplements or infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals (see section 201(ff) of the FD&C Act (21 U.S.C. 321(ff)) and section 417(a)(2) of the FD&C Act). Subject to certain exceptions, a "responsible party" is required to submit a report to FDA through the RFR, as soon as practicable, but in no case later than 24 hours after determining that an article of food is a reportable food (see section 417(d) of the FD&C Act). Under section 417(a)(1) of the FD&C Act, a "responsible party" with respect to an article of food is defined as

"a person that submits the registration under section 415(a) [of the FD&C Act (21 U.S.C. 350d)] for a food facility that is required to register under section 415(a), at which such article of food is manufactured, processed, packed, or held." The FD&C Act specifies that the term "person" includes individuals, partnerships, corporations, and associations (section 201(e) of the FD&C Act). A Federal, State, or local public health official may submit a report about a reportable food to FDA through the RFR (section 417(d)(3) of the FD&C Act).

Several terms are used to describe the RFR system as a whole, as well as its components. Reportable food reports are submitted through the Department of Health and Human Services Safety Reporting Portal at http://www.safetyreporting.hhs.gov/, which we refer to in this document as "the Safety Reporting Portal" or "SRP." The term "Registry" refers to the database maintained by FDA to catalogue reports that have been submitted through the Safety Reporting Portal, and that Agency review has determined to be reports for foods that meet the standard for "reportable foods." The terms "Reportable Food Registry" and "RFR" refer to the system as a whole. This terminology is consistent with terms FDA uses in its annual reports on the RFR. (See "The Reportable Food Registry: A New Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration: First Annual Report: September 8, 2009-September 7, 2010" (January 2011); "The Reportable Food Registry: Targeting Inspection Resources and Identifying Patterns of Adulteration: Second Annual Report: September 8, 2010-September 7, 2011" (April 2012); and "The Reportable Food Registry: Targeting Inspection Resources and Identifying Patterns of Adulteration: Third Annual Report: September 8, 2011-September 7, 2012" (April 2013), available at http://www.fda.gov/ReportableFoodRegistry).

The RFR reporting requirements cover reportable foods that are not under the exclusive jurisdiction of the U.S. Department of Agriculture, which include human food (except infant

formula and dietary supplements) and animal food/feed (including pet food) regulated by FDA. (Other mandatory reporting systems exist for infant formula and dietary supplements.[1]) Submissions through the Safety Reporting Portal provide early warning to FDA about potential serious public health risks related to reportable foods and increase the speed with which the Agency and its partners at the State and local levels can investigate and take appropriate action, including ensuring that reportable foods are removed from commerce when necessary.

FDA's RFR does not receive reportable food reports from consumers through the Safety Reporting Portal. Instead, FDA has established other reporting forms for receiving and responding to consumer emergencies, complaints, questions, and concerns about FDA-regulated foods. (See, e.g., "Your Guide to Reporting Problems to FDA" at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm095859.htm).

Reportable food reports submitted by responsible parties or public health officials, such as Federal, State, or local public health officials, are categorized and tracked by FDA. The initial report concerning a reportable food that FDA generally receives from either a responsible party or a public health official is designated as the primary report for that reportable food. All other reports subsequently received from a responsible party (i.e., either by an immediate previous source (upstream) or an immediate subsequent recipient (downstream)) of a reportable food for which a primary report has been submitted are designated as subsequent reports. After consultation with the responsible party that submitted an initial report, FDA may require such responsible party to amend the initial report to include contact information for certain parties directly linked in the supply chain (section 417(d)(6)(A) of the FD&C Act). This type of report,

[1]A manufacturer, packer, or distributor of a dietary supplement whose name appears on the label of a dietary supplement marketed in the United States must submit to FDA any report received of a serious adverse event associated with such dietary supplement when used in the United States, accompanied by a copy of the dietary supplement's label, under section 761 of the FD&C Act (21 U.S.C. 379aa-1). Infant formula manufacturers must comply with notification requirements for violative infant formula in 21 CFR 107.240.

which corrects or adds to an initial report, is an amended report. The responsible party may also provide corrections or add new information to a report at any time voluntarily. FDA may also require a responsible party that has submitted an initial report to notify the immediate previous source (upstream) or the immediate subsequent recipient (downstream) of the food for which the responsible party has submitted an initial report, if FDA deems necessary (see section 417(d)(6)(B) of the FD&C Act). If another responsible party, such as the immediate previous source or immediate subsequent recipient of the food, receives a notification regarding a food for which an initial report has been submitted, FDA may require such responsible party to submit a report to FDA regarding that reportable food (see section 417(d)(7) of the FD&C Act). This type of report, as indicated previously, is a subsequent report as it contains additional information regarding the reportable food from a responsible party other than the responsible party that submitted the initial report. If a responsible party receives a notification with respect to a food and the responsible party has already submitted an initial report or subsequent report to FDA with respect to such food, the responsible party is required to amend such report to include contact information for certain parties directly linked in the supply chain and provide the unique report number(s) issued through the Safety Reporting Portal for report(s) (by which FDA is able to link reports about the reportable food and identify the supply chain) for such reportable food (see section 417(d)(8) of the FD&C Act).

After reports are submitted to FDA through the Safety Reporting Portal, FDA reviews and assesses the information for purposes of identifying reportable foods, entering information into the Registry, issuing an alert as FDA deems necessary, and exercising other existing food safety authorities to protect the public health (see sections 417(b)(2) and (c) of the FD&C Act).

Due to the potential for confusion, it is important to explain that there are key differences between FDA's RFR and food recall programs. Generally, FDA's food recall program has been the primary channel of food product safety communication between FDA, consumers, and others in the supply chain. The RFR is a separate program, and its general purpose has been to provide a "reliable mechanism to track patterns of adulteration in food…[to] support efforts by the [FDA] to target limited inspection resources to protect the public health" (Public Law 110-085, section 1005(a)(4)). Where the food recall program would, in part, gather and communicate information helpful to consumers who may encounter a recalled food, such as safe product disposal instructions, the RFR gathers information to identify and track a reportable food in the supply chain. The FSMA amendments to section 417 of the FD&C Act will give the RFR a greater role in informing the public in the event of a potential public health emergency.

B. FSMA Amendments to the Reportable Food Registry

On January 4, 2011, FSMA (Public Law 111-353) was signed into law. FSMA generally amended the FD&C Act to provide for a modernized, prevention-based food safety system. FSMA amended section 417 of the FD&C Act, which governs the RFR, in relevant part by adding paragraphs (f), (g), and (h) (Public Law 111-353, 124 Stat. 3885, 3951-3953). Section 417(f), as amended by FSMA, provides that, within 18 months after the date of enactment of FSMA, the Secretary of Health and Human Services (the Secretary) (and by delegation, FDA) may require a responsible party to submit to FDA "consumer-oriented information" regarding a reportable food with the exception of fruits and vegetables that are raw agricultural commodities. The consumer-oriented information must include the following: (1) A description of the article of food; (2) affected product identification codes, such as the Universal Product Code (UPC), stock keeping unit (SKU), or lot or batch numbers sufficient for the consumer to identify the

article of food; (3) contact information for the responsible party; and (4) any other information FDA determines is necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food (section 417(f)(4) of the FD&C Act). Section 417(g)(1) of the FD&C Act, as amended by FSMA, requires FDA to prepare the consumer-oriented information described in section 417(f) as a standardized one-page summary, and publish the one-page summary on FDA's Web site in a format that can be easily printed by a grocery store for purposes of consumer notification.

A grocery store that is part of a chain of establishments with 15 or more physical locations ("chain grocery store") that sold a reportable food that is the subject of a one-page summary published on FDA's Web site must notify consumers by: (1) Prominently displaying the one-page summary or information from such summary, through a method described in section 417(h)(2) of the FD&C Act, no later than 24 hours after the one-page summary is published on FDA's Web site, and (2) maintain the display for 14 days (section 417(h)(1) of the FD&C Act). The chain grocery store must also include in the consumer notification the date and time that the one-page summary was posted on the FDA's Web site (section 417(g)(2) of the FD&C Act).

Section 417(h)(2) of the FD&C Act, as amended by FSMA, requires that, within 1 year after the date of enactment of FSMA, FDA develop and publish "a list of acceptable conspicuous locations and manners" from which a chain grocery store must select at least one method for displaying a consumer notification about the reportable food. Section 417(h)(2) provides that the list of acceptable conspicuous locations and manners must include the following:

- "Posting the notification at or near the register;"
- "Providing the location of the reportable food;"

- "Providing targeted recall information given to customers upon purchase of food;" and
- "Other such prominent and conspicuous locations and manners utilized by grocery stores as of the date of the enactment of [FSMA (i.e., as of January 4, 2011)] to provide notice of such recalls to consumers as considered appropriate by the Secretary."

While sections 417(f) and 417(h)(2) of the FD&C Act include statutory deadlines within 18 and 12 months of the enactment of FSMA, respectively, FDA is issuing this ANPRM, rather than a notice of proposed rulemaking, to solicit further input from the public regarding issues related to the FSMA amendments to section 417 of the FD&C Act. As discussed in the paragraphs that follow, FDA believes that the information it obtains through this ANPRM will assist the Agency in implementing and efficiently enforcing the FSMA amendments to section 417 of the FD&C Act.

II. June 6, 2011, Public Meeting and Request for Comments

On May 26, 2011, FDA issued a Federal Register notice announcing a public meeting scheduled for June 6, 2011, entitled "FDA Food Safety Modernization Act: Focus on Inspections and Compliance" (FSMA public meeting notice) and requesting comments (76 FR 30727). The purpose of the public meeting was to provide interested persons an opportunity to discuss implementation of inspections and compliance under FSMA, and to give the public an opportunity to provide information and share views to inform FDA's FSMA implementation strategies related to, among other things, implementation of the new provisions in section 417 of the FD&C Act. The FSMA public meeting notice presented the following questions related to the FSMA amendments to section 417 of the FD&C Act:

- What information is necessary to enable a consumer to accurately identify whether the consumer is in possession of a reportable food?

- What methods could best be used by grocery stores to inform consumers of information to enable them to identify whether they possess a reportable food?
- Are there other approaches to getting key information in the hands of consumers in real time that FDA should also consider pursuing?
- Who should FDA consider to be a grocery store subject to the consumer notification requirement in section 417(h) of the FD&C Act?
- What methods are grocery stores currently using to provide notice of food recalls to consumers?

At the public meeting, FDA provided opportunities for individuals to make presentations during an open public and Webcast comment session. A transcript of FDA's remarks at the opening session, the open public and Webcast comment session, and the listening session is available on FDA's Web site at (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm255954.htm). No public comments regarding the FSMA amendments to section 417 of the FD&C Act were received during the public meeting sessions. Stakeholders were given other opportunities to express their views during breakout sessions focused on specific topics, including a session on section 417 of the FD&C Act. These sessions were not recorded.

In the FSMA public meeting notice, FDA also requested comments, and noted that electronic or written comments could be submitted to the Division of Dockets Management regardless of whether commenters attended the public meeting. FDA opened Docket No. FDA-2011-N-0366 for public comments. In response to this request, FDA received three comments. The comments were from trade associations and a consumer group. These comments are discussed in section III.

III. Issues and Requests for Data and Information

As noted previously, FDA only received three comments regarding the FSMA amendments to section 417 of the FD&C Act. While these comments provided useful input, additional input from the public would assist the Agency in implementing and efficiently enforcing the FSMA amendments to section 417 of the FD&C Act. In addition to the issues described in the FSMA public meeting notice, there are several other issues related to the new requirements in section 417 for which FDA believes further comment, data, and information would be helpful to the Agency in implementing and enforcing the new requirements. As discussed in the paragraphs that follow, FDA is soliciting input regarding what information responsible parties should be required to provide to the Agency in consumer-oriented information submissions for reportable foods to enable consumers to accurately identify whether they possess such foods, as specified in section 417(f)(4) of the FD&C Act (FDA "may require a responsible party to submit to [FDA] consumer-oriented information regarding a reportable food, which shall include…any other information [FDA] determines is necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food."). FDA anticipates that additional input from the public, including consumers and stakeholders, regarding what information would allow consumers to determine whether they possess reportable foods will be critical in FDA's implementation of section 417(f) of the FD&C Act.

FDA is also soliciting input regarding manners and locations used by grocery stores to provide food recall information to consumers, as specified in section 417(h)(2) of the FD&C Act (FDA "shall develop and publish a list of acceptable conspicuous locations and manners, from which grocery stores shall select at least one, for providing the notification required in [section 417(h)(1) of the FD&C Act] . . .[which] shall include…other such prominent and conspicuous

locations and manners utilized by grocery stores as of the date of the enactment of [FSMA] to provide notice of such recalls to consumers . . .").There may be several manners and locations in which grocery stores provide or have provided food recall information to consumers. Further, grocery stores and consumers can provide more information to FDA regarding these manners and locations, including the advantages and disadvantages of particular approaches.

In addition, FDA is soliciting information regarding potential impacts to and costs incurred by chain grocery stores related to posting consumer notifications, as required by section 417(h) of the FD&C Act. Because grocery stores likely have experience with providing notices to consumers, these stores likely have data and information that could assist the Agency in estimating associated costs and burdens related to compliance. Such information could also assist the Agency in establishing requirements to efficiently enforce the FSMA amendments to section 417 of the FD&C Act.

FDA anticipates that information from stakeholders and the public regarding these issues, along with the other issues described in the paragraphs that follow, will significantly assist the Agency in developing requirements to implement section 417 of FD&C Act and efficiently enforce such requirements. For these reasons, FDA is issuing this ANPRM to solicit additional comments, data, and other information related to the FSMA amendments to section 417 of the FD&C Act.

Issue 1: Consumer-Oriented Information Submissions and Consumer Notifications

Question 1a: What information should FDA require be included in consumer-oriented information submissions and consumer notifications for a reportable food to enable a consumer to accurately identify whether he or she is in possession of the reportable food?

Section 417(f) of the FD&C Act provides that the consumer-oriented information submitted to FDA by a responsible party must include: (1) A description of the article of food; (2) affected product identification codes, such as UPC, SKU, or lot or batch numbers sufficient for the consumer to identify the article of food; (3) contact information for the responsible party; and (4) "any other information the Secretary determines is necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food." Section 417(g)(1) requires that FDA prepare the consumer-oriented information as a standardized one-page summary and publish such one-page summary on FDA's Web site in a format that can be easily printed by grocery stores for the purposes of consumer notification. In response to a similar question presented in the FSMA public meeting notice, two commenters asserted that the consumer-oriented information should include the reason for the recall of the reportable food, if applicable. Another commenter recommended that the consumer-oriented information include a picture of the product and product label, state when the product was sold, and state what consumers should do with the product.

FDA is interested in additional data and information regarding what information should be required in consumer-oriented information submissions and consumer notifications for reportable foods to enable a consumer to accurately identify whether such consumer is in possession of the reportable food. FDA is also interested in data and information regarding whether the one-page summary of consumer-oriented information posted at FDA's Web site

should contain other information, such as advice to consumers on disposing of a reportable food product.

Question 1b: Should FDA require responsible parties to submit consumer-oriented information to FDA, as described in section 417(f) of the FD&C Act, for reportable foods that are not available, or will not be available, for sale to consumers in chain grocery stores or otherwise available for sale to consumers at the retail food market?

As noted previously, a "responsible party" generally is required to submit a report to FDA through the Safety Reporting Portal, as soon as practicable, but in no case later than 24 hours after determining that an article of food is a reportable food (see section 417(d) of the FD&C Act). In addition, section 417(f) of the FD&C Act provides that FDA may require a responsible party to submit to FDA consumer-oriented information regarding a reportable food (except for fruits and vegetables that are raw agricultural commodities). It is possible that there may be a reportable food, for which a responsible party is required to submit a report to FDA through the Safety Reporting Portal under section 417(d), that has not or will not reach the retail food market, including chain grocery stores. For example, many reportable food reports concern food ingredients and bulk commercial products that are not sold at the retail level. One of the purposes of the RFR is to identify makers of foods sold at retail who have received an ingredient that is the subject of a reportable food report to stop shipment of possibly contaminated foods before they are sold at retail. Under section 417(f) of the FD&C Act, a responsible party may also be required to submit to FDA consumer-oriented information for such a reportable food. Section 417(h)(1) makes clear that unless a chain grocery store sold a food that is the subject of a one-page summary published by FDA, the grocery store is not required to post a consumer notification described in section 417(g) about such food. FDA is interested in comments or other

information regarding whether FDA should require responsible parties to submit the consumer-oriented information described in section 417(f) for all reportable foods, including those that have not been available, or will not be available, for sale to consumers in chain grocery stores or otherwise available for sale to consumers at the retail food market.

Question 1c: FDA is interested in additional data and information from industry and consumer groups regarding consumer preferences for receiving information. For the one-page summaries of consumer-oriented information prepared by FDA and published on FDA's Web site, what structure and format would be the most useful to grocery stores and consumers? To what extent, if any, should the consumer-oriented information be provided in languages other than English?

Question 1d: Should FDA revise and republish a one-page summary of consumer-oriented information on FDA's Web site if the published information no longer provides the information necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food? For example, a recall expanding to include additional lots, and corrections in amended industry reports could create this scenario. If a one-page summary is revised and republished on FDA's Web site, should this trigger additional posting obligations for chain grocery stores?

Question 1e: What mechanisms can be employed so that chain grocery stores are aware that a one-page summary of consumer-oriented information for a reportable food has been published on the Agency's Web site, or that a previously published one-page summary has been revised?

Issue 2: Grocery Stores

Question 2a: What types of retail establishments should FDA consider to be "grocery stores" within the meaning of section 417(h) of the FD&C Act? Section 417(h)(1) provides in relevant part that if a chain grocery store sold a reportable food that is the subject of a one-page consumer-oriented information summary published on FDA's Web site, the chain grocery store must prominently display the one-page summary or information from the one-page summary within 24 hours after the one-page summary is published on FDA's Web site and maintain such display for 14 days. The FD&C Act does not define the term "grocery store." FDA requests comment on what types of retail establishments should be subject to the consumer notification requirements of section 417(h). Please provide an explanation for your response and any supporting data.

Comments that FDA received in response to the FSMA public meeting notice supported a broad definition of the term "grocery store" to encompass all retail establishments in which the sale of groceries is a primary business activity, including supermarkets, warehouse stores, wholesale club stores, convenience stores, and other stores that are part of a chain. One commenter noted that consumers may buy groceries online from both grocery store chains and other online retailers, and stated that these retailers should also be required to provide the consumer notifications described in section 417(h) of the FD&C Act. Two commenters recommended that, in developing a definition of the term "grocery store" for purposes of implementing section 417(h), FDA consider the definition of "retail food establishment," which includes grocery stores, in FDA's regulations for registration of food facilities at 21 CFR 1.227(b)(11).

Issue 3: Posting Consumer Notifications

Question 3a: How can a chain grocery store prominently display or provide a consumer notification via a conspicuous location or manner as described in section 417(h)(2) of the FD&C Act? Section 417(h)(1) of the FD&C Act provides in relevant part that if a chain grocery store sold a reportable food that is the subject of a one-page consumer-oriented information summary published on FDA's Web site, the chain grocery store must "prominently display such summary or the information from such summary via at least one of the methods identified in [section 417(h)(2)]." Section 417(h)(2) provides in relevant part that FDA shall develop and publish "a list of acceptable conspicuous locations and manners, from which grocery stores shall select at least one, for providing [consumer notifications]." Further, section 417(h)(2) provides that such list must include: (1) Posting the notification at or near the register; (2) providing the location of the reportable food; (3) providing targeted recall information given to customers upon purchase of a food; and (4) other such prominent and conspicuous locations and manners utilized by grocery stores as of the date of enactment of FSMA (i.e., January 4, 2011) to provide notice of such recalls to consumers as considered appropriate by FDA.

Question 3b: How can a chain grocery store prominently display or provide a consumer notification "at or near the register" as described in section 417(h)(2)(A) of the FD&C Act?

Question 3c: How can a chain grocery store prominently display or provide a consumer notification in a way that provides "the location of the reportable food," as described in section 417(h)(2)(B) of the FD&C Act?

Question 3d: How can a chain grocery store prominently display or provide a consumer notification in a way that provides "targeted recall information given to customers upon purchase of a food," as described in section 417(h)(2)(C) of the FD&C Act?

Question 3e: Section 417(h)(2) of the FD&C Act requires FDA to develop and publish a "list of acceptable conspicuous locations and manners" for chain grocery stores to post the consumer notifications described in section 417(g), and describes certain locations and manners. Section 417(h)(2)(D) provides in relevant part that such a list must include "other such prominent and conspicuous locations and manners utilized by grocery stores as of the date of enactment of [FSMA] to provide notice of . . .recalls to consumers as considered appropriate by [FDA]". What methods, manners, and/or locations, if any, have grocery stores or other retail food establishments used to effectively notify consumers about food recalls?

One comment that FDA received in response to the FSMA public meeting notice stated that FDA regulations implementing the consumer notification requirements of section 417 of the FD&C Act or related guidance should provide retailers with the flexibility to choose among different approaches to notifying consumers about food recall information. The commenter stated that the regulations should "afford the opportunity for new ideas and modes of notification and not be so prescriptive as to limit innovation." Section 417(h)(2)(D) of the FD&C Act specifies that the other manners and locations that must be included on the list developed and published by FDA (as considered appropriate by FDA) are those used by grocery stores as of the date of enactment of FSMA to provide notice of food recalls that are "conspicuous" and "prominent." In light of this requirement, FDA is particularly interested in data and information on the most innovative and effective approaches used by grocery stores or other retail food establishments to notify consumers about food recalls in manners and locations that are conspicuous and prominent.

One commenter recommended that, where purchases of food have occurred over the Internet, electronically contacting consumers is effective because the retailer knows exactly what

the consumer purchased and has reliable contact information for the consumer. The commenters noted that these consumers may never see a posting in a physical store. Two commenters recommended the use of loyalty cards as a tool to notify customers. One of these commenters cited a report by a retailer that noted that the retailer was able to electronically notify 90 percent of purchasers (17 of 19) of a recalled food item.

One commenter stated that retailers currently notify consumers of food recalls by: (1) Posting information at or near the register; (2) posting information at the area where the food is displayed; (3) loyalty card or membership notifications by email, phone, or mail; (4) providing printout information to consumers at checkout; (5) Web site posting; (6) posting information at kiosks in the store; and (7) posting information on a bulletin board or similar information area. The comment suggested that FDA allow retailers to choose one or more manners of notification, or use different manners for different recalls. The commenter identified factors that may be relevant to the manner used, including the size of recall; whether the product was distributed nationally or more narrowly; the type of product; the target customers; the shelf life of the product, and the product's use as an ingredient in other foods.

Question 3f: What factors could influence a chain grocery store's decision about whether to display a one-page summary of consumer-oriented information regarding a reportable food as published on FDA's Web site, or instead to display the information from the FDA summary?

Section 417(h)(1) of the FD&C Act requires in relevant part that chain grocery stores prominently display, in the prescribed timeframe, either the consumer-oriented information one-page summary published on FDA's Web site "or the information from such summary."

Question 3g: Could compliance with the consumer notification requirements of section 417(h) of the FD&C Act by chain grocery stores affect the voluntary or mandatory display of other information regarding a food recall by retail establishments?

One commenter stated that food retailers receive product recall notifications primarily from their suppliers or manufacturers, usually before the information is provided by FDA or through the RFR. The commenter stated that in addition to removing the product from sale, food retailers take action to notify consumers. The commenter argued that if FDA links notifying consumers about recalls to the RFR one-page summaries prepared by FDA and published on FDA's Web site, it could result in a delay compared to current practices for notifying consumers about recalls, or could result in duplicative notices. The commenter recommended that food retailers who notify consumers about food recalls before FDA information is available not be required to provide any subsequent notifications, unless information about the recall has changed.

FDA is interested in receiving further comment on the issues raised in these comments. We note that nothing in the new requirements in section 417 of the FD&C Act precludes a chain grocery store from posting its own notice regarding a food recall before FDA publishes on its Web site a one-page summary of consumer-oriented information regarding a reportable food. However, regardless of the actions a responsible party or grocery store may take prior to FDA's publication of a one-page summary, the consumer notification requirements of section 417(h) would still apply. Accordingly, if a chain grocery store sold a reportable food that is the subject of a one-page summary, the grocery store would still be required to prominently display the one-page summary or the information from the summary within 24 hours after the summary is published on FDA's Web site and must maintain the display for 14 days.

Question 3h: What, if any, impact will the consumer notification requirements in section 417(h) have on grocery store operations? For example, how might the requirements affect resources if resources are spent monitoring FDA's Web site for new consumer notifications to be posted, or resources are spent posting such notifications or the information from such notifications?

Question 3i: What are the estimated costs to chain grocery stores, per store and per reportable food, associated with displaying consumer notifications as required by section 417(h)?

Question 3j: How much time (hours per reportable food) is currently used by grocery store and other retail food establishment employees (including managers) to notify consumers about reportable foods? What is the estimated change, if any, in the time spent on notifying consumers about reportable foods as a result of the consumer notification requirements in section 417(h) of the FD&C Act?

Question 3k: Should chain grocery stores be permitted to use multiple manners and locations, as identified by FDA, to post consumer notifications consecutively for a total of 14 days?

Section 417(h)(1) of the FD&C Act provides in relevant part that a chain grocery store that sold a reportable food that is the subject of a one-page summary published on FDA's Web site must prominently display such summary or the information from such summary, and maintain such display for 14 days. One commenter suggested that the 14-day time period should begin when the retailer first notifies consumers about a recall. Further, the commenter stated that for other methods of informing consumers about food recalls a 14-day duration might not be practicable (e.g., repeated phone calls to the same consumer for 14 days). The commenter also stated that the 14-day time period should include all notification manners used by the grocery

store. The commenter noted, as an example, that a grocery could post a sign for 2 days notifying consumers about a recall for a food product whose shelf life is long past, and then the grocery store could post the information for the next 12 days on the retailer's Web site. Because of the statutory terms in section 417(h) of the FD&C Act regarding a chain grocery store "prominently display[ing]" an FDA one-page summary or information from such summary and "maintain[ing] the display for 14 days," it seems unlikely that the telephone calls described in the comment would satisfy section 417(h). FDA is interested in further comment and information regarding manners and locations for posting consumer notifications for the 14-day time period specified in section 417(h).

Issue 4: Other Issues

Question 4a: As noted previously, the term "reportable food" does not include dietary supplements or infant formula (see sections 201(ff) and 417(a)(2) of the FD&C Act). Further, as discussed previously, section 417(f) of the FD&C Act, as amended by FSMA, provides that FDA may require a responsible party to submit to FDA "consumer-oriented information" regarding a reportable food with the exception of fruits and vegetables that are raw agricultural commodities. Based on these exceptions and exclusions, responsible parties may not submit to FDA consumer-oriented information, under section 417(f) of the FD&C Act, for dietary supplements, infant formula, and fruits and vegetables that are raw agricultural commodities. There may be potential public health impacts if consumer notifications for reportable foods do not include information on dietary supplements, infant formula, and fruits and vegetables that are raw agricultural commodities, particularly if the public believes that such consumer notifications are meant to encompass all food products regulated by FDA. FDA seeks comments or other information on whether consumer notifications posted by chain grocery stores, as specified by section 417(h) of

the FD&C Act, should include information advising consumers that such notifications do not cover certain foods, such as a statement asserting that that the consumer notifications do not include reportable food or recall information for dietary supplements, infant formula, and fruits and vegetables that are raw agricultural commodities, and consumers should consult FDA's Web site for any relevant information for these products.

Question 4b: There may be a situation where FDA is aware of a class 1 recall for a reportable food for which a responsible party would be required to submit to FDA consumer-oriented information for such reportable food under section 417(f) of the FD&C Act, but the responsible party failed to submit such information to FDA. In such situations, should FDA prepare and publish a one-page summary of consumer-oriented information, if known, for such reportable food, and require chain grocery stores that sold the reportable food to post such summary or the information from such summary, as specified in section 417(h) of the FD&C Act?

IV. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Please note that this is not related to the request in the Federal Register of May 25, 2010 (75 FR 29350) (Docket No. FDA-2009-D-0260), for comments regarding the finalization of the current RFR, 2d Edition, draft guidance.

Dated: March 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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