labeling statements on food packages may affect how consumers perceive a product or a label, which may in turn affect their dietary choices. Results of the study will not be used to develop population estimates.

To help design and refine the questionnaire, FDA plans to conduct cognitive interviews by screening 72 panelists in order to obtain 9 participants in the interviews. Each screening is expected to take 5 minutes (0.083 hour) and each cognitive interview is expected to take one hour. The total for cognitive interview activities is 15 hours (6 hours + 9 hours). Subsequently, we plan to conduct pretests of the questionnaire before it is administered in the study. We expect that 1,600 invitations, each taking 2 minutes (0.033 hour), will need to be sent to panelists to have 200 of them complete a 15-minute (0.25 hour) pretest. The total for the pretest activities is 103 hours (53 hours + 50 hours). For the survey, we estimate that 21,600 invitations, each taking 2 minutes (0.033 hour) to complete, will need to be sent to the consumer panel to have 2,700 of its members complete a 15-minute (0.25 hour) questionnaire. The total for the survey activities is 1,388 hours (713 hours + 675 hours). Thus, the total estimated burden is 1,506 hours. FDA's burden estimate is based on prior experience with research that is similar to this proposed study.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) [2]	Total hours
Cognitive interview screener	72	1	72	5/60	6
Cognitive interview	9	1	9	1	9
Pretest invitation	1,600	1	1,600	2/60	53
Pretest	200	1	200	15/60	50
Survey invitation	21,600	1	21,600	2/60	713
Survey	2,700	1	2,700	15/60	675
Total					1,506

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

II. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857, under Docket No. FDA–2011–N–0320 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. We have verified all Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

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3. Kantor, L. S., J.N. Variyam, J.E. Allshouse, J.J. Putnam, and B.H. Lin, "Choose a variety of grains daily, especially whole grains: A challenge for consumers," *Journal of Nutrition,* 131, 473S–486S, 2001.
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5. *Supermarket News,* "Report: Whole Grains Gain Momentum," September 2010, available at *http://supermarketnews.com/news/whole_grains_0917/#.*
6. Arvola, A., L.Lähteenmäki, M. Dean, M. Vassallo, M. Winkelmann, E. Claupein, A. Saba, and R. Shepherd, "Consumers' beliefs about whole and refined grain products in the UK, Italy and Finland," *Journal of Cereal Science,* 46, 197–206, 2007.
7. Kantor, L. S., J.N. Variyam, J.E. Allshouse, J.J. Putnam, and B.H.Lin, "Choose a variety of grains daily, especially whole grains: A challenge for consumers," *Journal of Nutrition,* 131, 473S–486S, 2001.
8. Marquart, L., K.L. Wiemer, J.M. Jones, and B.Jacob, "Whole grain health claims in the U.S.A. and other efforts to increase whole-grain consumption," *Proceedings of the Nutrition Society,* 62, 151–159, 2003.
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10. Willis, Josephine M., and K.G. Grunert, "A Review of Research on Consumer Response to Nutrition Information on Food Packaging," 2007.
11. Kellogg Co. "A Survey of Consumers' Whole Grain & Fiber Consumption Behaviors, and the Perception of Whole Grain Foods as a Source of Dietary Fiber," 2010. FDA Docket No. 2006–D–0298, July 2010, available at *http://www.regulations.gov/#!documentDetail;D=FDA-2006-D-0298-0016.*

Dated: May 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–13060 Filed 5–25–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0366]

Food and Drug Administration Food Safety Modernization Act: Focus on Inspections and Compliance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled "FDA Food Safety Modernization Act: Focus on Inspections and Compliance." The purpose of the public meeting is to provide interested persons an opportunity to discuss implementation of inspections and compliance under the recently enacted FDA Food Safety Modernization Act (FSMA). More specifically, the public will have an opportunity to provide information and share views that will inform FDA's

FSMA implementation strategies relative to enforcement authorities; frequency and targeting of facility inspections; manner of inspection in a preventive controls environment; and improving the reportable food registry (RFR).

DATES: See table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Patricia M. Kuntze, Office of External Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5322, Silver Spring, MD 20993, 301–796–8641, *Patricia.Kuntze@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FSMA (Pub. L. 111–353) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish the foundation for a modernized, prevention-based food safety system. The legislation recognizes that inspection is an important means of assessing industry compliance with the law and holding industry accountable for their responsibility to produce a safe product. FDA will meet this expectation by:

- Using the new enforcement authorities granted by FSMA,
- Applying its inspection resources in a risk-based manner, and
- Adopting inspection approaches that promote the efficient and effective use of existing resources.

Section 102 of FSMA, among other things, amends section 415 of the FD&C Act (21 U.S.C. 350d) for various purposes, including authorizing the Secretary of Health and Human Services to suspend registration of a facility if she determines that food manufactured, processed, packed, received, or held by the facility poses a reasonable probability of serious adverse health consequences or death and the facility either created, caused, or was otherwise responsible for that reasonable probability or knew of, or had reason to know of, such reasonable probability and packed, received, or held the food. A facility that is under suspension is prohibited from introducing food into commerce in the United States.

Section 201 of FSMA, among other things, creates a new section 421 of the FD&C Act (21 U.S.C. 350j) that establishes a mandated inspection frequency, based on risk, for food facilities that are required to register under section 415 of the FD&C Act and requires the frequency of inspection of such facilities to increase immediately. All high-risk domestic facilities must be inspected within 5 years of FSMA's enactment and no less than every 3 years thereafter. Non-high-risk domestic facilities must be inspected within 7 years of FSMA's enactment and no less than every 5 years thereafter. Within 1 year of FSMA's enactment, the law directs FDA to inspect at least 600 foreign facilities and to double those inspections every year for the next 5 years.

Section 206 of FSMA creates a new section 423 of the FD&C Act (21 U.S.C. 3501) to provide FDA with mandatory recall authority for foods other than infant formula. This authority applies when FDA determines that there is a reasonable probability that an article of food is adulterated under section 402 of the FD&C Act (21 U.S.C. 342) or misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)) and the use of or exposure to such article of food will cause serious adverse health consequences or death to humans or animals.

Section 207 of FSMA amends section 304(h)(1)(A) of the FD&C Act (21 U.S.C. 334(h)(1)(A)) to provide FDA with a more flexible standard for administratively detaining human and animal food products that are potentially in violation of the FD&C Act. Under the new law, FDA may administratively detain food if FDA has reason to believe that the food is adulterated or misbranded. Administrative detention is the procedure FDA uses to keep suspect food from being moved.

Section 211 of FSMA amends section 417 of the FD&C Act (21 U.S.C. 350f), among other things, to require FDA to publish, on the Web, an easily printable one page summary of certain consumer-oriented information regarding certain reportable foods, including information necessary to enable a consumer to accurately identify whether the consumer is in possession of the reportable food. Grocery stores that sold a reportable food that is the subject of a summary posting and that are part of a chain of establishments with 15 or more physical locations will be required to prominently display such summary or the information from such summary via at least one of the methods to be identified by FDA within 24 hours after FDA publishes the summary.

II. Purpose and Format of the Meeting

If you wish to attend and/or present at the meeting scheduled for June 6, 2011, please register by e-mail to *http://www.blsmeetings.net/FDAInspection&Compliance* by May 31, 2011. FDA is holding the public meeting to receive input from the public to inform FDA's implementation of the FSMA provisions identified previously in this document.

In general, the meeting format will include introductory presentations by FDA. Listening to our stakeholders is the primary purpose of this meeting. In order to meet this goal, FDA will provide multiple opportunities for individuals to actively express their views by making presentations at the meeting, participating in a total of three 75-minute breakout sessions on the provisions discussed at the meeting, and submitting written comments to the docket(s) within 30 days after this meeting. Participants can select up to three of the following four breakout sessions: Enforcement authorities, frequency and targeting of facility inspections, manner of inspection in a preventive controls environment, and improving the RFR.

FDA requests comment on the following questions in the break-out sessions:

1. Enforcement Authorities

- How do you suggest FDA employ the use of its revised administrative detention authority in a preventive controls environment?
- State regulators—can you provide examples where you have recently used your embargo/detention authorities? Can you describe examples where States have used embargo in situations where the subject food was produced contrary to established food safety preventive control standards; for instance, contrary to those standards defined under the juice or seafood Hazard Analysis and Critical Control Points rules?
- How do you see FDA implementing food facility registration suspension, and under what circumstances should FDA use its suspension authority? Under what circumstances should FDA use its mandatory food recall authority? Under what circumstances do you envision FDA using food facility registration suspension in conjunction with ordering a mandatory food recall?

2. Frequency and Targeting of Facility Inspections

- What data sources are available that could assist with the designation of high risk/non-high risk facility inventories? What data sources could assist with targeting foreign firms for inspection?
- What criteria should FDA consider when defining its high risk and non-high risk facility inventories? If the criteria you suggest require use of data that FDA does not currently collect or otherwise possess, how should FDA acquire that information?
- How should FDA evaluate or "weigh" the criteria to determine risk?

What factor(s) should be considered the most important and should this vary depending on the circumstances?

3. Manner of Inspection in a Preventive Controls Environment

- What inspection approaches could FDA use to satisfy the domestic and foreign inspection frequency mandates, including by working with State and local governments?
- What inspection tools (*e.g.,* new technologies) could FDA use to meet the domestic and foreign inspection frequency mandates?
- How might FDA use firms' written preventive control plans that will be required in the future under section 103 of FSMA, or information from those plans, to prioritize FDA's work and develop inspectional strategies?
- How should FDA work with foreign governments with respect to inspections of those food facilities in their countries that offer food products for import to the United States?

4. Improving the RFR

- 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?

There will be an interactive Web cast; see section III of this document. If you would like to participate at the meeting via the Web cast, please register at *http://www.blsmeetings.net/FDAInspection&Compliance.* In order to provide Web cast participants with information before and after the meeting, we request attendees provide their name, their affiliation, and e-mail when registering. It is recommended that attendees via Web cast test their Internet connection to confirm access of the Web cast prior to the meeting. To test this connection, visit *http://fda.yorkcast.com/webcast/Catalog/catalogs/default.aspx* and click on "CDRH Television Tutorial and Firewall Test."

III. How To Participate in the Meeting

Stakeholders will have an opportunity to provide oral comments. Due to limited space and time, FDA encourages all persons who wish to attend the meeting, either onsite or by Web cast, including those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meeting, to register in advance and to provide the specific topic or issue to be addressed and the approximate desired length of their presentation. Depending on the number of requests for such oral presentations, there may be a need to limit the time of each oral presentation (*e.g.,* 3 minutes each). If time permits, individuals or organizations that did not register in advance may be granted the opportunity for such an oral presentation. FDA would like to maximize the number of stakeholders who make a presentation at the meeting and will do our best to accommodate all persons who wish to make a presentation or express their views at the meeting. FDA anticipates that there will be several opportunities to speak in breakout sessions and an interactive Web cast will also be available for stakeholders who are not onsite.

FDA encourages persons and groups who have similar interests to consolidate their information for presentation through a single representative. After reviewing the presentation requests, FDA will notify each participant before the meeting of the amount of time available and the approximate time their presentation is scheduled to begin. There is no fee to register for the public meeting and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Onsite registration will be accepted after all pre-registered attendees are seated. Table 1 of this document provides information on participating in the meeting and on submitting comments to the docket (see table 2 of this document for a list of docket numbers and corresponding sections of FSMA).

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING AND SUBMITTING COMMENTS

	Date	Electronic address	Address (nonelectronic)	Other information
Date of Public Meeting.	June 6, 2011, 9 a.m. to 5:30 p.m..	.....	FDA White Oak Campus, The Great Room, Bldg. 31, rm. 1503, 10903 New Hampshire Ave., Silver Spring, MD 20993.	Registration begins at 7:30 a.m.
Web cast Registration.	Ongoing	*http://www.blsmeetings.net/FDAInspection&Compliance.* It is recommended that attendees via Webcast test their Internet connection to confirm access to the Webcast prior to the meeting. To test this connection, visit *http://fda.yorkcast.com/webcast/Catalog/catalogs/default.aspx* and click on "CDRH Television Tutorial and Firewall Test".		
Advance Registration.	By May 31, 2011.	*http://www.blsmeetings.net/FDAInspection&Compliance.*	.....	Registration to attend the meeting will also be accepted onsite on the day of the meeting, as space permits. Registration information may be posted without change to *http://www.regulations.gov,* including any personal information provided.

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING AND SUBMITTING COMMENTS—Continued

	Date	Electronic address	Address (nonelectronic)	Other information
Request special accommodations due to disability.	By May 31, 2011.	.....	*Patricia M. Kuntze, 301–796–8641, e-mail: Patricia.Kuntze@fda.hhs.gov.*	
Make a request for oral presentation.	By May 31, 2011.	*http://www.blsmeetings.net/FDAInspection&Compliance.*	.....	Written material associated with an oral presentation should be submitted in Microsoft PowerPoint, Microsoft Word, or Adobe Portable Document Format and may be posted without change to *http://www.regulations.gov,* including any personal information provided.
Provide a brief description of the oral presentation and any written material for the presentation.	By May 31, 2011.	*http://www.blsmeetings.net/FDAInspection&Compliance.*	.....	All comments must include the Agency name and the docket number corresponding with the section of FSMA on which you are commenting (see table 2 of this document for a list of docket numbers and corresponding sections of FSMA). All received comments may be posted without change to *http://www.regulations.gov,* including any personal information provided.
Submit electronic or written comments.	Submit comments by July 6, 2011.	*Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.*	FAX: 301–827–6870. Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.	FDA encourages the submission of electronic comments by using the Federal eRulemaking Portal. For additional information on submitting comments, see section IV of this document.

IV. Comments

Regardless of attendance at the public meeting, interested persons may submit to the Division of Dockets Management (see table 1 of this document) either electronic or written comments for consideration at or after the meeting in addition to, or in place of, a request for an opportunity to make an oral presentation. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments.

TABLE 2

Section of FSMA	Topic	Docket No.
102	Registration of Food Facilities—Suspension of Registration	FDA–2011–N–0390
201	Targeting of Inspection Resources for Domestic Facilities and Foreign Facilities—Identification and Inspection of Facilities.	FDA–2011–N–0391
206	Mandatory Recall Authority	FDA–2011–N–0392
207	Administrative Detention of Food	FDA–2011–N–0393
211	Improving the Reportable Food Registry	FDA–2011–N–0394

Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov* and *http://www.fda.gov/Food/FoodSafety/FSMA/default.htm.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

Dated: May 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–13059 Filed 5–25–11; 8:45 am]

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