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

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

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.


Leslie Kux,
Acting Assistant Commissioner for Policy.
[FR Doc. 2011–13060 Filed 5–25–11; 8:45 am]
BILLING CODE 4160–01–P
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. 350j) 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.fda.gov/FOIA/FOIALaws/FOIAnotice/FOIANotice/FOIANoticeList/FOIANoticeList.html.

A. For Further Information Contact:

Patricia 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.

B. For Further Information Contact:

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I. For Further Information Contact:

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Patricia 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.
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 inspection tools could FDA use to satisfy the domestic and foreign inspection frequency mandates, including by working with State and local governments?
- What inspection approaches could FDA take to meet the domestic and foreign inspection frequency mandates?
- How could 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?

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?
- 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?

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 Webcast, 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 Webcast 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>
<thead>
<tr>
<th>Date of Public Meeting</th>
<th>Date</th>
<th>Electronic address</th>
<th>Address (nonelectronic)</th>
<th>Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Web cast Registration</td>
<td>June 6, 2011, 9 a.m. to 5:30 p.m.</td>
<td><a href="http://www.blsmeetings.net/FDAInspection&amp;Compliance">http://www.blsmeetings.net/FDAInspection&amp;Compliance</a>.</td>
<td>FDA White Oak Campus, The Great Room, Bldg. 31, rm. 1503, 10903 New Hampshire Ave., Silver Spring, MD 20993.</td>
<td>Registration begins at 7:30 a.m.</td>
</tr>
<tr>
<td>Advance Registration</td>
<td>By May 31, 2011</td>
<td><a href="http://www.blsmeetings.net/FDAInspection&amp;Compliance">http://www.blsmeetings.net/FDAInspection&amp;Compliance</a>.</td>
<td></td>
<td>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 <a href="http://www.regulations.gov">http://www.regulations.gov</a>, including any personal information provided.</td>
</tr>
</tbody>
</table>
TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING AND SUBMITTING COMMENTS—Continued

<table>
<thead>
<tr>
<th>Request special accommodations due to disability. Make a request for oral presentation.</th>
<th>Date</th>
<th>Electronic address</th>
<th>Address (nonelectronic)</th>
<th>Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Request special accommodations due to disability. Make a request for oral presentation.</td>
<td>By May 31, 2011.</td>
<td><a href="http://www.blsmeetings.net/">http://www.blsmeetings.net/</a> FDAInspection&amp;Compliance.</td>
<td>Patricia M. Kuntze, 301–796–8641, e-mail: <a href="mailto:Patricia.Kuntze@fda.hhs.gov">Patricia.Kuntze@fda.hhs.gov</a>.</td>
<td>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 <a href="http://www.regulations.gov">http://www.regulations.gov</a>, including any personal information provided. 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 <a href="http://www.regulations.gov">http://www.regulations.gov</a>, including any personal information provided.</td>
</tr>
<tr>
<td>Submit electronic or written comments.</td>
<td>Submit comments by July 6, 2011.</td>
<td>Federal eRulemaking Portal: <a href="http://www.regulations.gov">http://www.regulations.gov</a>. Follow the instructions for submitting comments.</td>
<td>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.</td>
<td>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 <a href="http://www.regulations.gov">http://www.regulations.gov</a>, including any personal information provided. 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.</td>
</tr>
</tbody>
</table>

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 written or electronic 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

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

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]