

plan to continue this activity in 2011 in three different locations. In March 2011, the meeting will be held in Dallas, TX. After this meeting, CDRH will host one more this year in the San Francisco, CA, area.

## II. Public Meeting

The objective of this public meeting is to engage in a dialogue about issues that are of importance to the public.

The public meeting will open with an introduction of CDRH senior staff in attendance. Following introductions, Dr. Jeffrey Shuren, the Director of CDRH, will describe CDRH's strategic priorities for 2011. Members of the public will then be given the opportunity to present comments to CDRH senior staff followed by a question and answer session during which any member of the public may ask questions of the CDRH senior staff on any topic of interest.

In advance of the meeting, additional information, including a meeting agenda with a speakers' schedule, will be made available on the Internet. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at <http://www.regulations.gov>. This information will also be available at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (select the appropriate meeting from the list).

## III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. 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 (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: March 4, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2011-N-0134, FDA-2011-N-0143, FDA-2011-N-0144, FDA-2011-N-0145, and FDA-2011-N-0146]

### FDA Food Safety Modernization Act: Title III—A New Paradigm for Importers; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; request for comment.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting entitled "FDA Food Safety Modernization Act: Title III—A New Paradigm for Importers." The purpose of the public meeting is to provide interested persons an opportunity to discuss implementation of the import safety provisions of the recently enacted FDA Food Safety Modernization Act (FSMA). FDA is seeking information on importer verification, the Voluntary Qualified Importer Program, import certifications for food, and third-party accreditation. In a separate notice published elsewhere in this issue of the **Federal Register**, FDA is announcing a public hearing to provide stakeholders the opportunity to discuss FDA's use of international comparability assessments as a mechanism to enhance the safety of imported foods and animal feed and lessons learned through equivalence determinations. The public hearing will include a separate discussion of FDA's efforts to gather information from regulators in other countries regarding the regulatory policies, practices, and programs they currently use to ensure the safety of foods and animal feed imported into their countries.

**DATES:** See "How to Participate in the Meeting" 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](mailto: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 that emphasizes accountability for

domestic and foreign food and animal feed firms in the supply chain from farm to U.S. table. In particular, title III of FSMA significantly enhances FDA's authority for oversight of the millions of food products that enter the United States each year and, among other things, requires FDA to develop regulations, guidance, and to otherwise implement the following provisions:

Section 301. Foreign Supplier Verification Program (FSVP) requires importers to conduct risk-based foreign supplier verification activities to verify that imported food is not 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)) (relating to allergens) and is produced in compliance with FDA's preventive controls requirements and produce safety standards, where applicable. Facilities in compliance with FDA's seafood, juice, or low-acid canned food products requirements are exempted in whole or in part from the FSVP requirements. The statute directs FDA to exempt, by notice in the **Federal Register**, importers of food imported into the United States in small quantities for research uses or for personal consumption. The statute further directs FDA to issue implementing regulations and guidance on FSVPs.

Section 302. Voluntary qualified importer program (VQIP) requires FDA to establish a voluntary, user-fee funded program to expedite entry into the United States of imported food from eligible, qualified importers. To be eligible to participate in VQIP, an importer must offer food for importation from a facility that has a certification by an accredited third party. FDA will qualify eligible importers to participate in VQIP based on risk considerations. The statute directs FDA to issue guidance on participation in and compliance with VQIP.

Section 303. Authority to require import certifications for food authorizes FDA, based on risk considerations, to require an article of food offered for import into the United States to be accompanied by certifications or other assurances that the food complies with relevant provisions of the FD&C Act. Certifications may be issued by designated foreign governments or accredited third parties.

Section 307. Accreditation of third-party auditors directs FDA to establish a system for the recognition of accreditation bodies that accredit third-party auditors to issue certifications for purposes of the import certification for food and VQIP provisions described previously in this document. Foreign

governments, foreign cooperatives, and any other third parties (including private entities) are eligible to be considered for accreditation as third-party auditors. The statute further provides that if FDA has not, within a specified timeframe, identified and recognized an accreditation body to meet the requirements of this provision, FDA may directly accredit third-party auditors. The statute directs FDA to issue implementing regulations, including provisions on conflicts of interest, financial ties, and unannounced audits, as well as model accreditation standards, including requirements for regulatory audit reports.

In a separate notice published elsewhere in this issue of the **Federal Register**, FDA is announcing a public hearing March 30 and 31, 2011, to provide stakeholders the opportunity to discuss FDA's use of international comparability assessments as a mechanism to enhance the safety of imported foods and animal feed and lessons learned through equivalence determinations. In addition, there will be a separate discussion of FDA's efforts to gather information from regulators in other countries regarding the regulatory policies, practices, and programs they currently use to ensure the safety of foods and animal feed imported into their countries.

## II. Purpose and Format of the Meeting

If you wish to attend and/or present at the meeting scheduled for March 29,

2011, please register by e-mail to <http://www.blsm meetings.net/FDAImportSafety> by March 22, 2011. FDA is holding the public meeting on the FSMA imports provisions to receive input from the public to inform the development of the regulations and guidance 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 break-out sessions on the provisions discussed at the meeting, and submitting written comments to the docket(s) (see table 2 of this document for a list of docket numbers and corresponding sections of FSMA) within 30 days after this meeting. There will be an interactive webcast; see section III of this document, "How to Participate in the Meeting."

## 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, 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 break-out 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.

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 ON SUBMITTING COMMENTS

	Date	Electronic address	Address (non-electronic)	Other information
Date of Public Meeting.	March 29, 2011, 9 a.m. to 5 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.
Webcast .....	March 29, 2011, 9 a.m. to 5 p.m.	<a href="https://collaboration.fda.gov/foodsafety/">https://collaboration.fda.gov/foodsafety/</a> .	.....	<ul style="list-style-type: none"> <li>If you have never attended a ConnectPRO meeting: Test your connection: <a href="https://collaboration.fda.gov/common/help/en/support/meeting_test.htm">https://collaboration.fda.gov/common/help/en/support/meeting_test.htm</a> Get a quick overview: <a href="http://www.adobe.com/go/connectpro_overview">http://www.adobe.com/go/connectpro_overview</a><sup>1</sup></li> <li>The webcast will provide closed captioning.</li> </ul>
Advance Registration.	By March 22, 2011.	<a href="http://www.blsm meetings.net/FDAImportSafety">http://www.blsm meetings.net/FDAImportSafety</a> .	.....	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.
Request special accommodations due to disability.	By March 22, 2011.	.....	Patricia M. Kuntze, 301-796-8641, email: <a href="mailto:Patricia.Kuntze@fda.hhs.gov">Patricia.Kuntze@fda.hhs.gov</a> .	

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

	Date	Electronic address	Address (non-electronic)	Other information
Make a request for oral presentation.	By March 22, 2011.	<a href="http://www.blsmeetings.net/FDAImportSafety">http://www.blsmeetings.net/FDAImportSafety</a> .	.....	Requests made on the day of the meeting to make an oral presentation may be granted as time permits. Information on requests to make an oral presentation may be posted without change to <a href="http://www.regulations.gov">http://www.regulations.gov</a> , including any personal information provided.
Provide a brief description of the oral presentation and any written material for the presentation.	By March 22, 2011.	<a href="http://www.blsmeetings.net/FDAImportSafety">http://www.blsmeetings.net/FDAImportSafety</a> .	.....	Written material associated with an oral presentation should be submitted in Microsoft PowerPoint, Microsoft Word, or Adobe Portable Document Format (PDF) and may be posted without change to <a href="http://www.regulations.gov">http://www.regulations.gov</a> , including any personal information provided.
Submit electronic or written comments.	Submit comments by April 29, 2011.	Federal eRulemaking Portal: <a href="http://www.regulations.gov">http://www.regulations.gov</a> . 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.	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 the “Comments” heading of the <b>SUPPLEMENTARY INFORMATION</b> section of this document.

<sup>1</sup> Adobe, the Adobe logo, Acrobat and Acrobat Connect are either registered trademarks or trademarks of Adobe Systems Incorporated in the United States and/or other countries.

#### 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. Because multiple docket numbers are associated with this

document, please include with your comments the docket number(s) that corresponds 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).

TABLE 2

Section of FSMA	Topic	Docket No.
301 .....	Foreign supplier verification program .....	FDA–2011–N–0143
302 .....	Voluntary qualified importer program .....	FDA–2011–N–0144
303 .....	Authority to require import certifications for food .....	FDA–2011–N–0145
307 .....	Accreditation of third-party auditors .....	FDA–2011–N–0146

Comments that address more than one docket must be filed with each docket to ensure consideration. 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 (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: March 9, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*  
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