

presentation may be granted if time permits.

Persons who registered in advance for the hearing should check in at the onsite registration desk between 8:30 a.m. and 9 a.m. Persons who wish to register onsite on the day of the hearing should do so at the registration desk between 8:30 a.m. and 9 a.m. FDA encourages all participants to attend the entire hearing.

#### V. Request for Comments

Interested persons may submit to the Division of Dockets Management (*see* table 1 of this document) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

#### VI. 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.

#### VII. References

The following references are on display at the Division of Dockets Management (*see* Transcripts), between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the following Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. President's Food Safety Working Group findings, <http://www.foodsafetyworkinggroup.gov/ContentKeyFindings/HomeKeyFindings.htm>.
2. Codex Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification systems (CAC/GL 53/2003): [http://www.codexalimentarius.net/download/standards/10047/CXG\\_053e.pdf](http://www.codexalimentarius.net/download/standards/10047/CXG_053e.pdf).

Dated: March 9, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-5943 Filed 3-10-11; 4:15 pm]

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### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### Town Hall Discussion With the Director of the Center for Devices and Radiological Health and Other Senior Center Management

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

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

The Food and Drug Administration (FDA) is announcing a public meeting entitled "Town Hall Discussion With the Director of the Center for Devices and Radiological Health and Other Senior Center Management." The purpose of this public meeting in the Orlando, FL, area is to engage in a dialogue about issues of importance to FDA's Center for Devices and Radiological Health (CDRH) and to members of the public, including the medical device industry, health care professionals, patients, and consumers.

**Date and Time:** The public meeting will be held on May 5, 2011, from 8 a.m. to 12 noon EST.

**Location:** The public meeting will be held at the Sheraton Orlando Downtown Hotel, 400 West Livingston St., Orlando, FL 32801. Attendees requiring sleeping rooms should call 401-843-6664 and request the group rate for the "Food & Drug Administration Town Hall Meeting" room block. The meeting will not be videotaped or Web cast.

**Contact:** Heather Howell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4320, Silver Spring, MD 20993, 301-796-5718, e-mail:

[heather.howell@fda.hhs.gov](mailto:heather.howell@fda.hhs.gov).

**Registration and Requests for Oral Presentations:** If you wish to attend the public meeting, you must register online at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm244462.htm>. Persons without Internet access may call Heather Howell at 301-796-5718 to register for the meeting.

Provide complete contact information for each attendee, including name, title, company or organization, address, email, and telephone and fax number.

Registration requests must be received by 5 p.m. EST on Friday, April 22, 2011.

If you wish to make an oral presentation during any of the sessions at the meeting (*see* section II of this document), you must indicate this at the time of registration. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.

Registration is free and will be on a first-come-first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration the day of the public meeting will be provided on a space-available basis beginning at 7 a.m. EST.

If you need special accommodations due to a disability, please contact Susan Monahan, 301-796-5661 or [susan.monahan@fda.hhs.gov](mailto:susan.monahan@fda.hhs.gov), at least 7 days in advance of the meeting.

**Comments:** FDA is holding this public meeting to share information and discuss issues of importance to the public, including the medical device industry, health care professionals, patients, and consumers.

Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments.

It is no longer necessary to send two copies of mailed 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.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In 2010, CDRH held three Town Hall meetings in Minneapolis, MN, Boston, MA, and Los Angeles, CA, to provide the public with a new venue to discuss issues of interest with the Center. Any member of the public was invited to provide comments to or ask questions of CDRH participants. We received positive feedback on these meetings and

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