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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 16, 106, 110, 112, 114, 117, 120, 123, 129, 179, and 211

[Docket Nos. FDA-2011-N-0920 and FDA-2011-N-0921]

Food and Drug Administration Food Safety Modernization Act: Proposed Rules to Establish Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption and for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is providing public meeting registration information for two FSMA related public meetings announced in the January 31, 2013, Federal Register. These public meetings will be held along with the February 28 to March 1, 2013, Washington, DC public meeting to discuss the proposed rules to establish standards for the growing, harvesting, packing, and holding of produce for human consumption (the produce safety proposed rule) and for current good manufacturing practice and hazard analysis and risk-based preventive controls for human food (the preventive controls proposed rule). These proposed rules are the first of several proposed rules that would establish the foundation of, and central framework for, the modern food safety system envisioned by Congress in the FDA Food Safety Modernization Act (FSMA). The purpose of the public meetings is to solicit oral stakeholder and public comments on the proposed rules and to inform the public about the

rulemaking process (including how to submit comments, data, and other information to the rulemaking dockets), and to respond to questions about the proposed rules.

DATES: See section II "How to Participate in the Public Meeting" in the SUPPLEMENTARY INFORMATION section of this document for dates and times of the Chicago, IL and Portland, OR public meetings, closing dates for advance registration, and information on deadlines for submitting either electronic or written comments to FDA's Division of Dockets Management.

ADDRESSES: See section II "How to Participate in the Public Meeting" in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT:

For questions about registering for these meetings, to register by phone, or to submit a notice of participation by mail, fax, or email: Courtney Treece, Planning Professionals, Ltd., 1210 West McDermott Dr., suite 111, Allen, TX 75013, 704-258-4983, FAX: 469-854-6992, email: ctreece@planningprofessionals.com.

For general questions about these meetings, to request an opportunity to make an oral presentation at one of the public meetings, to submit the full text, comprehensive outline, or summary of an oral presentation, or for special accommodations due to a disability, contact: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1731, email: Juanita.yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FSMA (Public Law 111-353) was signed into law by President Obama on January 4, 2011, to better protect public health by helping to ensure the safety and security of the food

supply. FSMA amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish the foundation of a modernized, prevention-based food safety system. Among other things, FSMA requires FDA to issue regulations requiring preventive controls for human and animal food and set standards for produce safety.

FSMA was the first major legislative reform of FDA's food safety authorities in more than 70 years, even though FDA has increased the focus of its food safety efforts on prevention over the past several years. For example, applying the concept of Hazard Analysis and Critical Control Point (HACCP) that was pioneered by industry in the late 1960s, FDA established HACCP-based regulations for seafood (21 CFR part 123) in 1995 (60 FR 65096, December 18, 1995) and for juice (21 CFR part 120) in 2001 (66 FR 6138, January 19, 2001). Similarly, in 1996, the U.S. Department of Agriculture's Food Safety and Inspection Service instituted HACCP-based rules for meat and poultry (9 CFR part 417) (61 FR 38806, July 25, 1996).

In the Federal Register of January 16, 2013 (78 FR 3503 and 78 FR 3646), FDA announced the establishment of two dockets so that the public can review the produce safety proposed rule and the preventive controls proposed rule and submit comments to the Agency. These proposed rulemakings are the first of several key proposals in furtherance of FSMA's food safety mandate. The produce safety proposed rule would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables, grown for human consumption. The produce safety proposed rule would set forth procedures, processes, and practices that FDA expects would reduce foodborne illness associated with the consumption of produce. The produce safety proposed rule and related fact sheets are available on FDA's FSMA Web page located at http://www.fda.gov/Food/FoodSafety/FSMA/default.htm.

The preventive controls proposed rule would apply to human food and require domestic and foreign facilities that are required to register under the FD&C Act to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, monitor results, and act to correct problems that arise. The preventive controls proposed rule and related fact sheets are available on FDA's FSMA Web page located at http://www.fda.gov/Food/FoodSafety/FSMA/default.htm.

In the Federal Register of January 31, 2013 (78 FR 6762), FDA announced the first public meeting in a series of three public meetings entitled "The Food Safety Modernization Act Public Meeting on Proposed Rules for Produce Safety and for Preventive Controls for Human Food" so that the food industry, consumers, foreign governments, and other stakeholders can evaluate and comment on the proposals. FDA also noted that the Agency intended to hold additional public meetings in Chicago, IL and Portland, OR and that those specific locations, dates, and registration information for these meetings would appear in a separate Federal Register document to publish shortly. It was also noted that all three public meetings would have the same agenda and are intended to facilitate and support the proposed rules' evaluation and commenting process.

In this document, FDA is providing the locations, dates, and registration information for the Chicago, IL and Portland, OR public meetings.

II. How to Participate in the Public Meeting

FDA is holding the public meetings on the produce safety proposed rule and the preventive controls proposed rule to inform the public about the rulemaking process, including how to submit comments, data, and other information to the rulemaking docket; to respond to questions about the proposed rules; and to provide an opportunity for interested persons to make

oral presentations. Due to limited space and time, FDA encourages all persons who wish to attend the public meetings to register in advance. There is no fee to register for the public meetings, and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Onsite registration will be accepted, as space permits, after all preregistered attendees are seated.

Those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meetings are asked to submit a request and to provide the specific topic or issue to be addressed. Due to the anticipated high level of interest in presenting public comment and limited time available, FDA is allocating 3 minutes to each speaker to make an oral presentation. Speakers will be limited to making oral remarks; there will not be an opportunity to display materials such as slide shows, videos, or other media during the meeting. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make an oral presentation. FDA would like to maximize the number of individuals who make a presentation at the meetings and will do our best to accommodate all persons who wish to make a presentation or express their opinions at the meeting.

FDA encourages persons and groups who have similar interests to consolidate their information for presentation by a single representative at a single location. After reviewing the presentation requests, FDA will notify each participant before the meeting of the approximate time their presentation is scheduled to begin, and remind them of the presentation format (i.e., 3-minute oral presentation without visual media).

While oral presentations from specific individuals and organizations will be necessarily limited due to time constraints during the public meeting, stakeholders may submit electronic or written comments discussing any issues of concern to the administrative record (the docket) for

the rulemaking. All relevant data and documentation should be submitted with the comments to the relevant docket (i.e., for the produce safety proposed rule, http://www.regulations.gov/#!docketDetail;D=FDA-2011-N-0921; and for the preventive controls proposed rule, http://www.regulations.gov/#!docketDetail;D=FDA-2011-N-0920).

Table 1 of this document provides information on participation in the public meetings:

Table 1.--Information on Participation in the Meetings and on Submitting Comments to the Rulemaking Dockets

	Date	Electronic Address	Address	Other Information
Washington, DC Public meeting	February 28, 2013, from 8:30 a.m. to 5 p.m. and March 1, 2013, from 8:30 a.m. to 12 noon.		Jefferson Auditorium, U.S. Department of Agriculture (USDA), Wing 5 Entrance, 14th and Independence Ave. SW., Washington, DC 20024. Photo ID Required.	Onsite registration both days from 8 a.m. to 8:30 a.m.
Washington, DC Advance registration	By February 20, 2013	Individuals who wish to participate in person are asked to preregister at http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.	We encourage you to use electronic registration if possible.[1]	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
Washington, DC Request to make an oral presentation.	By February 8, 2013	http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm[2].		Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to http://www.regulations.gov, including any personal information provided.
Washington, DC Request special accommodations due to a disability.	By February 15, 2013	Juanita Yates, email: Juanita.yates@fda.hhs.gov.	See FOR FURTHER INFORMATION CONTACT.	

Table 1.--Information on Participation in the Meetings and on Submitting Comments to the Rulemaking Dockets

	Date	Electronic Address	Address	Other Information
Chicago, IL Public meeting	March 11, 2013, from 8:30 a.m. to 5 p.m. and March 12, 2013, from 8:30 a.m. to 12 noon.		The Westin–Michigan Avenue, 909 North Michigan Ave., Chicago, IL 60611	Onsite registration both days from 8 a.m. to 8:30 a.m.
Chicago, IL Advance registration	By March 1, 2013	Individuals who wish to participate in person are asked to preregister at http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.	We encourage you to use electronic registration if possible.[1]	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
Chicago, IL Request to make an oral presentation.	By February 21, 2013	http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm[2].		Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to http://www.regulations.gov, including any personal information provided.
Chicago, IL Request special accommodations due to a disability.	By February 21, 2013	Juanita Yates, email: Juanita.yates@fda.hhs.gov.	See FOR FURTHER INFORMATION CONTACT.	

Table 1.--Information on Participation in the Meetings and on Submitting Comments to the Rulemaking Dockets

	Date	Electronic Address	Address	Other Information
Portland, OR Public meeting	March 27, 2013, from 8:30 a.m. to 5 p.m. and March 28, 2013, from 8:30 a.m. to 12 noon.		Crown Plaza Portland Downtown Convention Center, 1441 NE 2nd Ave., Portland, OR 97232	Onsite registration both days from 8 a.m. to 8:30 a.m.
Portland, OR Advance registration	By March 18, 2013	Individuals who wish to participate in person are asked to preregister at http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.	We encourage you to use electronic registration if possible.[1]	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
Portland, OR Request to make an oral presentation.	By March 8, 2013	http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm[2].		Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to http://www.regulations.gov, including any personal information provided.
Portland, OR Request special accommodations due to a disability.	By March 8, 2013	Juanita Yates, email: Juanita.yates@fda.hhs.gov.	See FOR FURTHER INFORMATION CONTACT.	
Submit electronic or written comments.	By May 16, 2013	Docket Nos. FDA-2011-N-0920 and FDA-2011-N-0921. Preventive Controls for Human Food Proposed Rule: http://www.regulations.gov/#!docketDetail;D=FDA-2011-N-0920. Produce Safety Proposed Rule: http://www.regulations.gov/#!docketDetail;D=FDA-2011-N-0921.		

[1] You may also register via email, mail, or fax. Please include your name, title, firm name, address, and phone and FAX numbers in your registration information and send to Courtney Treece (see FOR FURTHER INFORMATION CONTACT). Onsite registration will also be available.

[2] You may also request to make an oral presentation at the public meeting via email. Please include your name, title, firm name, address, and phone and fax numbers as well as the full text, comprehensive outline, or summary of your oral presentation, and send to Juanita Yates (see FOR FURTHER INFORMATION CONTACT).

III. Comments, Transcripts, and Recorded Video

Information and data submitted voluntarily to FDA during the public meetings will become part of the administrative record for the relevant rulemaking and will be accessible to the public at http://www.regulations.gov. The transcript of the proceedings from the public meetings will become part of the administrative record for each of the rulemakings. Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov and at FDA's FSMA Web site at http://www.fda.gov/Food/FoodSafety/FSMA/. It may also be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript for each public meeting 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 the Division of Freedom of Information (ELEM-1029), 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Additionally, FDA will be video recording the first public meeting in Washington, D.C. Once the recorded video is available, it will be accessible at FDA's FSMA Web site at http://www.fda.gov/Food/FoodSafety/FSMA/.

Dated: February 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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