



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 121

[Docket No. FDA-2013-N-1425]

Focused Mitigation Strategies to Protect Food Against Intentional Adulteration; Public Meetings on Proposed Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meetings.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing two public meetings to discuss the proposed rule to require domestic and foreign food facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to address hazards that may be intentionally introduced by acts of terrorism. FDA proposed these requirements as part of our implementation of the FDA Food Safety Modernization Act (FSMA). The purpose of the public meetings is to inform the public of the provisions of the proposed rule and the rulemaking process (including how to submit comments, data, and other information to the rulemaking docket) as well as solicit oral stakeholder and public comments on the proposed rule and to respond to questions about the rule.

DATES: See section II, “How to Participate in the Public Meeting” in the SUPPLEMENTARY INFORMATION section for dates and times of the 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.

FOR FURTHER INFORMATION CONTACT: For questions about registering for the meeting, to register by phone, or to submit a notice of participation by mail, FAX, or email, contact: Nick Cane, Nakamoto Group, Inc., 11820 Parklawn Dr., suite 240, Rockville, MD 20852, 240-357-1176, FAX: 301-468-6536, email: [nick.cane@nakamotogroup.com](mailto:nick.cane@nakamotogroup.com). For general questions about the meeting; to request an opportunity to make an oral presentation at the public meeting; 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](mailto: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 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 domestic and foreign food facilities that are required to register under the FD&C Act to address hazards that may be intentionally introduced by acts of terrorism. These food facilities would be required to identify and implement focused mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation. We expect the rulemaking would help to protect food from intentional adulteration caused by acts of terrorism.

FDA is announcing additional public meetings so that the food industry, consumers, foreign governments, and other stakeholders can better evaluate and comment on the proposals. These meetings, following the College Park, MD, public event on February 20, are the final two public meetings FDA plans to hold during the proposed rule comment period. All three public meetings are intended to facilitate and support the proposed rule's evaluation and commenting process.

## II. How to Participate in the Public Meetings

FDA is holding the public meetings on "Focused Mitigation Strategies to Protect Food Against Intentional Adulteration" to: (1) Inform the public about the rulemaking process, including how to submit comments, data, and other information to the rulemaking docket; (2) respond to questions about the proposed rules; and (3) 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 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 meetings. 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 each meeting and will do our best to accommodate all persons who wish to make a presentation or express their opinions at a meeting.

FDA encourages persons and groups who have similar interests to consolidate their information for presentation by a single representative. 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 meetings, 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., Docket No. FDA-2013-N-1425.

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
Chicago, IL, Public meeting	February 27, 2014	<a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm">http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm</a>	Hilton Chicago, 720 South Michigan Ave., Chicago, IL 60605	Onsite registration from 8 a.m. to 8:30 a.m.
Chicago, IL, Advance registration	Until February 18, 2014	<a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm">http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm</a>	We encourage you to use electronic registration if possible. <sup>1</sup>	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
Chicago, IL, Request to make a Public Comment	February 10, 2014	<a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm">http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm</a> <sup>2</sup>		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 <a href="http://www.regulations.gov">http://www.regulations.gov</a> , including any personal information provided.
Chicago, IL, Request special accommodations due to a disability	February 10, 2014	Juanita Yates, email: <a href="mailto:Juanita.yates@fda.hhs.gov">Juanita.yates@fda.hhs.gov</a>	See FOR FURTHER INFORMATION CONTACT	
Chicago, IL, Closing date for electronic or written comments	March 31, 2014	Docket No. FDA-2013-N-1425		
Anaheim, CA, Public meeting	March 13, 2014	<a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm">http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm</a>	Sheraton Park Hotel, 1855 South Harbor Blvd., Anaheim, CA 92802	Onsite registration from 8 a.m. to 8:30 a.m.
Anaheim, CA, Advance registration	Until March 4, 2014	<a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm">http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm</a>	We encourage you to use electronic registration if possible. <sup>1</sup>	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.

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

	Date	Electronic Address	Address	Other Information
Anaheim, CA, Request to make a Public Comment	February 18, 2014	<a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm">http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247568.htm</a> <sup>2</sup>		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 <a href="http://www.regulations.gov">http://www.regulations.gov</a> , including any personal information provided.
Anaheim, CA, Request special accommodations due to a disability	February 18, 2014	Juanita Yates, email: <a href="mailto:Juanita.yates@fda.hhs.gov">Juanita.yates@fda.hhs.gov</a>	See FOR FURTHER INFORMATION CONTACT	
Anaheim, CA, Closing date for electronic or written comments	March 31, 2014	Docket No. FDA-2013-N-1425		

<sup>1</sup>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: Nick Cane, Nakamoto Group, Inc., 11820 Parklawn Dr., suite 240, Rockville, MD 20852, 240-357-1176, FAX: 301-468-6536, email: [nick.cane@nakamotogroup.com](mailto:nick.cane@nakamotogroup.com). Onsite registration will also be available.

<sup>2</sup>You may also request to make an oral presentation at the public meetings 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, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1731, email: [Juanita.yates@fda.hhs.gov](mailto:Juanita.yates@fda.hhs.gov).

### 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 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 the rulemaking. 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/GuidanceRegulation/FSMA/default.htm>. 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 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 and live Web casting both of the public meetings. Once the recorded video is available, it will be accessible at FDA's FSMA Web site at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>.

Dated: January 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.