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 Meeting on Proposed Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing a public meeting 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 is proposing these requirements as part of our implementation of the FDA Food Safety Modernization Act (FSMA). The purpose of the public meeting 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 of this document for date and time of the public meeting, 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 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.*

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: J*uanita.yates@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FSMA (Pub. L. 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.

Along with this public meeting, FDA is considering additional public meetings on this subject or other public engagement opportunities. Any further public meetings on this subject would be announced at a later time in the **Federal Register**.

II. How To Participate in the Public Meeting

FDA is holding the public meeting 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 meeting to register in advance. 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, 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 meeting 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 public 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 public meeting and will do our best to accommodate all persons who wish to make a presentation or express their opinions at the public 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).

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

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING AND ON SUBMITTING COMMENTS TO THE RULEMAKING DOCKETS

	Date	Electronic address	Address	Other information
College Park, MD public meeting.	February 20, 2014, 8:30 a.m. to 3 p.m.	*https://collaboration.fda.gov/r38z65kh91j/.*	Wiley Auditorium, Harvey W. Wiley Federal Bldg., 5100 Paint Branch Pkwy., College Park, MD 20740.	

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

	Date	Electronic address	Address	Other information
Deadline for registration	February 7, 2014	*http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm377956.htm.* Docket No. FDA–2013–N–1425.	We encourage you to use electronic registration if possible [1].	There is no registration fee for the public meeting. Early registration is recommended because seating is limited.
Request to make a public comment.	January 17, 2014	*http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm* [2].		Requests made on the day of the public 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.
Request special accommodations due to a disability.	January 17, 2014	Juanita Yates, email: *Juanita.yates@fda.hhs.gov.*	See **FOR FURTHER INFORMATION CONTACT**.	
Closing date for electronic or written comments.	March 31, 2014	Docket No. FDA–2013–N–1425.		

[1] For questions about registering for the public 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.*

[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, 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.*

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., Docket No. FDA–2013–N–1425.

III. Comments, Transcripts, and Recorded Video

Information and data submitted voluntarily to FDA during the public meeting 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 meeting 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/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 live webcasting and recording the public meeting. 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: December 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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