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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 121

[Docket No. FDA-2018-D-1398]

Mitigation Strategies to Protect Food Against Intentional Adulteration: Draft Guidance for Industry; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting entitled "Mitigation Strategies to Protect Food Against Intentional Adulteration: Draft Guidance for Industry." The purpose of the public meeting is to discuss the draft guidance for compliance and implementation of the "Mitigation Strategies to Protect Food Against Intentional Adulteration" rule, which was issued under the FDA Food Safety Modernization Act.

DATES: The public meeting will be held on April 17, 2019 (from 8:30 a.m. to 2 p.m.). Submit either electronic or written comments on this public meeting by July 5, 2019, in order for comments to be considered before work begins on the final guidance. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Harvey Wiley Building Auditorium (first floor), 5001 Campus Dr., College Park, MD 20740. Public meeting participants (non-FDA employees) will undergo routine security check procedures.

You may submit comments as follows. Please submit comments by July 5, 2019, for your comments to be considered before we begin work on the final guidance.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-D-1398 for "Mitigation Strategies to Protect Food Against Intentional Adulteration: Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015,

or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *For questions about registering for the meeting or to register by phone:* Melissa Schroeder, SIDEM, 1775 Eye St., NW, Ste. 1150, Washington, DC 20006, 240-393-4496, EventSupport@Sidemgroup.com.

For general questions about the meeting, to request an opportunity to make oral comments or to request special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition, (HFS-009), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1731, Juanita.Yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Mitigation Strategies to Protect Food Against Intentional Adulteration rule (IA rule, 21 CFR part 121, published in the *Federal Register* of May 27, 2016, 81 FR 34165) requires domestic and foreign food facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to address hazards that may be introduced with the intention to cause wide scale public health harm. These food facilities are required to conduct a vulnerability assessment to identify significant vulnerabilities and actionable process steps and implement mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at

actionable process steps in a food operation. The rule is part of the Agency's ongoing efforts to implement the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353).

In the *Federal Register* of June 20, 2018 (83 FR 28651), we announced the first installment of the draft guidance on complying with the IA rule, "Mitigation Strategies to Protect Food Against Intentional Adulteration: Draft Guidance for Industry." More recently, in the *Federal Register* of March 6, 2019 (84 FR 8103), we announced the availability of the second installment of the draft guidance. Both installments provide information on and recommendations for compliance with important requirements of the IA rule. The comment period on both installments of the draft guidance is open until July 5, 2019, for comments to be considered before work in begun on a final guidance.[1]

FDA is announcing a public meeting entitled, "Mitigation Strategies to Protect Food Against Intentional Adulteration: Draft Guidance for Industry." The meeting will be held during the comment period on the draft guidance.

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 draft guidance (Docket No. FDA-2018-D-1398).

II. Purpose and Format of the Public Meeting

The purpose of the public meeting is to provide information and facilitate comments so that stakeholders can better evaluate and provide input on the draft guidance. We invite interested parties to provide information and offer comments related to the IA rule draft guidance. During the public meeting, we will present information on the draft guidance, with

[1] Under FDA's Good Guidance Practices regulation, anyone may comment on an FDA guidance document at any time (*see* 21 CFR 10.115(g)(5)).

emphasis on chapters related to rule requirements for vulnerability assessments; mitigation strategies; food defense monitoring; and education, training, or experience. There will be an opportunity for questions, as well as an opportunity for open public comment.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website by April 10, 2019: https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability. Persons interested in attending this public meeting must register by April 10, 2019, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public meeting.

For questions about registering for the meeting or to register by phone, please contact Melissa Schroeder (see FOR FURTHER INFORMATION CONTACT)

If you need special accommodations due to a disability, please contact Juanita Yates, (see FOR FURTHER INFORMATION CONTACT) no later than March 28, 2019.

Requests for Oral Presentations: During online or telephone registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests

to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by April 3, 2019. All requests to make oral presentations must be received by March 28, 2019. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at https://www.regulations.gov. It may also be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.

Dated: March 14, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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