DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1398]

Mitigation Strategies To Protect Food Against Intentional Adulteration; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a draft guidance for industry entitled ''Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.'' This draft guidance document, when finalized, will help food facilities that manufacture, process, pack, or hold food, and that are required to register under the Federal Food, Drug, and Cosmetic Act (FD&C Act) comply with the requirements of our regulation entitled ''Mitigation Strategies to Protect Food Against Intentional Adulteration.''

DATES: Submit either electronic or written comments on the draft guidance by December 17, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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: 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ryan Newkirk, Center for Food Safety and Applied Nutrition (HFS–005), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–3712, *ryan.newkirk@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur.

FSMA added to the FD&C Act several new sections that reference intentional adulteration. For example, section 418 of the FD&C Act (21 U.S.C. 350g) addresses intentional adulteration in the context of facilities that manufacture, process, pack, or hold food, and that are required to register under section 415 (21 U.S.C. 350d). Section 420 of the FD&C Act (21 U.S.C. 350i) addresses intentional adulteration in the context of high-risk foods and exempts farms except for farms that produce milk.

We are announcing the availability of a draft guidance for industry entitled ''Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.'' This multi-chapter draft guidance for industry is intended to help food facilities required to comply develop and implement some of the components of a food defense plan, and meet other requirements under 21 CFR part 121. We are announcing the availability of the following chapters:

- Introduction
- Chapter One—The Food Defense Plan
- Chapter Two—Vulnerability Assessment to Identify Significant

Vulnerabilities and Actionable Process Steps

- Chapter Three—Mitigation Strategies for Actionable Process Steps
- Chapter Four—Mitigation Strategies Management Components: Food Defense Monitoring
- Appendix—Food Defense Plan Worksheets

We intend to announce the availability for public comment of additional and expanded chapters of the draft guidance as we complete them.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on food defense measures against intentional adulteration for the regulation ''Mitigation Strategies to Protect Food Against Intentional Adulteration.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 507 have been approved under OMB control number 0910–0789.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Regulatory Information/Guidances/default.htm* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: June 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–13222 Filed 6–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Standards Subcommittee Meeting.

Date and Times: Tuesday, July 17, 2018: 9:00 a.m.–5:00 p.m. (EDT), Wednesday, July 18, 2018: 8:30 a.m.–3:00 p.m. (EDT)

Place: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW, Rm. 705A, Washington, DC 20201.

Status: Open. There will be three opportunities for public comment during the meeting: At the end of the first day, at the end of the morning of the second day, and prior to the meeting close on the second day.

Purpose: The NCVHS Charter stipulates that the Committee study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information and report to the Secretary of Health and Human Services (HHS) with recommendations and legislative proposals for such standards and electronic exchange. NCVHS also is charged with advising HHS on health data collection needs and strategies, and reviewing and monitoring the Department's data and information systems to identify needs, opportunities, and problems.

In this regard, NCVHS is taking a contemporary look at the health terminology and vocabulary landscape in order to advise the HHS Secretary regarding: (1) The changing environment and implications for timing and approach to health terminology and vocabulary standards adoption; (2) Needs, opportunities, and problems with development, dissemination, maintenance, and adoption of health terminology and vocabulary standards; and (3) Actions that HHS might take to improve development, dissemination, maintenance, and adoption of standards.

NCVHS is holding an expert roundtable meeting, in conjunction with the National Library of Medicine (NLM) in order to: (1) Assess strengths, weaknesses and gaps in the U.S. health terminology and vocabulary (T/V) environment; (2) Consider areas for near term improvement in the development, maintenance, dissemination and adoption of named code sets; (3) Discuss opportunities for improved governance, coordination and communication across terminology and vocabulary developers and their stakeholders; (4) Identify top priority gaps in the U.S. health terminology and vocabulary coverage; and (5) Envision a roadmap for introducing improvements over the next decade. Invited experts will have the opportunity to provide extensive input to the subcommittee as it studies these questions and finalizes an Environmental Scan report of the current state of the U.S. health terminology and vocabulary (T/V) environment.

The times and topics for this meeting are subject to change. Please refer to the posted agenda for any updates.

Contact Persons for More Information: Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, telephone (301) 458–4715. Information pertaining to meeting content may be obtained from Vivian Auld, National Institutes of Health, National Library of Medicine, 8600 Rockville Pike, Bethesda, Maryland, 20894–3833, telephone (301) 496–7974. Summaries of meetings and a roster of Committee members are available on the NCVHS website: *www.ncvhs.hhs.gov,* where further information including a meeting agenda and instructions to access the live audio broadcast of the meeting will be posted.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (770) 488–3210 as soon as possible.

Dated: June 14, 2018.

Laina Bush,

Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2018–13179 Filed 6–19–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.