4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 112, 117, and 507

[Docket No. FDA-2016-D-2841]

Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a draft guidance for industry entitled "Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry." This draft guidance explains our current thinking on disclosure statements made by an entity, in documents accompanying food, that certain hazards have not been controlled by that entity as required by certain provisions in four final rules. This document describes our current thinking on how to describe the hazard under each of the four rules and which documents we consider to be "documents of the trade" for the purpose of disclosure statements.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL

REGISTER]. Submit either electronic or written comments on the proposed collection of information by [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2016-D-2841 for "Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration (HFS-300), 5001 Campus Drive, College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

With regard to this draft guidance:

For questions regarding this draft guidance as it relates to our regulation entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food," contact Jenny Scott, Center for Food Safety and Applied Nutrition, (HFS-300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2166.

For questions regarding this draft guidance as it relates to our regulation entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals," contact Jeanette Murphy, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6246.

For questions regarding this draft guidance as it relates to our regulation entitled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," contact Samir Assar, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-401-1636.

For questions regarding this draft guidance as it relates to our regulation entitled "Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals," contact Rebecca Buckner, Office of Food and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4576.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled "Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry." We are issuing the draft guidance 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 this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

The draft guidance relates to four of the seven foundational rules that we have established in Title 21 of the Code of Federal Regulations (21 CFR) as part of our implementation of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353). Table 1 lists these four rules. Each of these rules includes "customer provisions" as specified in table 1.

Table 1.--The Four Foundational FSMA Rules Relevant to the Draft Guidance

Title and Abbreviations for the Purpose of This Document	Regulatory Codification	"Customer Provisions"	Publication
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (part 117)	21 CFR part 117	21 CFR 117.136(a)(2), (3), and (4)	80 FR 55908, September 17, 2015
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (part 507)	21 CFR part 507	21 CFR 507.36(a)(2), (3), and (4)	80 FR 56170, September 17, 2015
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (produce safety regulation)	21 CFR part 112	21 CFR 112.2(b)	80 FR 74354, November 27, 2015
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (FSVP regulation)	21 CFR part 1, subpart L	21 CFR 1.507(a)(2)(i), (a)(3)(i), and (a)(4)(i)	80 FR 74226, November 27, 2015

The "customer provisions" of part 117 and part 507 each include a requirement for a "disclosure statement" in which a manufacturer/processor must disclose, in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]" in certain circumstances. Likewise, the "customer provisions" of the FSVP regulation include a requirement for a "disclosure statement" in which an importer must disclose, in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]" in certain circumstances. The "customer provisions" of the produce safety regulation relate to an exemption from that regulation that includes a requirement for a "disclosure statement" in which a farm must disclose, in documents accompanying the food, in accordance with the practice of

the trade, that the food is "not processed to adequately reduce the presence of microorganisms of public health significance."

The draft guidance responds to industry questions regarding these requirements for a disclosure statement. On March 23, 2016, FDA met with a food trade association at their request to listen to concerns regarding the customer provisions of part 117 (Ref. 1), including concerns regarding the disclosure statement in part 117. At the meeting, the trade association expressed concern about providing a disclosure statement when multiple hazards may be present, including chemical hazards (such as mycotoxins) and physical hazards (such as stones in raw agricultural commodities), as well as for multiple biological hazards (such as microbial pathogens). The trade association also asked us to allow a variety of types of documents that accompany the food to have the disclosure statement (e.g., contractual agreements, websites referenced on labels and in contracts, labels, letters of guarantee, shipment- specific certificates of analysis, shipping documents, specifications, and terms and conditions).

The trade association focused its discussion on the requirements of part 117, but noted that it had parallel concerns for the analogous provisions of part 507 and the FSVP regulation (Ref. 1). Although the trade association did not express concern with the disclosure statement in the produce safety regulation, we believe it will be helpful to businesses subject to the produce safety regulation, to include our current thinking on the disclosure statement in all four rules that have requirements for a disclosure statement, not just the three rules mentioned by the trade association.

II. 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 117 have been approved under OMB control number 0910-0751. The collections of information in 21 CFR part 507 have been approved under OMB control number 0910-0789. The collections of information in 21 CFR part 112 have been approved under OMB control number 0910-0816. The collections of information in 21 CFR part 1, subpart L have been approved under OMB control number 0910-0752.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/FoodGuidances or http://www.regulations.gov. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

IV. References

The following references are on display in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at http://www.regulations.gov.

1. Grocery Manufacturers Association, "21 CFR 117.136. Industry Impacts from Disclosure and Written Assurance Requirements," 2016.

Dated: October 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-26245 Filed: 10/28/2016 8:45 am; Publication Date: 10/31/2016]