4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 117, and 507

[Docket No. FDA-2020-D-1108]

Temporary Policy Regarding Preventive Controls and Foreign Supplier Verification Programs Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled "Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency." The guidance communicates the Agency's intention not to enforce certain onsite audit requirements in three of our food safety regulations in certain circumstances related to the impact of the coronavirus if other supplier verification methods that are designed to provide sufficient assurance that hazards have been significantly minimized or prevented are used instead during the period of onsite audit delay.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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-2020-D-1108 for "Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency." 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.govinfo.gov/content/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 § 10.115(g)(5) (21 CFR 10.115(g)(5))).

Submit written requests for single copies of the guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-300), 5001 Campus Dr., 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 guidance.

FOR FURTHER INFORMATION CONTACT: *For questions relating to Current Good Manufacturing Practices (CGMP), Hazard Analysis, and Risk-Based Preventive Controls for Human Food*: 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 relating to CGMP, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals: Jeanette Murphy, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6246.

For questions relating to Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals: Charlotte Christin, Office of Food Policy and Response, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-7526.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled "Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency." We are issuing this guidance consistent with our good guidance practices regulation (§ 10.115). In accordance with § 10.115(g)(2), we are implementing the guidance immediately because we have determined that prior public participation is not feasible or appropriate. Although the guidance document is immediately in effect, FDA will accept comments at any time. The guidance represents the current thinking of FDA on this topic. 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 document concerns certain supplier verification requirements contained in three of the seven foundational regulations that we have established in Title 21 of the Code of Federal Regulations (CFR) as part of our implementation of the FDA Food Safety Modernization Act (Pub. L. 111-353). The three final regulations are entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" (part 117 (21 CFR part 117)) (https://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm); "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" (part 507 (21 CFR part 507)) (https://www.fda.gov/food/guidanceregulation/fsma/ucm366510.htm); and "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" (part 1, subpart L (21 CFR part 1, subpart L)) (https://www.fda.gov/food/guidanceregulation/fsma/ucm361902.htm).

In brief, each of these regulations requires a supply-chain or supplier verification program in certain circumstances when a supplier is controlling a hazard. In addition, each of these regulations provides for onsite audits of suppliers under certain circumstances to verify that the hazard is being controlled.

The purpose of the guidance is to state the current intent of FDA, in certain circumstances related to the impact of the coronavirus, not to enforce requirements in the three regulations to conduct onsite audits of food suppliers when other supplier verification methods are used to provide sufficient assurance that hazards have been significantly minimized or prevented, during the period of onsite audit delay.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. 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. 3501-3521). The collections of information in part 117 have been approved under OMB control number 0910-0751. The collections of information in part 507 have been approved under OMB control number 0910-0789. The collections of information in 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 guidance at either https://www.fda.gov/FoodGuidances or https://www.regulations.gov. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: March 17, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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