



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 11, 16, 106, 110, 111, 112, 114, 117, 120, 123, 129, 179, 211, and 507

[Docket No. FDA-2017-N-6908]

Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled “Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs.” This guidance states agency compliance policy regarding certain entities and/or activities related to the “farm” definition, written assurances, food contact substances, and human food by-products for use as animal food.

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-2017-N-6908 for "Enforcement Policy for Certain Entities Subject to Requirements in the CGMP and

Preventive Controls Regulations, the Produce Safety Regulation, and the Foreign Supplier Verification Programs Regulation.” 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 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 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 for Importers of Food for Humans and Animals: Rebecca Buckner, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4576.

For questions relating to Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Samir Assar, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1636.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled “Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry.” We are issuing the guidance consistent with our good guidance practices regulation (21 CFR 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 is not subject to Executive Order 12866.

This guidance document concerns 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). The four final rules are entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” (published in the *Federal Register* of September 17, 2015, 80 FR 55908) (<https://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm>) (part 117); “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals” (published in the *Federal Register* of September 17, 2015, 80 FR 51670) (<https://www.fda.gov/food/guidanceregulation/fsma/ucm366510.htm>) (part 507); “Foreign

Supplier Verification Programs for Importers of Food for Humans and Animals” (published in the *Federal Register* of November 27, 2015, 80 FR 74226)

(<https://www.fda.gov/food/guidanceregulation/fsma/ucm361902.htm>) (FSVP regulation); and

“Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human

Consumption” (published in the *Federal Register* of November 27, 2015, 80 FR 74354)

(<https://www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm>) (produce safety regulation or part 112).

In the guidance, we state compliance policy for certain entities and/or activities under these four rules:

- Specific facilities subject to part 117 and/or part 507:
 - Certain facilities that would qualify as secondary activities farms except for the ownership of the facility (e.g., certain produce packinghouses and warehouses, egg packinghouses, grain elevators, cotton ginneries);
 - Facilities that would qualify as farms if they did not color RACs;
 - Facilities that would qualify as secondary activities farms except that they pack, package, label, and/or hold processed food that consists only of RACs that have been dried/dehydrated to create a distinct commodity (e.g., dried beans);
 - Farm mixed-type facilities making silage food for animals;
- Written assurances under the “customer provisions” in part 117 and related rules;
- Importation of food contact substances under the FSVP regulation; and
- Certain human food by-products for use as animal food, with regard to certain requirements under part 507.

II. Paperwork Reduction Act of 1995

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

II. 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: January 2, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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