



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-2018-D-1378]

The Food and Drug Administration Food Safety Modernization Act; Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules: What You Need to Know About the Food and Drug Administration Regulation; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a guidance for industry entitled “The FDA Food Safety Modernization Act; Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules: What You Need to Know About the Food and Drug Administration Regulation--Small Entity Compliance Guide.” The small entity compliance guide (SECG) is intended to help small entities comply with the final rule entitled “The Food and Drug Administration Food Safety Modernization Act; Extension and Clarification for Certain Provisions of Four Implementing Rules.”

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-2018-D-1378 for “The FDA Food Safety Modernization Act; Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules: What You Need to Know About the Food and Drug Administration Regulation--Small Entity Compliance Guide.” 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 (HFS-300), Food and Drug Administration, 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 Practice, 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 Current Good Manufacturing Practice, 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

In the *Federal Register* of August 24, 2016 (81 FR 57784), we issued a final rule entitled “The Food and Drug Administration Food Safety Modernization Act; Extension and Clarification for Certain Provisions of Four Implementing Rules” (the final rule) that extended compliance dates to address concerns about the practicality of compliance with certain provisions, consider changes to the regulatory text, and better align compliance dates across the rules. The final rule became effective August 24, 2016.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612) and determined that the final rule will not have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121, as amended by Pub. L. 110-28), we are making available the SECG to reduce the burden of determining how to comply by further explaining and clarifying the actions that a small entity must take to comply with the rule.

We are issuing this SECG consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). This SECG 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 is not subject to Executive Order 12866.

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

III. Electronic Access

Persons with access to the internet may obtain the SECG 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: May 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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