Contains Nonbinding Recommendations

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 FDA Regulation: Guidance for Industry

Small Entity Compliance Guide

Additional copies are available from:
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(Tel) 301-796-4500
http://www.fda.gov/Food/Guidances

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments on the guidance to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2018-D-1378 listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine

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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 FDA Regulation: Guidance for Industry [1]

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This guidance represents the current thinking of the Food and Drug Administration (FDA or we) 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. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

On August 24, 2016, FDA published in the *Federal Register* a final rule that extended the dates for compliance with certain provisions in four final rules:

- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR part 117);
- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR part 507);
- Standards for Growing, Harvesting, Packing, or Holding of Produce for Human Consumption (21 CFR Part 112); and
- Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (21 CFR Part 1, Subpart L).

[1] This guidance has been prepared by the Office of Food and Veterinary Medicine at the U.S. Food and Drug Administration.

FDA extended the compliance dates of these four rules 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 on August 24, 2016.

On January 5, 2018, FDA issued a guidance document 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". This guidance document states the intent of FDA not to enforce certain regulatory requirements as they currently apply to certain entities and/or activities.

The January 2018 guidance document covers essentially all of the regulatory provisions addressed in the August 2016 final rule:

- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR part 117);
- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR part 507);
- Standards for Growing, Harvesting, Packing, or Holding of Produce for Human Consumption (21 CFR Part 112); and
- Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (21 CFR Part 1, Subpart L).

Entities seeking additional detail on FDA's policy regarding its intent not to enforce the regulatory provisions discussed in the August 2016 final rule should consult the January 2018 final guidance 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". (https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm590646.htm)

We have prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121, as amended by Public Law 110-28). This guidance document is intended to assist small entities in complying with the final rule entitled "The Food and Drug Administration Food Safety Modernization Act; Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules" (81 FR 52284). The rule is binding and has the full force and effect of law.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.