4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0146]

Third-Party Auditor/Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled "Third-Party Auditor/Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards." The draft guidance, when finalized, will contain FDA recommendations on third-party auditor/certification body qualifications for accreditation to conduct food safety audits and to issue food and/or facility certifications under an FDA program required by the FDA Food Safety Modernization Act (FSMA).

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you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments by [**INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Submit written requests for single copies of the draft guidance to Charlotte A. Christin, Office of Compliance, Center for Food Safety and Applied Nutrition (HFS-605), Food and Drug Administration, 5100 Paint Branch Pkwy., 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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Charlotte A. Christin, Center for Food Safety and Applied Nutrition (HFS-605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-3708.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry and FDA staff entitled "Third-Party Auditor/Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards" (draft guidance). This draft guidance is being made available consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on "Third-Party Auditor/Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes and regulations.

Section 808 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 384d) was added by FSMA and directs FDA to establish a program for the recognition of accreditation bodies that accredit third-party auditors/certification bodies to conduct food safety audits and to issue food and/or facility certifications that FDA may use in certain circumstances to facilitate the entry of foods presented for import. Section 808(b)(2) of the FD&C Act requires FDA to develop model accreditation standards that recognized accreditation bodies shall use to qualify third-party auditors/certification bodies for accreditation, and in so doing, to look to existing standards for certification bodies (as of the date of enactment of FSMA) to avoid unnecessary duplication of efforts and costs. This draft guidance, when finalized, will constitute the model accreditation standards referred to in section 808(b)(2) of the FD&C Act. The draft guidance contains FDA recommendations on third-party auditor/certification body qualifications for accreditation to conduct food safety audits and to issue food and/or facility certifications under an FDA program required by FSMA.

FDA was guided in developing this draft guidance, in part, by the National Technology Transfer and Advancement Act of 1995, which directs Federal Agencies to use voluntary consensus standards in lieu of government-unique standards, except where inconsistent with law or otherwise impractical.

In developing the draft guidance, FDA considered several voluntary consensus standards for their relevance to the qualifications of third-party auditors/certification bodies that would certify foreign food facilities and/or their foods for conformance with the requirements of the FD&C Act. FDA also sought to identify the standards most commonly used by stakeholders (e.g., other governments, public and private accreditation bodies, the food industry, and the international standards community) in qualifying third-party auditors/certification bodies for

conducting food safety audits. As a result, FDA was guided in developing the draft model accreditation standards guidance document by International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) ISO/IEC 17021: Conformity Assessment--Requirements for bodies providing audit and certification management systems (2011) ("ISO/IEC 17021:2011") and included an appendix containing a crosswalk between ISO/IEC 17021:2011 and ISO/IEC 17065: Conformity assessment--Requirements for bodies certifying products, processes and services ("ISO/IEC 17065:2012").

The draft guidance document is issued as a companion to the proposed rule "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" that was published in the Federal Register of July 29, 2013 (78 FR 45781). When this guidance is finalized, it will serve as a companion guidance document to the final rule.

II. Paperwork Reduction Act of 1995

This draft guidance refers to proposed collections of information described in FDA's July 29, 2013, proposed rule on Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, which this draft guidance is intended to interpret. The proposed collections of information in the proposed rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). As required by the PRA, FDA has published an analysis of the information collection provisions of the proposed rule (see 78 FR 45781 at 45825, reference 25, pages 216-239, available at http:///www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm) and has submitted the proposed collections to OMB for approval.

III. Comments

Interested persons may submit either electronic comments regarding the draft guidance to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. 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.

Dated: July 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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