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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

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

Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards; Guidance for Industry and Food and Drug Administration Staff; 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 and FDA staff entitled "Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards." The guidance contains FDA recommendations on third-party 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). The guidance is intended to describe the standards for accreditation of third-party certification bodies as required under the final rule entitled "Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications." In addition, this guidance discusses specific clauses of ISO/IEC 17021: 2015 and industry practice that are currently being used by third-party certification bodies and that FDA recommends accreditation bodies consider as a model when making accreditation decisions.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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-2011-N-0146 for "Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards; Guidance for Industry and Food and Drug Administration Staff." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the 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: Charlotte A. Christin, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-7526.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry and FDA staff entitled "Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards." We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). 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.

In the Federal Register of July 24, 2015 (80 FR 44137), we made available a draft guidance entitled "Draft Guidance for Industry and Food and Drug Administration Staff: Third-Party Auditor/Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards" and gave interested parties an opportunity to submit comments by October 7, 2015, for us to consider before beginning work on the final version of the guidance. 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 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 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 guidance constitutes the model accreditation standards referred to in section 808(b)(2) of the FD&C Act. The guidance contains FDA recommendations on third-party 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 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 guidance, FDA considered several voluntary consensus standards for their relevance to the qualifications of third-party 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 certification bodies for conducting food safety audits. As a result, FDA was guided in developing the 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 (2015) (ISO/IEC 17021:2015) and ISO/IEC 17065: Conformity Assessment -- Requirements for bodies certifying products, processes and services (2012) (ISO/IEC 17065:2012).

We received several comments on the draft guidance and have modified the final guidance where appropriate. We revised the guidance for clarity and conformance with the final rule. We also updated references to the ISO/IEC standards. The guidance announced in this notice finalizes the draft guidance dated July 2015.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collection 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 regarding "Accreditation of Third Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications," have been approved under OMB control number 0910-0750.

III. Electronic Access

Persons with access to the Internet may obtain the 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: December 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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