



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2022-D-0370]

The Accredited Third-Party Certification Program: Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a draft guidance for industry entitled “The Accredited Third-Party Certification Program: Questions and Answers.” The draft guidance, when finalized, will answer frequently asked questions relating to the requirements of the Accredited Third-Party Certification Program, and is intended to assist accreditation bodies’, third-party certification bodies’, and eligible entities’ understanding of the regulation and program requirements.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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-2022-D-0370 for "The Accredited Third-Party Certification Program: Questions and Answers." 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, 240-402-7500.

- 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.govinfo.gov/content/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, 240-402-7500.

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 draft guidance to the Center for Food Safety and Applied Nutrition, 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 draft guidance.

FOR FURTHER INFORMATION CONTACT: Doriliz De Leon, Center for Food Safety and Applied Nutrition (HFS-607), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2772.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled “The Accredited Third-Party Certification Program: Questions and Answers.” We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 alternate approach if it satisfies the requirements of the applicable statutes and regulations.

The FDA Food Safety Modernization Act (Pub. L. 111-353) added section 808 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384d), which directs FDA to establish a program for accreditation of third-party certification bodies to conduct food safety audits and to certify that eligible foreign food entities (including registered foreign food facilities) and food produced by such entities meet applicable FDA requirements for purposes of sections 801(q) (21 U.S.C. 381(q)) and 806 (21 U.S.C. 384b) of the FD&C Act. On November 27, 2015, FDA issued the final rule, “Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications” (also referred to as the TPP regulation) (80 FR 74569; 21 CFR part 1, subpart M). This draft guidance, when finalized, will answer frequently asked questions relating to the requirements of the Accredited Third-Party Certification Program established in 21 CFR part 1, subpart M (21 CFR 1.600 through 1.695, 21 CFR 1.700 through 1.725), and is intended to assist the accreditation bodies’, third-party certification bodies’, and eligible entities’ understanding of the TPP regulation and program requirements.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is

not required. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information under the TPP regulation in 21 CFR part 1, subpart M have been approved under OMB control number 0910-0750.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: April 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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