

21 CFR part; guidance	Topic	OMB control No.
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program".	Q-submissions; pre-submissions	0910-0756

Dated: April 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-07684 Filed 4-8-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-5225]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Foreign Supplier Verification Programs for Food Importers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 11, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0752. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three

White Flint North, 10A-45, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Foreign Supplier Verification Programs (FSVP) for Food Importers—21 CFR Part 1, Subpart L

OMB Control Number 0910-0752—Extension

This information collection supports FDA regulations in 21 CFR part 1, subpart L (21 CFR 1.500 through 1.514 (§§ 1.500 through (§§ 1.514))), which help to implement section 805 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384a). Section 805 authorizes the Agency's FSVP and establishes requirements applicable to imported food. Respondents to the information collection are importers, as defined in section 805(a)(1) of the FD&C Act. The regulations are intended to provide verification that imported food is produced in compliance with statutory requirements that include the implementation of appropriate risk-based preventive controls. The regulations also establish that importers of foods must develop, maintain, and follow an FSVP that provides adequate assurances a foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 of the FD&C Act (21 U.S.C. 350g) (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (21 U.S.C. 350h) (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with

sections 402 (21 U.S.C. 342) (regarding adulteration) and 403(w) (21 U.S.C. 343(w)) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the FD&C Act. The regulations also provide for certain exemptions. To assist respondents with understanding the requirements we have developed Agency guidance, available at: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals>.

Specifically, regulations in § 1.501 set forth the applicability of requirements for FSVP, while regulations in §§ 1.502 through 1.508, prescribe specific activities for developing, maintaining, and following an FSVP; as well as for evaluating compliance and for identifying and correcting hazards. Finally, regulations in § 1.509 identify required data elements applicable to food products offered for importation into the United States, while regulations in § 1.510 govern required records, providing that records be made available to FDA upon request and that records be maintained electronically. On May 10, 2021, FDA launched the FSVP Importer Portal for FSVP Records Submission as a means for importers to upload FSVP records electronically and submit them to the Agency, after receiving a request for records from FDA. The portal may be found at <https://www.access.fda.gov/>, and a user guide is available at <https://www.fda.gov/media/148312/download>.

In the **Federal Register** of January 28, 2022 (87 FR 4607), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Exemption for food for research; 1.501(c)	36,360	40	1,454,400	0.083 (5 minutes)	120,715
Identifier for filing with U.S. Customs and Border Protection; 1.509.	56,800	157	8,917,600	0.02 (1.2 minutes)	178,352
Total	10,372,000	299,067

¹ There are no capital costs or operating and maintenance costs associated with the information collection.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN^{1 2}

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Controls for low-acid canned foods; 1.502(b)	2,443	4	9,772	1	9,772
Hazard determinations, controls, and audits; 1.504, 1.506, 1.511.	56,800	87.74	4,984,036	0.38 (23 minutes)	1,917,174
Written assurances for food produced under dietary supplement current good manufacturing practices; 1.511.	11,701	2.88	33,664	2.25	75,744
Document very small importer/certain small foreign supplier status; 1.512(b)(1).	50,450	1	50,450	1	50,450
Written assurances associated with very small importer/certain small foreign supplier; 1.512(b)(3).	50,450	2.79	141,084	2.25	317,439
Total	5,219,006	2,370,579

¹ There are no capital costs or operating and maintenance costs associated with the information collection.

² Figures have been rounded to the nearest one hundredth.

Upon evaluation of the information collection, we are retaining the currently approved burden estimates.

Dated: April 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-3049]

E8(R1) General Considerations for Clinical Studies; International Council for Harmonisation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “E8(R1) General Considerations for Clinical Studies.” The guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The guidance describes internationally accepted principles and practices for the design and conduct of clinical studies of drug and biological products. In addition, the guidance provides an overview of the types of clinical studies that may be performed and data sources used during the product’s life cycle. The guidance is intended to promote the quality of the studies submitted to regulatory authorities, while allowing for flexibility. This guidance revises the guidance for industry “E8 General

Considerations for Clinical Trials” issued in December 1997.

DATES: The announcement of the guidance is published in the **Federal Register** on April 11, 2022.

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-2019-D-3049 for “E8(R1) General Considerations for Clinical Studies.” 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