



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0349]

Agency Information Collection Activities; Proposed Collection; Comment Request; Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments of FDA's Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.

DATES: Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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-2025-N-0349 for "Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals." Received comments, those filed in a timely manner (see ADDRESSES), 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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals-

-21 CFR part 1; subpart L

OMB Control Number 0910-0752--Extension

This information collection helps support implementation of section 805 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384a), which requires persons who import food into the United States to perform risk-based foreign supplier verification activities as set forth in part 1, subpart L (21 CFR part 1, subpart L) (Foreign Supplier Verification Programs for Food Importers). The regulatory requirements are intended to verify that food imported into

the United States is as safe as food produced and sold within the United States. 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.

The information collection covers activities attendant to statutory and regulatory requirements applicable to establishing and maintaining FSVP records, including recordkeeping pertaining to the hazard controls set forth in the regulations. We have also established and maintain a webpage regarding the FSVP program at <https://www.fda.gov/food/conversations-experts-food-topics/what-do-importers-need-know-about-fsvp>, including relevant resources.

The regulations also include requirements pertaining to reporting to Customs and Border Protection (CBP) for subsequent transfer to FDA. The reporting requirements to CBP specify that the information must be provided electronically. The FSVP Importer Portal for FSVP Records Submission allows for importers to upload and submit records electronically, after receiving a written request from FDA. The portal may be found <https://www.access.fda.gov/>, and a user guide is available at <https://www.fda.gov/media/148312/download>. FDA has issued guidance for industry relating to the Unique Facility Identifier (UFI) requirement for FSVP importers found in § 1.509(a). “Recognition of Acceptable Unique Facility Identifier (UFI) for the Foreign Supplier Verification Program Regulation Guidance for Industry”(see <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-recognition-acceptable-unique-facility-identifier-ufi-foreign-supplier>) indicates that the Dun & Bradstreet (D&B) Data Universal Number System (DUNS) would be an acceptable UFI for FSVP importers to submit in compliance with § 1.509(a).

Respondents to the information collection are persons who import food into the United States.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden^{1, 2}

| 21 CFR Section | No. of Respondents | No. 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 |
| DUNS number for filing with CBP; §§ 1.509(c), 1.511(c), 1.512(b)(2) | 56,800 | 157 | 8,917,600 | 0.02 (1.2 minutes) | 178,352 |
| Total | | | | | 299,067 |

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

² Totals may not sum due to rounding.

Table 2.-Estimated Annual Recordkeeping Burden¹

| Activity; 21 CFR Section | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|--|----------------------|---------------------------------|----------------------|----------------------------------|-------------|
| Controls for Low Acid Canned Food; § 1.502(b) | 2,443 | 4 | 9,772 | 1 | 9,772 |
| FSVP Recordkeeping including hazard determination, written procedures, reevaluation; audits; and corrective actions: | | | | | |
| Determine and document hazards; § 1.504(a) | 11,701 | 1 | 11,701 | 3.5 | 40,954 |
| Review hazard analysis; § 1.504(d) | 11,701 | 7 | 81,907 | 0.33 (20 minutes) | 27,029 |
| Evaluation of food and foreign supplier; §§ 1.505(a)(2), 1.511(c)(1) | 11,701 | 1 | 11,701 | 4 | 46,804 |
| Approval of suppliers; §§ 1.505(b), 1.512(c)(1)(iii) | 8,191 | 1 | 8,191 | 12 | 98,292 |
| Reevaluation of food and foreign supplier; §§ 1.505(c), 1.512(c)(1)(ii)(A) | 11,701 | 365 | 4,270,865 | 0.25 (15 minutes) | 1,067,716 |
| Confirm or change requirements of foreign supplier verification activity; §§ 1.505(c), 1.512(c)(1)(ii)(A) | 2,340 | 1 | 2,340 | 2 | 4,680 |
| Review of other entities assessments; §§ 1.505(d), 1.512(c)(1)(iii) | 3,510 | 1 | 3,510 | 1.2 | 4,212 |
| Written procedures for use of approved foreign suppliers; §§ 1.506(a)(1), 1.511(c)(2), 1.512(c)(3)(i) | 11,701 | 1 | 11,701 | 8 | 93,608 |
| Review of written procedures; §§ 1.506(a)(2), 1.511(c)(2)(ii), 1.512(c)(3)(ii) | 11,701 | 1 | 11,701 | 1 | 11,701 |
| Written procedures for conducting verification activities; §§ 1.506(b), 1.511(c)(3) | 11,701 | 1 | 11,701 | 2 | 23,402 |

| Activity; 21 CFR Section | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|--|----------------------|---------------------------------|----------------------|----------------------------------|-------------|
| Determination and documentation of appropriate supplier verification activities; §§ 1.506(d)(1)-(2) 1.511(c)(5)(i) | 11,701 | 4 | 46,804 | 3.25 | 152,113 |
| Review of appropriate supplier verification activities determined by another entity; §§ 1.506(d)(3) 1.511(c)(5)(iii) | 11,701 | 2 | 23,402 | 0.33 (20 minutes) | 7,723 |
| Conduct/review audits; § 1.506(e)(1)(i), 1.511(c)(6)(i)(A) | 11,701 | 2 | 23,402 | 3 | 70,206 |
| Conduct periodic sampling/testing; §§ 1.506(e)(1)(ii), 1.511(c)(6)(i)(B) | 11,701 | 2 | 23,402 | 1 | 23,402 |
| Review records; §§ 1.506(e)(1)(iii), 1.511(c)(6)(i)(C) | 11,701 | 2 | 23,402 | 1.6 | 37,443 |
| Document your review of supplier verification activity records; §§ 1.506(e)(3), 1.511(c)(6)(iii) | 11,701 | 6 | 70,206 | 0.25 (15 minutes) | 17,552 |
| § 1.507(a)(1) | 11,701 | 3.17 | 37,082 | 1.25 | 46,353 |
| Written assurances; §§ 1.507(a)(2), 1.507(a)(3), and 1.507(a)(4) | 11,701 | 8.72 | 102,038 | 0.5 (30 minutes) | 51,019 |
| Disclosures that accompany assurances; §§ 1.507(a)(2), 1.507(a)(3), and 1.507(a)(4) | 102,038 | 1 | 102,038 | 0.5 (30 minutes) | 51,019 |
| Document assurances from customers; § 1.507(c) | 36,522 | 2.8 | 102,262 | 0.25 (15 minutes) | 25,566 |
| Document corrective actions; §§ 1.508(a) and 1.512(b)(4) | 2,340 | 1 | 2,340 | 2 | 4,680 |
| Investigate and determine FSVP adequacy; §§ 1.508(b), 1.511(c)(1) | 2,340 | 1 | 2,340 | 5 | 11,700 |
| Subtotal for FSVP Recordkeeping Itemized Above: | | | 4,984,036 | | 1,917,174 |
| Written assurances for food produced under dietary supplement CGMPs; § 1.511(b) | 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 | 2.8 | 141,084 | 2.25 | 317,439 |
| Total | | | | | 2,370,579 |

¹ Totals may not sum due to rounding.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to the currently approved burden estimate.

Dated: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-07592 Filed: 4/30/2025 8:45 am; Publication Date: 5/1/2025]