4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) 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: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0752. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, 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 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" (March 2017) (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.

In the *Federal Register* of May 1, 2025 (90 FR 18682), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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 Burden[1]

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

Activity; 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
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
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	37,092	1.25	46,365
Written assurances; §§ 1.507(a)(2), 1.507(a)(3), and 1.507(a)(4)	11,701	8.72	102,033	0.5 (30 minutes)	51,017

Activity; 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
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:					1,917,184
Written assurances for food produced under dietary supplement CGMPs; § 1.511(b)	11,701	2.88	33,699	2.25	75,823
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	141,260	2.25	317,835
Overall Total					2,371,064

[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. However, a miscalculation in the burden estimate was identified during a review of the prior renewal and has been corrected.

Dated: July 23, 2025.

Grace R. Graham

Deputy Commissioner for Policy, Legislation, and International Affairs.

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