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 0910–0331. 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–12M, 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.

Food Labeling: Notification Procedures for Statements on Dietary Supplements—21 CFR 101.93

OMB Control Number 0910–0331—Extension

Section 403(r)(6) of the FD&C Act (21 U.S.C. 343(r)(6)) and § 101.93 (21 CFR 101.93) require that, no later than 30 days after the first marketing, we be notified by the manufacturer, packer, or distributor of a dietary supplement that it is marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the FD&C Act. In accordance with these requirements, submissions must include: (1) the name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) the signature of a responsible individual or the person who can certify the accuracy of the information presented, and who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

Our electronic form (Form FDA 3955) allows respondents to the information collection to electronically submit notifications to FDA via the Food Applications Regulatory Management (FARM) system. Firms that prefer to submit a paper notification in an alternative format may opt to do so; however, Form FDA 3955 prompts respondents to include certain data elements in their structure/function claim notification (SFCN), as described in § 101.93, in a standard electronic format and helps respondents organize their SFCN to include only the information needed for our review of the claim. Note that the SFCN, whether electronic or paper, is used for all claims made pursuant to section 403(r)(6) of the FD&C Act, including nutrient deficiency claims and general well-being claims in addition to structure/function claims. The electronic form, and any optional elements prepared as attachments to the form (*e.g.,* label), can be submitted in electronic format via FARM. Submissions of SFCNs will continue to be allowed in paper format. We use this information to evaluate whether statements made for dietary ingredients or dietary supplements are permissible under section 403(r)(6) of the FD&C Act. We also provide information on our website at *https://www.fda.gov/food/information-industry-dietary-supplements/notifications-structurefunction-and-related-claims-dietary-supplement-labeling,* which may serve as a helpful resource to respondents.

Description of Respondents: Respondents to this collection of information include manufacturers, packers, or distributors of dietary supplements that bear section 403(r)(6) of the FD&C Act statements on their labels or labeling.

In the **Federal Register** of December 19, 2024 (89 FR 103835), we published a 60-day notice soliciting 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]

21 CFR section; activity; Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
101.93; Statements for Dietary Supplements; Form FDA 3955	3,690	1	3,690	0.75 (45 minutes)	2,768

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. This estimate is based on our experience with this information collection and the number of notifications received in the past 3 years, which has remained constant.

Dated: July 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14222 Filed 7–28–25; 8:45 am]

BILLING CODE 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 August 28, 2025.

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 web page 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	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
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	Number of recordkeepers	Number 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
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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
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
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.

[FR Doc. 2025–14228 Filed 7–28–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0338]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export Notification and Recordkeeping Requirements

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 August 28, 2025.

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 0910–0482. 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.

Export Notification and Recordkeeping Requirements—21 CFR 1.101

OMB Control Number 0910–0482—Extension

This information collection supports FDA regulations. Sections 801 and 802 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381 and 21 U.S.C. 382) charge the Secretary of Health and Human Services, through FDA, with the responsibility of helping to ensure that exports of unapproved new drugs, biologics, devices, animal drugs, food, cosmetics, and tobacco products that are not to be sold in the United States meet the requirements of the country to which the product is to be exported. The respondents to this information collection are exporters who have notified FDA of their intent to export unapproved products that may not be sold or offered for sale in domestic commerce in the United States as allowed under section 801(e) of the FD&C Act. In general, the notification identifies the product being exported (*e.g.,* name, description, and in some cases, country of destination) and specifies where the notifications were sent. These notifications are sent only for an initial export. Subsequent exports of the same product to the same destination or to certain countries identified in section 802(b) of the FD&C Act would not result in a notification to FDA.

Respondents to the information collection are exporters of products that may not be sold in the United States and are regulated by FDA's Center for Drug Evaluation and Research (CDER); Center for Biologics Evaluation and Research (CBER); Center for Devices and Radiological Health (CDRH); Center for Veterinary Medicine (CVM); and Center for Tobacco Products (CTP). Respondents to this collection of information maintain records