vouchers, and how priority review vouchers may be transferred to other sponsors.

The guidance also communicates that, under the FDA Reauthorization Act of 2017, section 524 of the FD&C Act requires attestation by the sponsor of eligibility for a priority review voucher upon submission of the marketing application.

Description of Respondents: Sponsors submitting applications under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Reporting under section 524 of the FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Priority Review Voucher Request	1	1	1	8	8
Notifications of Intent To Use a Voucher	2	1	2	8	16
Letters Indicating the Transfer of a Voucher Letter	1	1	1	8	8
Acknowledging the Receipt of a Transferred Voucher	1	1	1	8	8
Attestation of Eligibility	1	1	1	2	2
Total					42

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

Based on our evaluation of the information collection since the last OMB review and approval, the burden estimate decreased based on receipt of fewer vouchers and other information collection activities. Our estimated burden for the information collection reflects an overall decrease of 46 hours and a decrease of 8 responses.

Dated: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–07589 Filed 4–30–25; 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; 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 June 30, 2025.

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 June 30, 2025. 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 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'' (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	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

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

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
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 record keepers	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
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 4–30–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4754]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Financial Disclosure by Clinical Investigators

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 June 2, 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 0910–0396. 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.

Financial Disclosure by Clinical Investigators

OMB Control Number 0910–0396—Extension

Respondents to this collection are sponsors of marketing applications that contain clinical data from studies covered by the regulations. These sponsors represent pharmaceutical, biologic, and medical device firms. Respondents are also clinical investigators who provide financial information to the sponsors of marketing applications.

Table 1 shows information that is the basis of the estimated number of respondents in tables 2 through 4.

TABLE 1—ESTIMATED NUMBER OF APPLICATIONS, CLINICAL TRIALS, AND INVESTIGATORS SUBJECT TO THE REGULATION BY TYPE OF APPLICATION [1]

Application type	Total number of applications	Number of applications affected	Number of trials	Number of investigators
Drugs:				
New drug application (NDA), new molecular entity (NME)	35	35	3 to 10	3 to 100.
NDA non-NME	94	44	3 to 10	3 to 100.
NDA efficacy supplement	171	100	1 to 3	10 to 30.
Abbreviated new drug application (ANDA)	685	1	1.1	2.
ANDA supplement	10,366	1	1	2.
CBER Biologics:				
Biologics license application (BLA)	26	26	3 to 10	3 to 100.
BLA efficacy supplement	26	26	1 to 3	10 to 30.
CDER Biologics:				
BLAs	19	19	3 to 10	3 to 100.
BLA efficacy supplements	64	50	1 to 3	10 to 30.
Medical Devices:				
Premarket approval (PMA)	43	50	1 to 31	10 to 20.
PMA supplement	28	30	to 3	3 to 10
Reclassification devices	0	0	0	0.
510(k)	3,401	254	1	3 to 10.
De Novo requests	84	76	1 to 3	10 to 20.

[1] Source: Agency estimates.

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

Reporting Burden

Under § 54.4(a) (21 CFR 54.4(a)), applicants submitting an application that relies on clinical studies must submit a complete list of clinical investigators who participated in a covered clinical study, and must either certify to the absence of certain financial arrangements with clinical investigators (Form FDA 3454) or, under § 54.4(a)(3), disclose to FDA the nature of those arrangements and the steps taken by the applicant or sponsor to minimize the potential for bias (Form FDA 3455).

FDA estimates that almost all applicants submit a certification statement under § 54.4(a)(1) and (2). Preparation of the statement using Form FDA 3454 should require no more than 1 hour per study. The number of respondents is based on the estimated number of affected applications.

When certification is not possible and disclosure is made using Form FDA 3455, the applicant must describe, under § 54.4(a)(3), the financial arrangements or interests and the steps that were taken to minimize the potential for bias in the affected study. As the applicant would be fully aware of those arrangements and the steps taken to address them, describing them will be straightforward. The Agency estimates that it will take about 5 hours to prepare this narrative. Based on our experience with this collection, FDA estimates that approximately 10 percent of the respondents with affected