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

demonstrating their compliance with the requirements in 21 CFR 1.101.

In the **Federal Register** of May 1, 2025 (90 FR 18691), FDA 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]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notification requirements for exports; 1.101(d)					
CBER	5	92	460	15	6,900
CDER	5	2.4	12	15	180
CDRH	16	3.375	54	15	810
Total					7,890

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping requirements for exports; 101(b), (c), and (e)					
CBER	17	3	51	22	1,122
CDER	121	7.9	956	22	21,032
CDRH	16	3	48	22	1,056
CVM	26	3	78	22	1,716
Recordkeeping requirements for exports; 1.101(b)					
Office of Global Policy and Strategy	1	65	65	22	1,430
CTP	322	3	966	22	21,252
Total					47,608

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

In table 1, we estimate the number of respondents increased for biologics from 4 to 5. The number of respondents increased for drugs from 3 to 5. However, this increase is offset by respondents for devices as the estimated number of exporters decreased from 22 to 16. The number of responses per respondent increased for biologics from 35 to 92 resulting in an increase in burden for biologics reporting from 2,100 to 6,900. Despite decreases in the number of responses per respondent for drugs and devices, the increase in biologics reporting resulted in an overall total reporting burden increase from 5,985 to 7,890.

In table 2, we separated each center's recordkeeping to ensure consistency with table 1 and to accurately capture each center's burden estimates. The average No. of Records Per Recordkeeper increased from 4.12 to 14.15 which represents a total recordkeeping burden increase from 39,094 to 47,608.

Based on a review of Agency data, our estimated burden for the information collection reflects an overall increase of 10,419 hours and a corresponding increase of 514 responses. In the previous extension request FDA included burden for the Center for Food Safety and Applied Nutrition (now known as Human Foods Program (HFP)). However, upon reevaluation of these burden estimates, we have determined that the burden associated with HFP is already accounted for under OMB Control Number 0910–0793.

Dated: July 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0419]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Reporting

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,