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.

[FR Doc. 2025–14229 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–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,

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 0910–0437. 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.

Medical Device Reporting—21 CFR Part 803

OMB Control Number 0910–0437—Revision

This information collection supports FDA regulations, programs, forms, and guidance. Section 519 of the Federal Food Drug and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i) (Records and Reports on Devices) requires user facilities, manufacturers, and importers of medical devices to report adverse events involving medical devices to FDA and requires that medical device manufacturers and importers submit medical device reports (MDRs) electronically. These provisions are codified at part 803 (21 CFR part 803)—Medical Device Reporting. The regulations also provide for recordkeeping requirements and certain exemptions and alternative reporting. Additionally, the regulations permit user facilities to submit paper-based annual reports, for which we have provided form FDA 3419 entitled, ''Medical Device Reporting Annual User Facility Report.''

Respondents are required to report adverse events involving medical devices to the FDA. The information that is obtained from these reports will be used to evaluate risks associated with medical devices and enable FDA to take appropriate regulatory measures to protect the public health. Complete, accurate, and timely adverse event information is necessary for the identification of emerging device problems so the agency can protect the public health under section 519 of the FD&C Act. FDA makes the releasable information available to the public for downloading on its website (*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm*).

In an effort at reducing burden, we have developed the Voluntary Malfunction Summary Reporting (VMSR) Program for certain devices, which allows for respondent reporting of multiple malfunction events in a single report on a quarterly basis. The VMSR Program was established under section 519(a)(1)(B)(ii) of the FD&C Act. The associated FDA notification and order granting alternative entitled, ''Medical Devices and Device-led Combination Products; Voluntary Malfunction Summary Reporting Program for Manufacturers'' (83 FR 40973; 8/17/2018; *https://www.federalregister.gov/documents/2018/08/17/2018-17770/medical-devices-and-device-led-combination-products-voluntary-malfunction-summary-reporting-program*) grants an alternative under § 803.19 to permit manufacturer reporting of certain device malfunctions in summary form on a quarterly basis. The associated FDA guidance entitled ''Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers'' (August 2024; *https://www.fda.gov/media/163692/download*) is intended to help manufacturers better understand and use the VMSR Program.

The final order ''Microbiology Devices; Reclassification of Human Immunodeficiency Virus Serological Diagnostic and Supplemental Tests and Human Immunodeficiency Virus Nucleic Acid Diagnostic and Supplemental Tests'' (May 16, 2022; 87 FR 29661) established special controls for certain Human Immunodeficiency Virus (HIV) serological diagnostic and supplemental tests (21 CFR 866.3956) and for HIV nucleic acid tests (NATs) diagnostic and supplemental tests (21 CFR 866.3957) to support their classification into class II, including submission of a log of all complaints annually for a period of 5 years following FDA clearance of a traditional premarket notification (510(k)) submission for these devices. (Information collections associated with premarket notification (510(k)) are approved under OMB control number 0910–0120.)

Earlier notification through the submission of the complaint log enables us to more promptly determine whether public health issues have been adequately addressed. The agency would not otherwise evaluate the kind of complaint information that would be included in the log until an FDA inspection, which typically occurs less frequently than annually. Implementing these specific reporting measures as part of the special controls for these devices is necessary to provide a reasonable assurance of safety and effectiveness for HIV diagnostic and supplemental tests subject to the reclassification order.

Provisions of part 4 subpart B (21 CFR part 4, subpart B), provide that when information regarding an event that involves a death or serious injury, or an adverse event, associated with the use of a combination product is received by the product sponsor, the information must be provided to the other constituent part applicant(s) no later than 5 calendar days after receipt. Part 4 also explains how and where to submit reports and provides for associated recordkeeping. These requirements are described in part 803.

Respondents are manufacturers and importers of medical devices and device user facilities. Device user facility means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in § 803.3, which is not a physician's office (also defined in § 803.3). Respondents are also sponsors (manufacturers) of device-led combination products (see part 4, subpart B). Respondents also include manufacturers of HIV diagnostic and supplemental test devices.

Manufacturer and importer respondents submit reports electronically using FDA Form 3500A (approved under OMB control number 0910–0291) via either ''eSubmitter'' for low-volume reporters or Health Level Seven (HL7) Individual Case Study Report (ICSR) (HL7 ICSR) for high-volume reporters. User facilities reporting under §§ 803.30 and 803.32 have the option of electronic or paper-based reporting. User facility annual reporting under § 803.33 is paper-based, using form FDA 3419. Instructions for submitting the information are available in §§ 803.11, 803.12, and 803.20, and on FDA's public website at *https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities* (links to forms FDA 3500A and FDA 3419 are provided on the web page).

In the **Federal Register** of May 8, 2025 (90 FR 19490), 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

Activity/CFR section	FDA Form No.[2]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours[1]	Total operating and maintenance costs
21 CFR Part 803 "Medical Device Reporting," 21 CFR Part 4, subpart B "Postmarketing Safety Reporting for Combination Products," and FDA notification; order granting alternative entitled, "Medical Devices and Device-led Combination Products; Voluntary Malfunction Summary Reporting Program for Manufacturers"							
Exemptions—803.19		28	1	28	1	28	
User Facility Reporting—803.30 and 803.32.	FDA 3500A	296	18.99	5,621	0.35	1,967	
User Facility Annual Reporting—803.33.	FDA 3419	82	1	82	1	82	
Importer Reporting, Death and Serious Injury—803.40 and 803.42.	FDA 3500A	144	1,034.604	148,983	1	148,983	
Manufacturer Reporting—803.50 through 803.53.	FDA 3500A	1,871	1,240.1887	2,320,393	0.10	232,039	$18,710
Voluntary Malfunction Summary Reporting Program.	FDA 3500A	44	56.88	2,503	0.10	250	
Supplemental Reports—803.56	FDA 3500A	1,501	684.604	1,027,591	0.10	102,759	
21 CFR 866.3956 "Human immunodeficiency virus (HIV) serological diagnostic and/or supplemental test" and 866.3957 "Human immunodeficiency virus (HIV) nucleic acid (NAT) diagnostic and/or supplemental test"							
Special controls: submission of complaint log; 866.3956(b)(1)(iii) and 866.3957(b)(1)(iii).		10	1	10	3	30	
Total				3,505,211		486,138	18,710

[1] Numbers are rounded.
[2] Form FDA 3500A is approved under OMB Control No. 0910–0291. This ICR includes burden only for MDR submissions.

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[2]
MDR Procedures—803.17	1,871	1	1,871	3.3	6,174
MDR Files—803.18	1,871	1	1,871	1.5	2,807
Total			3,742		8,981

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN[1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours[2]
Importer Reporting, Death and Serious Injury—803.40 and 803.42	144	1,034.60	148,983	0.35	52,144

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

Upon review of this information collection, we updated the burden estimates based on internal data regarding MDRs received by FDA for fiscal year (FY) 2024. Device-led combination product reporting and disclosure under part 4, subpart B, are included in the burden estimates. Based on FY2024 data for ''Manufacturer Reporting 803.50 through 803.53,'' we estimate 1,871 respondents and 2,320,393 total annual responses.

The FDA notification and order granting alternative entitled, ''Medical Devices and Device-led Combination Products; Voluntary Malfunction Summary Reporting Program for Manufacturers'' grants an alternative under § 803.19 to permit manufacturer reporting of certain device malfunctions in summary form on a quarterly basis. The associated FDA guidance entitled ''Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers'' (August 2024) is intended to help manufacturers better understand and use the VMSR Program. The Voluntary Malfunction Summary Reporting (VMSR) Program does not apply to reportable death or serious injury events, which are required to be reported to FDA within the mandatory 30-calendar day timeframe, under §§ 803.50 and 803.52, or within the 5-work day timeframe under § 803.53. Thus, if a manufacturer participating in the program becomes aware of information reasonably suggesting that a device it markets may have caused or contributed to a death or serious injury, then the manufacturer must submit an individual MDR for that event because it involves a reportable death or serious injury. We expect that a summary report will take approximately the same amount of time to prepare as an individual report.

Unlike manufacturers, device user facilities are not required to submit malfunction reports under part 803. User facilities, such as hospitals or nursing homes, are required to submit MDRs to FDA and/or the manufacturer only for reportable death or serious injury events. (See section 519(b) of the FD&C Act; 21 CFR 803.30(a).) We believe that by permitting alternative reporting for certain devices, the VMSR Program may reduce burden on respondents who elect to participate and are otherwise subject to mandatory requirements.

Special controls established in the final order ''Microbiology Devices; Reclassification of Human Immunodeficiency Virus Serological Diagnostic and Supplemental Tests and Human Immunodeficiency Virus Nucleic Acid Diagnostic and Supplemental Tests'' to support the class II classification of certain HIV serological diagnostic and supplemental tests (21 CFR 866.3956) and for HIV NATs diagnostic and supplemental tests (21 CFR 866.3957) require the submission of a log of all complaints annually for a period of 5 years following FDA clearance of a traditional premarket notification (510(k)) submission for these devices. (Information collections associated with premarket notification (510(k)) are approved under OMB control number 0910–0120.) Although manufacturers of HIV serological diagnostic and supplemental tests and HIV NAT diagnostic and supplemental tests are already required to maintain complaint files and to review and evaluate complaints for these devices under 21 CFR 820.198, special controls are necessary to provide a reasonable assurance of safety and effectiveness of these devices. (Information collections associated with Quality System requirements under 21 CFR part 820 are approved under OMB control number 0910–0073.) We estimate it will take a manufacturer approximately 3 hours annually to review their existing records, prepare the complaint log, and submit to FDA.

We assume a cost of $10 associated with the payment of an annual fee to maintain e-certification will apply to each respondent. We estimate a total operating and maintenance cost of $18,710 ($10 × 1,871 respondents).

Since the last OMB approval, we have adjusted the respondent and response estimates based on FY 2024 data. We also adjusted the Average Burden per Response for ''Exemptions—803.19'' and ''Importer Reporting, Death and Serious Injury—803.40 and 803.42'' from 0.1 hour to 1 hour to correct an error introduced in a previous request for extension of this information collection. These adjustments have resulted in an overall increase of 1,527,443 total responses, and a corresponding increase of 323,806 total burden hours.

We are revising this information collection to add the FDA guidance entitled ''Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers'' (August 2024; *https://www.fda.gov/media/163692/download*), which is intended to help manufacturers better understand and use the VMSR Program. The guidance does not affect the burden estimates.

Dated: July 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14230 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–2193]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Products, User Fees, Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

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 0910–0749. 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.

Tobacco Products, User Fees, Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

OMB Control Number 0910–0749—Extension

This information collection supports Food and Drug Administration regulations. Tobacco products are generally governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 920) (21 U.S.C. 387–387t). Specifically, section 919 of the FD&C Act (21 U.S.C. 387s) governs tobacco user fees.

Section 919(a) requires FDA to ''assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products'' subject to the tobacco product provisions of the FD&C Act. Accordingly, section 919(b)(2)(B)(i) of the FD&C Act (21 U.S.C. 387s (b)(2)(B)(i)) identifies those tobacco products as: cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco.

FDA utilizes Form FDA 3852, entitled ''Report of Tobacco Product Removals Subject to Tax for Tobacco Product User Fee Assessment'', to facilitate the collection of data necessary for calculating tobacco product user fee assessments. This form is used by domestic manufacturers and importers of tobacco products to report the quantity of products removed from manufacturing facilities or imported into the United States for sale.

To implement the tobacco user fee program as prescribed in the FD&C Act (as summarized above), FDA must collect the information needed to accurately calculate tobacco user fee assessments. On May 10, 2016, FDA published a final rule that requires domestic manufacturers and importers of the applicable tobacco products (listed above) to submit this information to the FDA (81 FR 28707).

In the **Federal Register** of May 1, 2025 (90 FR 18687), FDA published a 60-day