4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0419]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Reporting

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 revision of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collections associated with requirements for medical device reporting for user facilities, manufacturers, importers, and distributors of medical devices.

DATES: Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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-0419 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Reporting." 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: 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: 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 revision 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.

Medical Device Reporting--21 CFR Part 803

OMB Control Number 0910-0437--Revision

This information collection supports Food and Drug Administration (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 web site (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 webpage).

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

Table 1.--Estimated Annual Reporting Burden

Activity/CFR Section	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours[1]	Total Capital Costs	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				3,505,201		486,138	)	18,710

[1] Numbers are rounded.

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[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	No. of Respondents	No. 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 x 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 1,374,708 total responses, and a corresponding increase of 262,681 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 estimated burden estimates.

Dated: May 5, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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