devices, the Agency reviews the MDRs submitted by both mandatory and voluntary reporters.

The VMSR Program (the Program) began in 2018 when FDA issued a notification in the **Federal Register** of August 17, 2018 (83 FR 40973) of an order granting an alternative under 21 CFR 803.19 that permits manufacturers of devices in eligible product codes to report certain device malfunction MDRs in summary form on a quarterly basis, subject to the conditions of the alternative. The Program is intended to streamline reporting for device malfunctions as outlined in the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter. As such, it is intended to yield benefits for FDA, the public, and manufacturers, such as increasing transparency for the public, helping FDA to process certain malfunction reports more efficiently, allowing both FDA and the public to identify malfunction trends more readily, and reducing the burden on manufacturers. FDA implemented the Program only after the Agency had conducted a pilot program [1] that demonstrated the value of a program for summary medical device reporting on malfunctions to public health, better use of Agency resources, and promotion of public transparency.

This draft guidance describes and clarifies several aspects of the Program. The draft guidance includes information on FDA's approach to determining the eligibility of product codes for the Program and the conditions for submitting MDRs for device malfunctions in summary format under the Program. The draft guidance also includes information on how manufacturers may submit information in the summary reporting format, including instructions on how to complete applicable sections of Form FDA 3500A.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 21007 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073

Dated: December 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–26729 Filed 12–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4599]

Content of Human Factors Information in Medical Device Marketing Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Content of Human Factors Information in Medical Device Marketing Submissions.'' This draft guidance provides a risk-based framework to guide manufacturers and FDA staff on the human factors information that should be included in a marketing submission to the Center for Devices and Radiological Health to facilitate the efficiency of the FDA review process. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by March 9, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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

[1] See Pilot Program for Medical Device Reporting on Malfunctions, 80 FR 50010.

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–2015–D–4599 for ''Content of Human Factors Information in Medical Device Marketing Submissions.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Content of Human Factors Information in Medical Device Marketing Submissions'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Tania Reina, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2502, Silver Spring, MD 20993–0002, 301–221–7499.

SUPPLEMENTARY INFORMATION:

I. Background

A unique aspect of medical devices is the critical role of device-user interface interactions for their safe use. Manufacturers routinely perform human factors assessments of the human-device interface during device development. This draft guidance provides a risk-based framework to guide manufacturers and FDA staff on the human factors information that should be included in a marketing submission to the Center for Devices and Radiological Health (CDRH) to facilitate the efficiency of the FDA review process.

On February 3, 2016, FDA announced in the **Federal Register** a draft guidance entitled ''List of Highest Priority Devices for Human Factors Review'' (81 FR 5756). FDA is issuing a revised draft guidance, now entitled ''Content of Human Factors Information in Medical Device Marketing Submissions,'' after considering stakeholder feedback on the draft guidance that issued February 3, 2016. This draft guidance provides FDA's risk-based policy regarding submission of human factors information for the purposes of premarket review in response to stakeholder feedback.

When finalized, this draft guidance is intended to be used to complement the FDA guidance ''Applying Human Factors and Usability Engineering to Medical Devices'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices*) (hereafter referred to as the Human Factors Guidance). After reviewing public comment on this draft guidance and upon its finalization, FDA intends to concurrently revise the Human Factors Guidance to incorporate the definitions included in this guidance, superseding the definitions in section 3 of the Human Factors Guidance. FDA also intends to concurrently revise the Human Factors Guidance by replacing Section 9 ''Documentation'' and Appendix A ''Human Factors and Usability Engineering Report'' of the Human Factors Guidance with cross-references to section V of this guidance, and by making any other revisions to the Human Factors Guidance as appropriate.

FDA recognizes and anticipates that the Agency and industry may need up to 60 days to perform activities to operationalize the policies within this guidance. If new information regarding the content of human factors information for marketing submissions is not included in a marketing submission received by FDA before or up to 60 days after the publication of the final guidance, CDRH staff does not generally intend to request such information during the review of the submission. CDRH does, however, intend to review any such information, if submitted.

This draft guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the topic thereof. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This draft guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Content of Human Factors Information in Medical Device Marketing Submissions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500052 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
860, subpart D	De Novo classification process	0910–0844
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073

Dated: December 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–26767 Filed 12–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Ending the HIV Epidemic Initiative Triannual Report, OMB No. 0915–0051—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than January 9, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *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.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 594–4394.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Ending the HIV Epidemic (EHE) Initiative Triannual Report OMB No. 0915–0051—Extension.

Abstract: HRSA's Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support services to low-income people with HIV. Since 1990, the RWHAP has developed a comprehensive system of safety net providers who deliver high quality direct health care and support services to over half a million people with HIV—more than 50 percent of all people with diagnosed HIV in the United States. Nearly two-thirds of clients (patients) live at or below 100 percent of the Federal poverty level and approximately three-quarters of RWHAP clients are racial/ethnic minorities.[1]

The Federal Ending the HIV Epidemic in the U.S. (EHE) initiative focuses on reducing the number of new HIV infections in the United States by at least 90 percent by 2030, which would be fewer than 3,000 per year.[2] Authorized by section 311(c) and title XXVI of the Public Health Service Act, this 10-year initiative beginning in fiscal year (FY) 2020 focuses on 48 counties; Washington, DC; San Juan, Puerto Rico; and seven states that have a substantial rural HIV burden. EHE initiative efforts focus on the following four key strategies that together can end the HIV epidemic in the United States:

1. Diagnose all people with HIV as early as possible.
2. Treat people with HIV rapidly and effectively to reach sustained viral suppression.
3. Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis and syringe services programs.
4. Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

The EHE initiative is a collaborative effort among key Department of Health and Human Services agencies, primarily HRSA, the Centers for Disease Control and Prevention, the National Institutes of Health, the Indian Health Service,

[1] HRSA. Ryan White HIV/AIDS Program Data Report, 2020.

[2] HRSA. Ending the HIV Epidemic in the U.S. *https://www.hrsa.gov/ending-hiv-epidemic.* Accessed July 12, 2022.