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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; 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 a final guidance titled "Content of Human Factors Information in Medical Device Marketing Submissions." This 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.

DATES: The announcement of the guidance is published in the *Federal Register* on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 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 guidance document titled "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. 5441, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 301-796-6353.

SUPPLEMENTARY INFORMATION:

I. Background

An important consideration for medical devices is the critical impact the device user interface design has on the safe and effective use of the device. Manufacturers routinely perform human factors assessments of the device user interface during device development. The purpose of this guidance is to provide a risk-based framework to guide

manufacturers and FDA staff on the human factors information that should be included in a marketing submission to CDRH to facilitate the efficiency of the FDA review process.

On February 3, 2016, FDA announced in the *Federal Register* a draft guidance titled "List of Highest Priority Devices for Human Factors Review" (81 FR 5756). FDA issued a revised draft guidance on December 9, 2022, titled "Content of Human Factors Information in Medical Device Marketing Submissions," after considering stakeholder feedback on the draft guidance that issued February 3, 2016. Accordingly, the "Content of Human Factors Information in Medical Device Marketing Submissions" draft guidance replaced the "List of Highest Priority Devices for Human Factors Review" draft guidance. The revised draft guidance provided FDA's risk-based draft policy regarding submission of human factors information for the purposes of premarket review in response to stakeholder feedback.

This final 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).

FDA recognizes and anticipates that the Agency and industry may need a minimum of 60 days to perform activities to operationalize the policies within this guidance. For regulatory submissions that are currently pending with FDA after publication of the guidance, as well as those submissions received before August 1, 2026, FDA generally does not anticipate that manufacturers will be ready to include the newly recommended information outlined in the guidance in their submission. FDA, however, intends to review any such information if submitted at any time.

A notice of availability of the draft guidance appeared in the *Federal Register* of December 9, 2022 (87 FR 75635). FDA considered comments received and revised the guidance as appropriate in response to the comments, including additional risk-based factors to consider when determining the Human Factors Submission Category, new illustrative examples and Appendices, and clarifications to the scope of the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Content of Human Factors Information in Medical Device Marketing Submissions. 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 guidance may do so by downloading an electronic copy from the internet. A search capability for all CDRH 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. 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 GUI01500052 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. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in the following table have been approved by OMB:

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 Use Devices; Humanitarian Device Exemption	0910-0332
860, subpart D	De Novo classification process	0910-0844
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program"	Q-submissions and Early Payor Feedback Request Programs for Medical Devices	0910-0756
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification	0910-0485
820	Current Good Manufacturing Practice (CGMP); Quality Management System Regulation (QMSR)	0910-0073

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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