4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-4599]

List of Highest Priority Devices for Human Factors Review; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "List of Highest Priority Devices for Human Factors Review." FDA is issuing this draft guidance document in order to inform medical device manufacturers which device types should have human factors data included in premarket submissions. FDA believes these device types have clear potential for serious harm resulting from use error and that review of human factors data in premarket submissions will help FDA evaluate the safety and effectiveness and substantial equivalence of these devices. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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 "List of Highest Priority Devices for Human Factors Review." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- 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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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:

http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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 "List of Highest Priority Devices for Human Factors Review" to the Office of the Center Director, Guidance and Policy Development, 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: Shannon Hoste, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2531, Silver Spring, MD 20993-0002, 240-402-3747, or shannon.hoste@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Human factors testing is a valuable component of product development for medical devices. FDA recommends that manufacturers consider human factors testing for medical devices as a part of a robust design control subsystem. This draft guidance, if finalized, will

inform medical device manufacturers which device types should have human factors data included in premarket submissions (i.e., for premarket approval 510(k)). FDA believes these device types have clear potential for serious harm resulting from use error and that review of human factors data in premarket submissions will help FDA evaluate the safety and effectiveness and substantial equivalence of these devices.

Elsewhere in this issue of the Federal Register, FDA is announcing the availability of the guidance document, "Applying Human Factors and Usability Engineering to Medical Devices," to assist industry in following appropriate human factors and usability engineering processes to maximize the likelihood that new medical devices will be safe and effective for the intended users, uses, and use environments. Devices that should include human factors data in premarket submissions are listed in this draft guidance. When and if this draft guidance is finalized, FDA recommends that for devices identified in the draft guidance, manufacturers should provide FDA with a report that summarizes the human factors or usability engineering processes they have followed, including any preliminary analyses and evaluations and human factors validation testing, results, and conclusions.

II. Significance of Guidance

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 the list of highest priority devices for human factors review. 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.

III. 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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of "List of Highest Priority Devices for Human Factors Review" 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 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 820 are approved under OMB control number 0910-0073; the collections of information in 21 CFR part 812 are approved under OMB control number 0910-0078; the collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subparts A through E are approved under OMB control number 0910-0231; the collections of information in 21 CFR part 814, subpart H are approved under OMB control number 0910-0332; the collections of information in 21 CFR parts 801 and 809 are approved under OMB control number 0910-0485; and the collections of information in the guidance document entitled "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and

Meetings with Food and Drug Administration Staff" are approved under OMB control number 0910-0756.

Dated: January 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-01889 Filed: 2/2/2016 8:45 am; Publication Date: 2/3/2016]