at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm* or at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of the draft guidance document entitled ''Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* or to *ocod@fda.hhs.gov,* or by calling 1–800–835–4709 or 240–402–7800, to receive an electronic copy of the document. Please use the document number GUD1500044 to identify the guidance you are requesting.

V. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information described in FDA regulations.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 801 have been approved under OMB control number 0910–0485, and the collections of information in 21 CFR part 830 have been approved under OMB control number 0910–0720.

Dated: January 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01892 Filed 2–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0469]

Applying Human Factors and Usability Engineering to Medical Devices; 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) is announcing the availability of the guidance entitled ''Applying Human Factors and Usability Engineering to Medical Devices.'' FDA has developed this guidance document 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. The recommendations in this guidance document are intended to support manufacturers in improving the design of medical devices to minimize potential use errors and resulting harm. FDA believes that these recommendations will enable manufacturers to assess and reduce risks associated with medical device use.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

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–2011–D–0469 for ''Applying Human Factors and Usability Engineering to Medical Devices.'' 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 guidance document entitled ''Applying Human Factors and Usability Engineering to Medical Devices'' 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

To understand use-related hazards, it is necessary to have an accurate and complete understanding of how a device will be used. Understanding and optimizing how people interact with technology is the subject of human factors engineering (HFE) and usability engineering (UE). HFE/UE considerations in the development of medical devices include the three major components of the device user system: (1) Device users; (2) device use environments; and (3) device user interfaces.

For safety-critical technologies such as medical devices, the process of eliminating or reducing design-related use problems that contribute to or cause unsafe or ineffective medical treatment is part of a process for controlling overall risk. For devices where harm could result from ''use errors,'' the dynamics of user interaction should be included in risk analysis and risk management. By incorporating these considerations into the device development process, manufacturers can reduce the overall risk level posed by their devices, thus decreasing adverse events associated with the device and avoiding potential device recalls.

In the **Federal Register** of June 22, 2011 (76 FR 36543), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by September 19, 2011. FDA received over 600 comments, which were generally supportive of the draft guidance document, but requested clarification in a number of areas. The most frequent types of comments requested revisions to the language or structure of the document, or clarification on risk mitigation and human factors testing methods, user populations for testing, training of test participants, determining the appropriate sample size in human factors testing, reporting of testing results in premarket submissions, and collecting human factors data as part of a clinical study. In response to these comments, FDA revised the guidance document to clarify the points identified and restructured the information for better readability and comprehension. This guidance supersedes the guidance entitled ''Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management'' dated July 18, 2000, which will be withdrawn.

II. Significance of 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 ''Applying Human Factors and Usability Engineering to Medical Devices.'' 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 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 ''Applying Human Factors and Usability Engineering to Medical Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1747 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and guidance. 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. 2016–01887 Filed 2–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0194]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Biosimilar User Fee Cover Sheet; Form FDA 3792

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Biosimilar User Fee Cover Sheet; Form FDA 3792'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On June 23, 2015, the Agency submitted a proposed collection of information entitled ''Biosimilar User Fee Cover Sheet; Form FDA 3792'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0718. The approval expires on December 31, 2018. A copy of the supporting statement for this