

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](mailto: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In the **Federal Register** of June 22, 2011 (76 FR 36543), FDA announced the availability of the draft guidance document.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 FDA received over 600 comments, which were generally supportive of the draft guidance document, but requested clarification in a number of areas.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](mailto: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]

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**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](mailto: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

information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: January 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-01883 Filed 2-2-16; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0253]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Postmarketing Adverse Drug Experience Reporting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Postmarketing Adverse Drug Experience Reporting" 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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On July 1, 2015, the Agency submitted a proposed collection of information entitled "Postmarketing Adverse Drug Experience Reporting" 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 0910-0230. The approval expires on December 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-01884 Filed 2-2-16; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0915]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application" 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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On July 2, 2015, the Agency submitted a proposed collection of information entitled "Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application" 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 0910-0636. The approval expires on December 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: January 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-01885 Filed 2-2-16; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-D-4848]

#### Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development; 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 a draft guidance for industry and FDA staff entitled "Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development." This document provides guidance to industry and FDA staff on the underlying principles of human factors (HF) studies during the development of combination products. Combination products are comprised of any combination of a drug and a device; a device and a biological product; a biological product and a drug; or a drug, a device, and a biological product.

**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 comments on 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 May 3, 2016.

**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>.