

Australia). In addition, virtually all major Federal patient safety reporting systems are included, such as those from the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Department of Defense (DoD), and the Department of Veterans Affairs (VA).

Since February 2005, AHRQ has convened the PSWG to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS—CDC, Centers for Medicare and Medicaid Services, FDA, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, National Library of Medicine, Office of the National Coordinator for Health Information Technology, Office of Public Health and Science, and Substance Abuse and Mental Health Services Administration—as well as the DoD and VA.

When developing Common Formats, AHRQ first reviews existing patient safety event reporting systems from a variety of health care organizations. In collaboration with the PSWG and Federal subject matter experts, AHRQ drafts and releases beta versions of the Common Formats for public review and comment. The PSWG assists AHRQ with assuring the consistency of definitions/formats with those of relevant government agencies as refinement of the Common Formats continues. To the extent practicable, the Common Formats are also aligned with World Health Organization (WHO) concepts, framework, and definitions for patient safety.

#### **Commenting on Common Formats: Common Formats for Surveillance—Hospital**

To allow for greater participation by the private sector in the subsequent development of the Common Formats, AHRQ engaged the NQF, a non-profit organization focused on health care quality, to solicit comments and advice to guide the further refinement of the Common Formats. The NQF then convenes an expert panel to review the comments received and provide feedback. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, revises and refines the Common Formats.

The Agency is specifically interested in obtaining feedback from both the private and public sectors to guide the improvement of the formats. Information on how to comment and provide feedback on the *Common Formats for Surveillance—Hospital* is available at: [http://](http://www.Qualityforum.ORG/projects/commonformats.aspx)

[www.Qualityforum.ORG/projects/commonformats.aspx](http://www.Qualityforum.ORG/projects/commonformats.aspx).

More information about the Common Formats can be obtained through AHRQ's PSO Web site: <http://www.PSO.AHRQ.gov/index.html>.

Dated: February 6, 2014.

**Richard Kronick,**  
*Director.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA–2010–D–0283]

#### **Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Final Guidance for Industry on Chemistry, Manufacturing, and Controls Postapproval Manufacturing Changes To Be Documented in Annual Reports**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Final Guidance for Industry on Chemistry, Manufacturing, and Controls Postapproval Manufacturing Changes to be Documented in Annual Reports” 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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On November 6, 2013, the Agency submitted a proposed collection of information entitled “Final Guidance for Industry on Chemistry, Manufacturing, and Controls Postapproval Manufacturing Changes to be Documented in Annual Reports” 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 0910–0758. The approval expires on January 31, 2017. A copy of the supporting statement for this information collection is available on

the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: February 10, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA–2013–N–0795]

#### **Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Devices; Third Party Review Under the Food and Drug Administration Modernization Act**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Medical Devices; Third Party Review Under the Food and Drug Administration Modernization Act (FDAMA)” 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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On December 19, 2013, the Agency submitted a proposed collection of information entitled “Medical Devices; Third Party Review Under FDAMA” 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 0910–0375. The approval expires on January 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: February 10, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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