The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at http://www.regulations.gov.

References


Leslie Kux,
Associate Commissioner for Policy.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Medical Device Reporting: Manufacturer, Importer, User Facility, and Distributor 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, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On August 31, 2015, the Agency submitted a proposed collection of information entitled “Medical Device Reporting: Manufacturer, Importer, User Facility, and Distributor 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 0910–0437. 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.

Leslie Kux,
Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2012–N–0110]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Device Reporting: Manufacturer, Importer, User Facility, and Distributor Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.