

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total Hours
<b>Main Study</b>					
Number to complete the screener (assumes 50% eligible) .....	3,300	1	3,300	0.08 (5 min.) .....	264
Number of completes .....	1,650	1	1,650	.42 (25 min.) .....	693
<b>Total Hours</b> .....					<b>1,149</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

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**

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14. Lang A., "The Limited Capacity Model of Motivated Mediated Message Processing," *The Sage Handbook of Mass Media Effects*, New York: Sage;2009:193–204.
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**Leslie Kux,**

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**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.

**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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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>.

Dated: February 25, 2016.

**Leslie Kux,**

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