proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Survey of Health Care Practitioners for Device Labeling Format and Content—21 CFR Part 801 (OMB Control Number 0910–NEW)

The purpose of this study is to compare existing device labeling from approximately six different types of medical devices with a standard content and format of the same labeling that FDA researchers will develop using the existing labeling as their source of the information.

Building upon the research methodology and success of the approach FDA used to evaluate drug labeling, we propose to measure the usability and usefulness of a draft standard content and format of device labeling against existing manufacturer labeling of the same device. This will support our research that has already been done to assess whether health care practitioners (HCPs) find the format and content of device labeling to be clear, understandable, useful, and user friendly (OMB control number 0910–0715). Findings will provide evidence to inform FDA's planned regulatory approach to standardizing medical device labeling across the United States.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Capital costs
HCPs participating at a hospital	8	1	8	2	16	
HCPs participating at FDA	30	1	30	4	120	$600
Total					136	600

[1] There are no operating and maintenance costs associated with this collection of information.

We will conduct the studies at three different sites including two area hospitals using their devices, existing labeling, and HCPs. We expect that the maximum time for testing will be 2 hours. Given a sample of 6 devices with 2 different labeling types, there will be 12 different labeling types to be tested. We plan to have eight people test each type of the labeling.

We will also conduct the studies on FDA's campus using medical devices received from medical device industry representatives through a material transfer agreement. To account for travel time and cost, we have included 2 additional hours and $20 per respondent in the burden estimate for HCPs participating at FDA.

Dated: September 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–21725 Filed 9–11–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1478]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Providing Waiver-Related Materials in Accordance With Draft Guidance for Industry on Providing Postmarket Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled Providing Waiver-Related Materials in Accordance with Draft Guidance for Industry on Providing ''Postmarket Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format'' 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 19, 2014, the Agency submitted a proposed collection of information entitled ''Providing Waiver-Related Materials in Accordance with Draft Guidance for Industry on Providing Postmarket Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format'' 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 0910–0771. The approval expires on August 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: September 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–21726 Filed 9–11–14; 8:45 am]

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