California, Florida, Illinois, Michigan, New York, North Carolina, Texas, Pennsylvania, Ohio, Louisiana, Missouri, Maryland, New Jersey, Indiana, Kentucky, Georgia, Tennessee, Washington, and Arizona based on beneficiary address as reported to the Social Security Administration and recorded in the Common Working File (CWF). For the demonstration, a prior authorization request can be completed by the (ordering) physician or treating practitioner and submitted to the appropriate DME MAC for an initial decision. The supplier may also submit the request on behalf of the physician or treating practitioner. The physician, treating practitioner or supplier who submits the request on behalf of the physician or treating practitioner, is referred to as the ''submitter.'' Under this demonstration, the submitter will submit to the DME MAC a request for prior authorization and all relevant documentation to support Medicare coverage of the PMD item.

Form Number: CMS–10421 (OMB control number: 0938–1169); *Frequency:* Occasionally; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 333,750; *Total Annual Responses:* 333,750; *Total Annual Hours:* 170,060. (For policy questions regarding this collection contact Daniel Schwartz at 410–786–4197.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* National Provider Identifier (NPI) Application and Update Form and Supporting Regulations in 45 CFR 142.408, 45 CFR 162.406, 45 CFR 162.408; *Use:* The National Provider Identifier (NPI) Application and Update Form is used by health care providers to apply for NPIs and furnish updates to the information they supplied on their initial applications. The form is also used to deactivate their NPIs if necessary. The NPI Application/Update form has been revised to provide additional guidance on how to accurately complete the form. The NPI Application/Update form has been revised to provide additional guidance on how to accurately complete the form. This collection includes clarification on information that is required on applications/changes. Minor changes on the application/update form include adding a 'Subpart' check box in the Other Name section and a revision within the PRA Disclosure Statement. This collection also includes changes to the instructions. *Form Number:* CMS–10114 (OMB control number: 0938–0931); *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profit, not-for-profit institutions, and Federal government; *Number of Respondents:* 608,880; *Total Annual Responses:* 608,880; *Total Annual Hours:* 112,660. (For policy questions regarding this collection contact Leslie Jones at 410–786–6599.)

Dated: September 9, 2014.

Martique Jones,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–21798 Filed 9–11–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0110]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Prescription Drug Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Prescription Drug Advertisements'' 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 12, 2014, the Agency submitted a proposed collection of information entitled ''Prescription Drug Advertisements'' 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 0910–0686. 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. 2014–21727 Filed 9–11–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1219]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey of Health Care Practitioners for Device Labeling Format and Content

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed information collection ''Survey of Health Care Practitioners for Device Labeling Format and Content.''

DATES: Submit either electronic or written comments on the collection of information by November 12, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each

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]

BILLING CODE 4164–01–P

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]

BILLING CODE 4164–01–P