this notice, you may make your request using one of following:
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT:
Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3526), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “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 publish a 30-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. Type of Information Collection Request: New collection (Request for a new OMB control number); Title of Information Collection: Small Business Health Options Program (SHOP) Effective Date and Termination Notice Requirements; Use: The CMS is requiring for plan years beginning on or after January 1, 2016, the SHOP must ensure that a QHP issuer notifies qualified employees, enrollees, and new enrollees in a QHP through the Small Business Health Options Program (SHOP) of the effective date of coverage. As required by the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameter for 2016 (CMS–9944–F), which went on display on February 20, 2015, if any enrollee’s coverage through the SHOP is terminated due to non-payment of premiums or a loss of the enrollee’s or employer group’s eligibility to participate in the SHOP, the SHOP must notify the enrollee or the qualified employer of the termination of such coverage. In the termination of coverage, the SHOP must include the termination date and reason for termination to the enrollee or qualified employer.

To aid in understanding levels of awareness and customer services needs associated with the SHOP associated with the Exchanges established by the Affordable Care Act, CMS will engage in collecting primary qualitative and quantitative research from Exchange target audiences. These surveys are part of a broader data collection effort designed to support the program goal to improve customer satisfaction for people and small businesses that are eligible for coverage through the SHOP. The CMS has designed three surveys to target different audiences, specifically agents and brokers, employers, and employees. Form Number: CMS–10555 (OMB Control Number: 0938–New); Frequency: Annually; biannually; Affected Public: Federal Government, State Governments, Private Sector (Business or other for-profits and Not-for-profit institutions); Number of Respondents: 2,885; Total Annual Responses: 5,770; Total Annual Hours: 50,425. (For policy questions regarding this collection contact Christelle Jang at (410) 786–8438.)

Dated: December 9, 2015.
William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

2. OMB No.: New collection.

Title: Administration for Native Americans Annual Data Collection (Annual Data Report).

OMB No.: New collection.

Description: Content and formatting changes are being made to the Objective Progress Report (OPR). Content changes are being made to the OPR, now known as the Annual Data Report (ADR) previously approved under information collection OMB No. 0980–0204. ANA has determined that the requirement for ANA grantees to submit information about the project activities on quarterly basis creates undue burden for Grantees. Therefore, ANA has reformatted the OPR to require Grantees submit an annual report instead of quarterly report when reporting on partnerships, youth and elder engagement, impact indicators, community involvement etc. This will reduce the administrative burden on Grantees, especially the smaller organizations. The majority of content being requested from the grantees essentially remain same except for the frequency of reporting. The other sections of the document with reference to “quarterly” information will be changed to reflect the shift from four-times a year reporting requirement to once per year and once at the end of the project period.

Respondents: Tribal Government, Native non-profit organizations, Tribal Colleges & Universities receiving ANA funding.

Annual Burden Estimates

The following is the hour of burden estimate for this information collection:

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
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<tbody>
<tr>
<td>ADR</td>
<td></td>
<td>275</td>
<td>2</td>
<td>2</td>
</tr>
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</table>

Estimated Total Annual Burden Hours: 275.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L’Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review;
Comment Request

Title: Administration for Native Americans Annual Data Collection (Annual Data Report).

OMB No.: New collection.

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Additional Information

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

**Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

**Name of Committee:** Circulatory System Devices Panel of the Medical Devices Advisory Committee.

**General Function of the Committee:** To provide advice and recommendations to the Agency on FDA’s regulatory issues.

**Date and Time:** The meeting will be held on Thursday, February 18, 2016, from 8 a.m. to 6 p.m.

**Location:** Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel telephone number is 301–977–8900.

**Contact Person:** Dimitrus Culbreath, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring, MD, 20993, Dimitrus.Culbreath@fda.hhs.gov, 301–796–6872, or FDA Advisory Committee Information Line, 1–800–355–6988, 301–443–0572 in the Washington, DC area. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s Web site at http://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**Agenda:** The Committee will discuss and make recommendations on clinical trial, postapproval study design, and physician training requirements for leadless cardiac pacemaker device technology. Specifically, the Committee will be asked to make recommendations on the acceptability of adverse event rates in acute and chronic timeframes as well as indications for use for this device type, given availability of other technologies with different adverse event profiles; required training and acceptability of observed learning curves for the new device type and necessary elements for postapproval study collection.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 11, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 3, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 4, 2016.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at 301–796–9638, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm11462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 8, 2015.

Jill Hartzler Warner,
Associate Commissioner for Special Medical Programs.

**FOR FURTHER INFORMATION CONTACT:** Information Collection Clearance staff, Information.Collection.Clearance@hhs.gov or (202) 690–6162.

BILLING CODE 4164–01–P