FOR FURTHER INFORMATION CONTACT: Donald Witters, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 62, Rm. 1130, Silver Spring, MD 20993–0002, 301–796–2483.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance to provide FDA's current thinking on the types of information that should be provided in a premarket submission to support a claim of electromagnetic compatibility for an electrically powered medical device. EMI is a hazard with associated risk for electrically powered medical devices. EMC assessment can help to ensure that the risks associated with performance degradation of electrically powered medical devices due to EMI are adequately mitigated.

The draft guidance includes information consistent with specifications described in FDA-recognized consensus national or international standards for EMC such as in the International Electrotechnical Commission (IEC) 60601–1–2: Edition 3: 2007–03, Medical Electrical Equipment—Part 1–2: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests; IEC 60601–1–2: Edition 4.0: 2014–01, Medical Electrical Equipment, Part 1–2: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Electromagnetic Disturbances—Requirements and Tests; Association for the Advancement of Medical Instrumentation (AAMI)/American National Standards Institute (ANSI)/IEC 60601–1–2: 2007/(R) 2012 Medical Electrical Equipment—Part 1–2: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests; and AAMI/ANSI/IEC 60601–1–2: 2014, Medical Electrical Equipment—Part 1–2: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Electromagnetic Disturbances—Requirements and Tests Standards that sponsors and manufacturers of electrically powered medical devices often reference. This draft guidance is intended to help ensure that clear and consistent information is provided in premarket submissions regarding medical device EMC and to facilitate the review of submissions with EMC claims.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on information that should be provided to support claims of electromagnetic compatibility of electrically powered medical devices. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400057 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231. The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120. The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078. The collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332. The collections of information in sections 520(m) and 515A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j and 21 U.S.C. 360e–1, respectively) and 613(b) of Food and Drug Administration Safety and Innovation Act have been approved under OMB control number 0910–0661.

Dated: October 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27818 Filed 10–30–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–4040–New–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit a new Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before January 4, 2016.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–6162.

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

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS–OS–4040–New–60D for reference.

Information Collection Request Title: DATA Act Sec. 5. ''Simplifying Federal Award Reporting'' Grants Pilot.

Abstract: Public Law 113–101, The Digital Accountability and Transparency Act of 2014 (DATA Act) expands the Federal Funding Accountability and Transparency Act of 2006 by increasing accountability and transparency in Federal spending. Section 5 of the DATA Act (''Sec. 5. Simplifying Federal Award Reporting'') tasks the Director of the Office of Management and Budget (OMB) to establish a pilot program (Sec. 5 (b)).

OMB has designated the Department of Health and Human Services (HHS) as the executing agent of the pilot program. Within HHS, the DATA Act Program Management Office (PMO) (DAP) has been established under the Office of the

Assistant Secretary for Financial Resources (ASFR) in order to implement this pilot program. ASFR/DAP, in coordination with Grants.gov, is requesting a generic clearance for the purpose of conducting tests under the pilot program to obtain qualitative and quantitative data and gain an understanding of the burden imposed on Federal recipients.

The DAP has designed several test models to evaluate recipient burden and assess quality of data. The goal of these test models is to determine whether new technology, data standards, processes, and forms aid in reducing recipient burden and increase the accuracy and quality of the data submitted. Under this clearance, a variety of methods (surveys, focus groups, etc.) could be used to collect data, with the exact nature of the questions currently undetermined. DAP expects these questions to include, but not be limited to, topics pertaining to the Standard Form (SF) 424, the Consolidated Federal Financial Reports, and the expanded Single Audit form (SF–SAC). If this data is not collected, the requirements of the DATA Act Section 5 pilot will not be met. The types of collections that this generic clearance covers include, but are not limited to:

- Surveys,
- Focus Groups,
- Other qualitative methods such as interviews, small discussion groups, and case studies.

Likely Respondents: Recipients of Federal contracts, grants, and sub-awards.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Estimated annual reporting burden				
Type of collection	Number of respondents	Annual frequency per response	Hours per response	Total hours
Surveys, Focus Groups, and other qualitative methods	300	1	56.25	16,875
Total	300			16,875

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2015–27860 Filed 10–30–15; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice To Propose the Redesignation of the Service Delivery Area for the Wampanoag Tribe of Gay Head (Aquinnah)

AGENCY: Indian Health Service, HHS.

ACTION: Notice; extension of the comment period.

SUMMARY: This document extends the comment period for the notice to propose Redesignation of the Service Delivery Area for the Wampanoag Tribe of Gay Head (Aquinnah), which was published in the **Federal Register** on October 5, 2015. The comment period for the notice, which would have ended on October 23, 2015, is extended by 30 days.

DATES: The comment period for the notice published in the **Federal Register** on August 24, 2015 (80 FR 51281) allowed for thirty days; the comment period was subsequently extended in the **Federal Register** (80 FR 60158) for an additional 30 days to October 23, 2015. This notice extends the comment period for an additional 30 days to November 22, 2015.

ADDRESSES: Because of staff and resource limitations, we cannot accept comments by facsimile transmission. You may submit comments in one of three ways (please choose only one of the ways listed):

1. *By regular mail.* You may mail written comments to the following address ONLY: Betty Gould, Regulations Officer, Indian Health Service, 801 Thompson, Avenue, TMP STE 450, Rockville, Maryland 20852.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

2. *By express or overnight mail.* You may send written comments to the above address.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to the address above. If you intend to deliver your comments to the Rockville address, please call telephone number (301) 443–1116 in advance to schedule your arrival with a staff member.

Comments will be made available for public inspection at the Rockville address from 8:30 a.m. to 5:00 p.m., Monday–Friday, approximately three weeks after publication of this notice.

FOR FURTHER INFORMATION CONTACT: Carl Harper, Director, Office of Resource Access and Partnerships, Indian Health Service, 801 Thompson Avenue, Rockville, Maryland 20852. Telephone: (301) 443–1553.

SUPPLEMENTARY INFORMATION: The notice that was published in the **Federal Register** on August 24, 2015 advises the public that the Indian Health Service proposes to expand the geographic boundaries of the Service Delivery Area for the Wampanoag Tribe of Gay Head (Aquinnah) of Massachusetts. The Aquinnah service delivery area is currently comprised of members of the Tribe residing in Martha's Vineyard, Dukes County in the State of Massachusetts.

The Bureau of Indian Affairs recognized the Wampanoag Tribe of Gay Head on February 10, 1987. Martha's Vineyard, Dukes County was designated as the Aquinnah service delivery area in the Wampanoag Tribal Council of Gay Head, Inc., Indian Claims Settlement Act of 1987, Public Law 100–95.

This comment period is being extended to allow all interested parties the opportunity to comment on the proposed rule. Therefore, we are extending the comment period until November 22, 2015.

Dated: October 23, 2015.

Robert G. McSwain,

Principal Deputy Director, Indian Health Service.

[FR Doc. 2015–27898 Filed 10–30–15; 8:45 am]

BILLING CODE 4165–16–P