to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ellis Unger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4212, Silver Spring, MD 20993–0002, 301–796–2240 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Treatment for Heart Failure: Endpoints for Drug Development.'' Heart failure causes substantial mortality and morbidity and has major effects on physical function and quality of life. This draft guidance clarifies that an effect on symptoms or physical function, without a favorable effect on survival or hospitalization, can be a basis for approving drugs to treat heart failure. It also provides recommendations to sponsors on the need to assess mortality effects of drugs under development to treat heart failure.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Treatment for Heart Failure: Endpoints for Drug Development.'' 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 statutes and regulations. This guidance is not subject to Executive Order 12866.

II. 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This draft guidance refers to previously approved collections of information found in FDA regulations.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).

FDA has OMB approval under the PRA for the submission of INDs, including protocol amendments and information amendments, in 21 CFR part 312, subpart B, and sponsors may request comment and advice on an IND as well as request meetings with FDA under subpart C (OMB control number 0910–0014). In addition, the following collections of information that have been approved by OMB would cover other submissions discussed in the draft guidance:

- Guidance for industry on formal meetings with sponsors and applicants for Prescription Drug User Fee Act products (OMB control number 0910–0429);
- Guidance for industry on clinical trial data monitoring committees (OMB control number 0910–0581);
- Guidance for industry on oversight of clinical investigations (OMB control number 0910–0733);
- International Council for Harmonization guidance for industry ''E6(R2) Good Clinical Practice'' (OMB control number 0910–0843);
- Protection of Human Subjects: Informed Consent; Institutional Review Boards (21 CFR parts 50 and 56) (OMB control number 0910–0755); and
- Institutional Review Boards (§ 56.115) (OMB control number 0910–0130).

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics,* or *https://www.regulations.gov.*

Dated: June 24, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13800 Filed 6–27–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Data Collection Tool for State Offices of Rural Health Grant Program, OMB No. 0915–0322—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than August 27, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Data Collection Tool for State Offices of Rural Health Grant Program, OMB No. 0915–0322—Revision

Abstract: The mission of the Federal Office of Rural Health Policy (FORHP) is to sustain and improve access to quality care services for rural communities. In its authorizing language (Section 711 of the Social Security Act [42 U.S.C. 912]), Congress charged FORHP with administering grants, cooperative agreements, and contracts to provide technical assistance and other activities as necessary to support activities related to improving health care in rural areas. In accordance with the Public Health Service Act, Section 338J (42 U.S.C. 254r), HRSA proposes to continue the State Offices of Rural Health (SORH) Grant Program data collection process.

Need and Proposed Use of the Information: FORHP seeks to continue gathering information from grantees on their efforts to provide technical assistance to clients within their state. SORH grantees submit a Technical Assistance Report that includes: (1) The total number of technical assistance encounters provided directly by the grantee, and (2) the total number of unduplicated clients that received direct technical assistance from the grantee. These measures will continue with additional measures being added in the following three categories: (1) Information disseminated, (2) information created, and (3) collaborative efforts by topic area and type of audience. These proposed new measures are being added to obtain a

more accurate depiction of the breadth of SORH work and are based on recommendations from the grantees. Submission of the Technical Assistance Report is required via the HRSA Electronic Handbook no later than 30 days after the end of each 12 month budget period.

Likely Respondents: Fifty State Offices of Rural Health.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Technical Assistance Report	50	1	50	13.5	675
Total	50		50		675

HRSA 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.

Maria G. Button,

Director, Division of the Executive Secretariat.

[FR Doc. 2019–13804 Filed 6–27–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council on Alzheimer's Research, Care, and Services provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. The Advisory Council will spend the majority of time during the July 29, 2019 meeting considering recommendations made by each of the three subcommittees to present to the Secretary of HHS and Congress. Additional presentations will include updates on the latest biomedical research findings, an overview of the *Healthy Brain Initiative: The Road Map for Indian Country,* and a discussion of the progress made since 2011 through the National Plan to Address Alzheimer's Disease. Federal workgroups will also provide updates.

DATES: The meeting will be held on July 29, 2019 from 9 a.m. to 4:30 p.m. EST.

ADDRESSES: The meeting will be held in Room 800 in the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.

Comments: Time is allocated on the agenda to hear public comments. The time for oral comments will be limited to two (2) minutes per individual. In lieu of oral comments, formal written comments may be submitted for the record to Helen Lamont, Ph.D., OASPE, 200 Independence Avenue SW, Room 424E, Washington, DC 20201. Comments may also be sent to *napa@hhs.gov*. Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Helen Lamont, 202–260–6075, *helen.lamont@hhs.gov*. Note: Seating may be limited. Those wishing to attend the meeting must send an email to *napa@hhs.gov* and put ''July 29 Meeting Attendance'' in the subject line by Friday, July 19 so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: The July 29, 2019 meeting of the Advisory Council will focus on considering recommendations made by each of the three subcommittees to present to the Secretary of HHS and Congress. There will also be updates on the latest biomedical research findings, an overview of the *Healthy Brain Initiative: The Road Map for Indian Country,* and a discussion of the progress made since 2011 through the National Plan to Address Alzheimer's Disease.

Procedure and Agenda: This meeting is open to the public. Please allow 30 minutes to go through security and walk to the meeting room. The meeting will also be webcast at *www.hhs.gov/live*.

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: June 24, 2019.

Brenda Destro,

Deputy Assistant Secretary for Planning and Evaluation, Office of Human Services Policy.

[FR Doc. 2019–13850 Filed 6–27–19; 8:45 am]

BILLING CODE 4150–15–P