FOR FURTHER INFORMATION CONTACT: Susan Levine, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1674, Silver Spring, MD 20993–0002, 240–402–7936.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Sameness Evaluations in an ANDA—Active Ingredients.'' This guidance is intended to assist applicants preparing an ANDA by providing recommendations on demonstrating sameness between the active ingredient in a proposed generic drug product and its RLD as required under section 505(j)(2)(ii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)(2)(ii)) and FDA's regulations at 21 CFR 314.94(a)(3)(i).

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (Hatch-Waxman Amendments) created an approval pathway for generic drug products under which applicants can submit an ANDA under section 505(j) of the FD&C Act. An ANDA relies on the Agency's previous finding of safety and effectiveness for an RLD and, as a result, may be approved without submission of the same type and extent of information that is required for approval of a new drug application to establish the safety and effectiveness of the proposed product. Among other things, an ANDA must contain information to show that the active ingredient of the proposed generic drug product is the ''same as'' that of the RLD (21 U.S.C. 355(j)(2)(A)(ii); 21 CFR 314.94(a)(5)). FDA may not approve an ANDA unless the ANDA contains sufficient information to show that, among other things, the active ingredient is the same as that of the reference listed drug (21 CFR 314.127(a)(3)). Accordingly, the ANDA applicant is responsible for providing sufficient information to demonstrate that the proposed generic drug product is the ''same as'' the RLD with respect to the active ingredient. To assist prospective applicants in evaluating and demonstrating sameness, this guidance provides information on active ingredient sameness considerations.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Sameness Evaluations in an ANDA—Active Ingredients.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is *not required* for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

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/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: November 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–24432 Filed 11–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0915–0345 Revision]

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: HRSA AIDS Drug Assistance Program (ADAP) Data Report

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 January 9, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 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 Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–9094.

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

Information Collection Request Title: HRSA Ryan White HIV/AIDS Program (RWHAP) AIDS Drug Assistance Program (ADAP) Data Report: (OMB No. 0915–0345).

Abstract: HRSA's RWHAP ADAP is authorized under Part B of the RWHAP legislation, codified in sections 2611 to 2631 of the Public Health Service Act, which provides grants to U.S. states and territories. RWHAP ADAP is a state and territory-administered program that provides Food and Drug Administration-approved medications to low-income people with HIV who have limited or no health coverage from private insurance, Medicaid, or Medicare. RWHAP ADAP funds may also be used to purchase health care coverage for eligible clients and for services that enhance access, adherence, and monitoring of drug treatments.

All 50 states, the District of Columbia, Puerto Rico, Guam, the U.S. Virgin Islands, and the five U.S. Pacific Territories or Associated Jurisdictions receive RWHAP Part B grant awards, including funds for RWHAP ADAP. RWHAP Part B reporting requirements include the annual submission of an ADAP Data Report (ADR), including a Recipient Report and a Client Report. The Recipient Report is a collection of basic information about grant recipient characteristics and policies including program administration, purchasing mechanisms, funding, and expenditures. The Client Report is a collection of client-level records (one record for each client enrolled in the RWHAP ADAP), which includes the client's encrypted unique identifier, basic demographic data, enrollment information, services received, and clinical data.

HRSA is proposing two revisions and one re-installment of questions to the ADR Recipient and Client Reports to

reflect program practices and support HRSA's analysis and understanding of program impact. Specifically, the Recipient Report includes the following proposed changes:

- Replacement of the Recertification Date variable with the Last Date of Eligibility Confirmation will remove the previous 6-month recertification requirement, which is no longer required by policy, *see* Policy Clarification Notice 21–02, and allow Recipients to report the latest eligibility confirmation date for existing clients;
- Reinstate a question that was inadvertently removed from the 2021 ADR that is needed to assess the quality of medication data; and
- Change the DUNS number variable to Unique Entity Identifier. On April 4, 2022, the federal government stopped using DUNs numbers, making it less burdensome for entities to do business with the federal government. As a result, Recipients no longer have to report the DUNs number in the ADR.

HRSA does not anticipate these proposed revisions resulting in a change in the reporting burden. New and revised data elements require reporting of information that should already be collected by recipients to meet legislative or programmatic requirements for the proper oversight and administration of the program.

Need and Proposed Use of the Information: RWHAP requires the submission of annual reports by the Secretary of Health and Human Services to the appropriate committees of Congress. HRSA uses the ADR to evaluate the national impact of the RWHAP ADAP by providing deidentified client-level data on individuals being served, services being delivered, and costs associated with these services. The client-level data is used to monitor health outcomes of people with HIV receiving care and treatment through the RWHAP ADAP, to monitor the use of RWHAP ADAP funds in addressing the HIV epidemic and its impact on communities, and to track progress toward achieving the goals identified in the National HIV/AIDS Strategy.

Likely Respondents: State ADAPs of RWHAP Part B recipients.

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
Grantee Report	54	1	54	6	324
Client-Level Report	54	1	54	81	4,374
Total	54		54		4,698

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, Executive Secretariat.

[FR Doc. 2022–24461 Filed 11–8–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

The meeting will be held as a virtual meeting and is open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The intramural programs and projects as well as the grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with intramural programs and projects as well as the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Alcohol Abuse and Alcoholism.

Date: February 9, 2023.

Closed: 11:00 a.m. to 11:30 a.m.

Agenda: Presentation of AABSC Report.

Closed: 11:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Open: 12:45 p.m. to 5:30 p.m.

Agenda: Presentations and other business of the Council.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Abraham P. Bautista, Ph.D., Executive Secretary, National Advisory Council Director, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700 B Rockledge Drive, Room 1458, MSC 6902, Bethesda, MD 20892, 301–443–9737, *bautista@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when