Agency ''continues to assess the needs and circumstances related to the policies in our COVID–19-related guidances, and we may alter our approach for individual guidances listed in this notice.'' (88 FR 15417 at 15418). Following the expiration of the COVID–19 PHE declaration on May 11, 2023, FDA has reviewed the Notifying FDA Guidance and the Potency Assay Guidance and determined that these two guidances are no longer needed because new draft guidances are available.

In March 2023 (88 FR 13126), the Agency issued the draft guidance document entitled ''Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting Viral Pathogens,'' which provides information to assist in the development of mAbs and other therapeutic proteins directly targeting viral proteins or host cell proteins mediating pathogenic mechanisms of infection. The draft guidance also provides detailed recommendations for drug developers with the goal of helping to ensure that drug developers provide adequate information to assess potency at each stage of a product's life cycle. FDA believes that many of the recommendations set forth in the 2021 Potency Assay Guidance are applicable outside the context of the COVID–19 PHE and are applicable to mAbs and other therapeutic protein directly targeting any viral surfaces (glycol) proteins mediating pathogenic mechanisms of infection, not just those that directly target SARS–CoV–2. In preparing the draft guidance, FDA considered comments received regarding the 2021 Potency Assay Guidance as well as the Agency's experience with SARS–CoV–2 and other viruses.

In April 2023 (88 FR 20526), the Agency issued the draft guidance for industry entitled ''Notification of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act'' to assist applicants and manufacturers in providing FDA timely, informative notifications about changes in the production of certain finished drugs and biological products as well as certain active pharmaceutical ingredients (API) that may, in turn, help the Agency in its effort to prevent and mitigate shortages. The draft guidance discusses the notification requirements under section 506C of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 356c), including requirements added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act)[2] related to notifying FDA about finished product and API manufacturing discontinuances and interruptions. The draft guidance provides recommendations for applicants and manufacturers to provide additional details and follow additional procedures to ensure FDA has the specific information it needs to help prevent or mitigate shortages. In addition, the draft guidance explains how FDA communicates information about products in shortage to the public. In preparing the draft guidance, FDA considered comments received on the 2020 Notifying FDA Guidance.

For the reasons discussed above, FDA is announcing the guidance entitled ''Notifying FDA of Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act'' (March 2020) and the guidance entitled ''COVID–19: Potency Assay Consideration for Monoclonal Antibodies and Other Therapeutic Proteins Targeting SARS–CoV–2 Infectivity'' (January 2021) will expire on November 7, 2023.

II. Expiration Date

The expiration date for the guidance documents in this document is November 7, 2023.

Dated: October 16, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–23071 Filed 10–18–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Rapid Uptake of Disseminated Interventions Evaluation, OMB No. 0906-xxxx

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than November 20, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Rapid Uptake of Disseminated Interventions (RUDI) Evaluation, OMB No. 0906-xxxx—New.

Abstract: HRSA dedicated significant resources and effort to developing novel intervention strategies aimed at eliminating disparities and improving HIV-related health outcomes for people with HIV. HRSA encourages and supports Ryan White HIV/AIDS Program (RWHAP) providers to implement interventions developed through its RWHAP Part F Special Projects of National Significance program and technical assistance initiatives that have been found to be effective, with adaptations for priority populations served as applicable. HRSA disseminates its RWHAP Part F Special Projects of National Significance and technical assistance initiative resources and products across a variety of dissemination channels, hoping to reach a maximum number of RWHAP recipients and subrecipients for whom these resources may meet an important need. This mixed-methods RUDI evaluation will use a web-based survey and virtual site visits to collect information from RWHAP recipients and subrecipients on the uptake, utility, and efficacy of the resources and products HRSA disseminates; the effectiveness of its dissemination processes; and the reach of its dissemination channels. HRSA will use

[2] The CARES Act (Pub. L. 116–136) was enacted on March 27, 2020. The CARES Act amendments to section 506C of the FD&C Act took effect on September 23, 2020. See section 3112(g) of the CARES Act.

the information to identify opportunities for strengthening its dissemination channels and resources to improve care and health outcomes for program participants. A 60-day notice was published in the **Federal Register** on July 12, 2023, Vol. 88, No. 132, pp. 44371–44373 (88 FR 44371). HRSA received no comments.

Need and Proposed Use of the Information: Currently, HRSA does not systematically gather information about the resources accessed by RWHAP providers, RWHAP recipients, or AIDS Education and Training Center (AETC) staff and the extent to which they use those resources to inform implementation of interventions.

The mixed-methods RUDI evaluation will help HRSA systematically assess and understand (1) how, where, and why recipients of RWHAP funding access and use its disseminated resources and products; and (2) the utility and effectiveness of the disseminated resources and products in caring for and treating people with HIV. HRSA will use the findings from the RUDI evaluation to develop strategies to maximize the uptake and impact of its disseminated resources and products, contributing to ending the HIV epidemic in the United States.

Likely Respondents: The mixed-methods RUDI evaluation includes a web-based survey of all RWHAP recipients and subrecipients nationally, individual and small group interviews with a sample of RWHAP recipients, virtual site visits with a sample of RWHAP providers, and individual interviews with all AETCs. The RUDI web-based survey design includes two versions of the survey that will be administered to non-overlapping respondents—the RUDI Recipients Survey for RWHAP Part A and B recipient administrative entities—and the RUDI Providers Survey for Part A and B subrecipients and Part C, D, and F recipients who provide direct care. Both versions ask about respondents' use of HRSA-disseminated resources, how they were helpful, what could be improved, and reasons for non-use where applicable. In addition, the RUDI Recipients Survey asks about the recipients' role in guiding their subrecipients to needed resources, and the RUDI Providers Survey asks about the providers' experience implementing interventions for which they used the resources. Both surveys are designed to be followed up with additional sets of interviews with a sample of the survey respondents to provide deeper understanding of their experience to support development of actionable recommendations pertaining to dissemination. Virtual site visits to RWHAP providers include interviews with an average of three staff within each provider organization that were part of an intervention implementation with assistance from HRSA resources. Individual interviews for Part A and B recipient administrative entities and AETCs will generate a complete picture of how those organizations use HRSA resources and how the resources or their dissemination could be improved for the future, especially when considered together with the survey responses and virtual site visit data from the RWHAP providers.

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

Respondent	Data collection	Number of respondents (RWHAP sites)	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
RWHAP recipients	RUDI—Recipient Survey	56	1	56	0.33	18.48
RWHAP provider	RUDI—Provider Survey	1,066	1	1,066	0.33	351.78
RWHAP recipients	Interviews	20	3	60	0.75	45.00
RWHAP provider	Virtual site visit interviews	40	3	120	1.00	120.00
AETC providers	Interviews	8	1	8	1.00	8.00
		1,190		1,310		543.26

Maria G. Button,

Director, Executive Secretariat.

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BILLING CODE 4165–15–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: Bureau of Health Workforce Performance Data Collection, OMB No. 0915–0061—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 December 18, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA