withdrawal of approval is warranted because the required post-approval confirmatory trial failed to verify clinical benefit and because available evidence demonstrates PEPAXTO is not shown to be safe or effective under its conditions of use. The Oncologic Drugs Advisory Committee (ODAC) convened on September 22, 2022, to discuss issues related to this proposed withdrawal. The ODAC voted 14 to 2 that the benefit-risk profile of melphalan flufenamide was not favorable for the currently indicated patient population. For additional background, please refer to CDER's letter to Oncopeptides Re: Section 506(c)(3)(B) Notice of Proposed Withdrawal of Approval; PEPAXTO (melphalan flufenamide) for injection; NDA 214383 (''Notice to Oncopeptides of Proposed Withdrawal of PEPAXTO'') and CDER's Proposed Withdrawal of PEPAXTO Decisional Memorandum, available at Docket No. FDA–2023–N–3167, *https://www.regulations.gov*.

II. Legal Standard for Withdrawal of Approval

Section 506(c) of the FD&C Act, as amended most recently by the Consolidated Appropriations Act of 2023 (Pub. L. 117–328), describes the accelerated approval of new drug applications and the procedures and authority governing expedited withdrawal of approval. FDA has the legal authority to use the expedited procedures to withdraw approval of a product that has received accelerated approval if, among other reasons, ''a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit'' (section 506(c)(3)(A)(ii) of the FD&C Act) or ''other evidence demonstrates that the product is not shown to be safe or effective under the conditions of use.'' (section 506(c)(3)(A)(iii) of the FD&C Act.)

III. Explanation for the Proposed Withdrawal

CDER proposes to withdraw approval of PEPAXTO because the required confirmatory study, Trial OP–103, also known as OCEAN, failed to verify clinical benefit and because available evidence demonstrates PEPAXTO is not shown to be safe or effective under its conditions of use. More specifically, the results failed to show that PEPAXTO had a significant effect on the primary endpoint of progression-free survival. Furthermore, the observed median overall survival was 5.3 months shorter in the PEPAXTO arm compared to the control arm. After considering all the available data and the discussion at the ODAC held in September 2022, CDER recommends withdrawing the accelerated approval for PEPAXTO. Please refer to CDER's ''Notice to Oncopeptides of Proposed Withdrawal of PEPAXTO'' and ''Proposed Withdrawal of PEPAXTO Decisional Memorandum'' for additional explanation.

IV. Opportunity for Public Comment on CDER's Proposal To Withdraw Approval of PEPAXTO

In accordance with the expedited withdrawal of approval procedures described in section 506(c)(3)(B)(ii) and (iii) of the FD&C Act, CDER is providing an opportunity for public comment on its proposal to withdraw approval of NDA 214383 (PEPAXTO) through the issuance of a **Federal Register** Notice. FDA will consider any such public comments it receives in making its decision on CDER's proposal to withdraw approval of NDA 214383 (PEPAXTO) and make available on its website and in the public docket a summary of such comments and FDA's response to them.

Dated: August 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–18320 Filed 8–24–23; 8:45 am]

BILLING CODE 4164–01–P

Act of 2023 (Pub. L. 117–328); see also 21 CFR 314.510.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Standardized Work Plan Form for Use With Applications to the Bureau of Health Workforce Research and Training Grants and Cooperative Agreements OMB No. 0906–0049—Extension

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 October 24, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 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 Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

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

Information Collection Request Title: Standardized Work Plan (SWP) Form for Use with Applications to the Bureau of Health Workforce (BHW) Research and Training Grants and Cooperative Agreements OMB No. 0906–0049—Extension.

Abstract: BHW requires applicants for training and research grants and cooperative agreements to submit work plans via the SWP form. Information in the SWP describes the timeframes and progress required during the grant period of performance to address each of the needs detailed in the Purpose and Need section of the application, as required in the Notice of Funding Opportunity announcement. Applicants use the SWP form when they submit their proposals, and award recipients and Project Officers use the SWP information to assist in monitoring progress once HRSA makes the awards. After awards are made, recipients complete a Quarterly Progress Update (QPU) to provide information to BHW on a quarterly basis on each activity listed in the SWP.

Need and Proposed Use of the Information: Information collected by the SWP form and QPUs standardizes and streamlines the data used by HRSA in reviewing applications and monitoring awardees. The form asks applicants to provide a description of the activities or steps the applicant will take to achieve each of the objectives proposed during the entire period of performance. The current standardized format and data submission by applicants increases efficiency in reviewing, awarding, and monitoring each project.

The QPU is completed via HRSA's Electronic Handbook system and

prompts recipients to report on progress of activities that were submitted using the SWP in the original application. The QPU automatically populates activities from the recipient's SWP form on a quarterly basis. For each activity listed in the submitted SWP for any particular quarter within the project period, recipients select and submit a single selection response for each activity status from a pull-down menu with five options: Activity is on Schedule, Activity is Complete, Timing is off track, Activity will be missed if action is not taken, and Activity cannot be achieved. Information provided is utilized by the program staff to regularly assess overall progress of program requirements and analyze data in order to monitor award recipient compliance and track progress against proposed targets and goals. Information gathered allows an improved and more efficient method for identifying whether projects' goals are being advanced or achieved, as set forth in 45 CFR 75.342. Program staff also use information provided over the period of performance to see emerging trends and to assess whether an award recipient requires technical assistance to address challenges that the award recipient may be experiencing with the implementation of the project. Seeking OMB extension approval comports with the regulatory requirement imposed by 45 CFR 75.206(a), Paperwork clearances.

Likely Respondents: Respondents are applicants for, and recipients of, BHW's research and training grants and cooperative agreements.

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 annual burden hours
Standardized Work Plan (SWP)	1,000	1	1,000	1.00	1,000
Quarterly Progress Update (QPU) Form	1,000	4	4,000	.10	400
Total	[1] 1,000		5,000		1,400

[1] The 1,000 Standardized Work Plan (SWP) respondents reflects the number of new grant applications submitted annually. The 1,000 Quarterly Progress Update (QPU) respondents reflects the current volume of funded, active grants.

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. 2023–18360 Filed 8–24–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Initial Review Group; Career Development for Established Investigators and Conference Grants Study Section.

Date: October 26–27, 2023.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rajasri Roy, Ph.D., M.P.H., Scientific Review Officer, Scientific Review Branch, National Institutes of Health, National Institute on Aging, 7201 Wisconsin Avenue, RM: 2W200, Bethesda, MD 20892, 301–496–6477, *rajasri.roy@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 21, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–18380 Filed 8–24–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute on Alcohol Abuse and Alcoholism.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Alcohol Abuse and Alcoholism, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute on Alcohol Abuse and Alcoholism.

Date: September 13–14, 2023.

Time: 9:00 a.m. to 5:00 p.m.