portions of your comment referencing any material that is not publicly available. Do not submit comments by email. ATSDR does not accept comments by email.

Donata Green,

Associate Director, Office of Policy, Planning and Partnerships, Agency for Toxic Substances and Disease Registry.

[FR Doc. 2024–09662 Filed 5–2–24; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10844]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by July 2, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number:____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10844 Small Biotech Exception and Biosimilar Delay Information Collection Request (ICR) for Initial Price Applicability Year 2027

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Small Biotech Exception and Biosimilar Delay Information Collection Request (ICR) for Initial Price Applicability Year 2027; *Use:* Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (Pub. L. 117–169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (the Act). The Information Collection Request Forms for the Small Biotech Exception and Biosimilar Delay Information Collection Request for Initial Price Applicability Year 2027 must be submitted to CMS before CMS establishes the selected drug list for initial price applicability year 2027.

Small Biotech Exception: In accordance with section 1192(d)(2) of the Act, the term ''negotiation-eligible drug'' excludes, with respect to the initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets the requirements for the exception for small biotech drugs (the ''Small Biotech Exception,'' or ''SBE''). This information is required in order for CMS to accurately identify whether a given drug meets the criteria for the Small Biotech Exception in accordance with section 1192(d)(2) of the Act. To ensure that only covered Part D drugs that meet the requirements for the SBE are excluded from the term ''negotiation-eligible drug,'' a manufacturer that seeks the SBE for its covered Part D drug (''Submitting Manufacturer'') must submit information to CMS about the company and its products in order for the drug to be considered for the exception. If the Submitting Manufacturer seeks the SBE for a covered Part D drug it acquired after December 31, 2021, the Submitting Manufacturer must also submit information related to the separate entity that had the Medicare Coverage Gap Discount Program agreement for the drug on December 31, 2021. If the Submitting Manufacturer was acquired by another entity after December 31, 2021, the Submitting Manufacturer must provide information regarding that acquiring entity for CMS to assess whether the acquisition triggers the limitation at section 1192(d)(2)(B)(ii) of the Act.

Biosimilar Delay: In accordance with section 1192(f)(1)(B) of the Act, the manufacturer of a biosimilar biological product (''Biosimilar Manufacturer'' of a ''Biosimilar'') may submit a request, prior to the selected drug publication date, for CMS' consideration to delay the inclusion of a negotiation-eligible drug that includes the reference product for the Biosimilar (such a negotiation-eligible drug is herein referred to as a

''Reference Drug'') on the selected drug list for a given initial price applicability year (the ''Biosimilar Delay''). This information is required in order for CMS to accurately determine if a drug meets the criteria for the Biosimilar Delay for initial price applicability year 2027 in accordance with section 1192(f) of the Act. To ensure that the delay of selection and negotiation of biologics is only applied if there is a high likelihood of biosimilar market entry that meets the requirements for the Biosimilar Delay, a Biosimilar Manufacturer that seeks the Biosimilar Delay must submit information to CMS related to the Biosimilar. This information includes identifying information for the Biosimilar and the Reference Drug; the licensure status of the Biosimilar; attestations that the Biosimilar Manufacturer is not the same or treated as the same entity as the Reference Manufacturer, that the Biosimilar Manufacturer and the Reference Manufacturer (who is the manufacturer of the Reference Drug) have not entered into an agreement that requires or incentivizes the Biosimilar Manufacturer to submit the Biosimilar Delay, or directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time; and documentation specified under section 1192(f)(3) of the Act to demonstrate there is a high likelihood of Biosimilar market entry within two years of the statutorily-defined selected drug publication date for initial price applicability year 2027. *Form Number:* CMS–10844 (OMB control number: 0938–1443); *Frequency:* Once; *Affected Public:* Private sector, Business or other for-profit; *Number of Respondents:* 25; *Number of Responses:* 25; *Total Annual Hours:* 415. (For policy questions regarding this collection contact Elisabeth Daniel at 667–290–8793.)

William N. Parham, III

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–09699 Filed 5–2–24; 8:45 am]

BILLING CODE 4120–01–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 Special Emphasis Panel; Lifestyle Intervention for Late-midlife Adults.

Date: May 29, 2024.

Time: 2:00 p.m. to 4:30 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: Janetta Lun, Ph.D., Scientific Review Officer, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue (#213), Bethesda, MD 20814, (301) 827–4588, *janetta.lun@nih.gov.*

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

Dated: April 29, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–09629 Filed 5–2–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meetings

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

The meetings 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 Eye Institute Special Emphasis Panel; Stimulating Access to Research in Residency (StARR) Applications.

Date: June 5, 2024.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700 Rockledge Dr., Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Brian Hoshaw, Ph.D., Designated Federal Official, Division of Extramural Research, National Eye Institute, National Institutes of Health, 6700 B Rockledge Dr., Rockville, MD 20892, 301–451–2020, *hoshawb@mail.nih.gov.*

Name of Committee: National Eye Institute Special Emphasis Panel; BRAIN Initiative-Related Research Education: Short Courses (R25).

Date: June 14, 2024.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700 Rockledge Dr., Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Brian Hoshaw, Ph.D., Designated Federal Official, Division of Extramural Research, National Eye Institute, National Institutes of Health, 6700 B Rockledge Dr., Rockville, MD 20892, 301–451–2020, *hoshawb@mail.nih.gov.*

Name of Committee: National Eye Institute Special Emphasis Panel; Secondary Data Analysis (R21) Applications.

Date: June 25, 2024.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700 Rockledge Dr., Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Brian Hoshaw, Ph.D., Designated Federal Official, Division of Extramural Research, National Eye Institute, National Institutes of Health, 6700 B Rockledge Dr., Rockville, MD 20892, 301–451–2020, *hoshawb@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: April 29, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–09627 Filed 5–2–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

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

The meetings 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