consideration of the matters which were to be the subject of this meeting on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(6), and (c)(9)(B) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b (c)(2), (c)(6), and (c)(9)(B)).

CONTACT PERSON FOR MORE INFORMATION: Requests for further information concerning the meeting may be directed to Debra A. Decker, Executive Secretary of the Corporation, at 202–898–8748.

Dated this the 30th day of April, 2024.

Federal Deposit Insurance Corporation.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2024–09752 Filed 5–1–24; 11:15 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[Docket No. ATSDR–2024–0001]

Availability of Three Draft Toxicological Profiles

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), within the Department of Health and Human Services (HHS), announces the opening of a docket to obtain comments on drafts of three updated toxicological profiles: acrolein, n-hexane, and naphthalene. This action is necessary as this is the opportunity for members of the public and organizations to submit comments on drafts of the profiles. The intended effect of this action is to ensure that the public can note any pertinent additional information or reports on studies about the health effects caused by exposure to the substances covered in these three profiles for review.

DATES: Written comments must be received on or before May 3, 2024.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR–2024–0001 by either of the methods listed below. Do not submit comments by email. ATSDR does not accept comments by email.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Agency for Toxic Substances and Disease Registry, Office of Innovation and Analytics, 4770 Buford Highway, Mail Stop S106–5, Atlanta, GA 30341–3717. Attn: Docket No. ATSDR–2024–0001.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Farhana Rahman, Agency for Toxic Substances and Disease Registry, Office of Innovation and Analytics, 4770 Buford Highway, Mail Stop S106–5, Atlanta, GA 30341–3717; Email: *ATSDRToxProfileFRNs@cdc.gov;* Phone: 770–488–1369 or 1–800–232–4636.

SUPPLEMENTARY INFORMATION: ATSDR has prepared drafts of three updated toxicological profiles based on current understanding of the health effects and availability of new studies and other information since their initial release. All toxicological profiles issued as ''Drafts for Public Comment'' represent the result of ATSDR's evidence-based evaluations of the available literature to provide important toxicological information on priority hazardous substances to the public and health professionals. ATSDR considers key studies for these substances during the profile development process, using a systematic review approach. To that end, ATSDR is seeking public comments and additional information or reports on studies about the health effects of these substances for review and potential inclusion in the profiles. ATSDR will evaluate the quality and relevance of such data or studies for possible inclusion in the profile.

Legislative Background

The Superfund Amendments and Reauthorization Act of 1986 (SARA) (42 U.S.C. 9601 *et seq.*) amended the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund) (42 U.S.C. 9601 *et seq.*) by establishing certain requirements for ATSDR and the U.S. Environmental Protection Agency (EPA) regarding the hazardous substances most commonly found at facilities on the CERCLA National Priorities List. Among these statutory requirements is a mandate for the Administrator of ATSDR to prepare toxicological profiles for each substance included on the priority list of hazardous substances (also called the Substance Priority List (SPL)). This list identifies 275 hazardous substances that ATSDR has determined pose the most significant potential threat to human health. The SPL is available online at *http://www.atsdr.cdc.gov/SPL.* ATSDR is also mandated to revise and publish updated toxicological profiles, as necessary, to reflect updated health effects and other information.

In addition, CERCLA provides ATSDR with the authority to prepare toxicological profiles for substances not found on the SPL. CERCLA authorizes ATSDR to establish and maintain an inventory of literature, research, and studies on the health effects of toxic substances (CERCLA section 104(i)(1)(B); 42 U.S.C. 9604(i)(1)(B)); to respond to requests for health consultations (CERCLA section 104(i)(4); 42 U.S.C. 9604(i)(4)); and to support the site-specific response actions conducted by the agency (CERCLA section 104(i)(6); 42 U.S.C. 9604(i)(6)).

Availability

The draft toxicological profiles and interaction profile are available online at *http://www.regulations.gov,* Docket No. ATSDR–2024–0001 and at *http://www.atsdr.cdc.gov/ToxProfiles.*

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. ATSDR will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. If you submit comments with reference to studies that are not publicly available such as unpublished research, those studies must be attached with your comment for review. Otherwise ATSDR may be unable to respond to

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