Ave., Bldg. 32, Rm. 5157, Silver Spring, MD 20993–0002, 301–796–8695, *shivana.srivastava@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link or call the advisory committee information line to learn about possible modifications about the meeting.

SUPPLEMENTARY INFORMATION: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

Agenda: On July 9, 2025, the PAC will meet to discuss post-marketing pediatric-focused safety reviews of the following products:

1. Center for Devices and Radiological Health
   a. LIPOSORBER LA–15 SYSTEM (Humanitarian Device Exemption (HDE))
   b. MEDTRONIC ACTIVA NEUROSTIMULATOR FOR DYSTONIA TREATMENT (HDE)
   c. MINIMALLY INVASIVE DEFORMITY CORRECTION (MID–C) SYSTEM (HDE)
   d. REFLECT SCOLIOSIS CORRECTION SYSTEM (HDE)
   e. THE TETHER—VERTEBRAL BODY TETHERING SYSTEM (HDE)
2. Center for Biologics Evaluation and Research
   a. DENGVAXIA (Dengue Tetravalent Vaccine, Live)
   b. EPICEL (cultured epidermal autografts) (HDE)
   c. FLUZONE QUADRIVALENT (Influenza Vaccine)
   d. GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant)
3. Center for Drug Evaluation and Research
   a. AUVI–Q AUTO–INJECTOR (epinephrine)
   b. DIOVAN (valsartan)
   c. ENTRESTO (sacubitril and valsartan)
   d. ERAXIS (anidulafungin)
   e. EUCRISA (crisaborole)
   f. EXJADE (deferasirox), JADENU (deferasirox), and JADENU SPRINKLE (deferasirox)
   g. FIASP (insulin aspart)
   h. JAKAFI (ruxolitinib phosphate) and OPZELURA (ruxolitinib)
   i. LATUDA (lurasidone hydrochloride)
   j. LILETTA (levonorgestrel-releasing intrauterine system)
   k. MYCAMINE (micafungin)
   l. NITYR (nitisinone)
   m. POTASSIUM PHOSPHATES (potassium phosphate, dibasic injection; potassium phosphate, monobasic)
   n. REPATHA (evolocumab)
   o. ROZLYTREK (entrectinib)
   p. STELARA (ustekinumab)
   q. SUTENT (sunitinib malate)
   r. TASIGNA (nilotinib)
   s. TOPICORT (desoximetasone)
   t. TRIUMEQ (abacavir, dolutegravir, lamivudine) and TRIUMEQ PD (abacavir, dolutegravir, lamivudine)
   u. XYREM (sodium oxybate)

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before July 2, 2025, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11:30 a.m. ET on July 9, 2025. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 24, 2025. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 25, 2025.

For press inquiries, please contact the HHS Press Room at *www.hhs.gov/press-room/index.html* or 202–690–6343.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Shivana Srivastava (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met. No participant will be prejudiced by this waiver, and the ends of justice will be served by allowing for this modification to FDA's advisory committee meeting procedures.

Dated: June 9, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–10749 Filed 6–12–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1559]

Rare Disease Innovation, Science, and Exploration Public Workshop Series; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following request for comments for a future public workshop series entitled ''Rare disease Innovation, Science, and Exploration (RISE) Workshop.'' The purpose of the public workshops will be to focus on challenges that are common to multiple diseases or a class of diseases, and for which evolving science offers innovative solutions. The workshops will primarily focus on cross-cutting or common issues and will not be focused on any specific product under review by the Agency.

DATES: Submit either electronic or written comments by December 31, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 31, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2025–N–1559 for ''Rare Disease Innovation, Science, and Exploration Public Workshop Series; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA' posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Philipa Friedman, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–7911, and *RDInnovationHub@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Background

The FDA is publishing this request for comments to obtain suggestions for topics for future RISE Workshops. The FDA Rare Disease Innovation Hub (Hub) supports the RISE Workshop series pursuant to its commitment to further advance regulatory science of rare disease therapies and the Agency's PDUFA VII commitments to enhance regulatory science and expedite drug development and rare disease product review under the Food, Drug, and Cosmetic Act.

The Hub-sponsored RISE workshop series focuses on challenges that are common to multiple diseases or a class of diseases, and for which evolving science offers innovative solutions. The workshops are open to the public and designed for interaction and discourse between the various rare disease community members and perspectives, including drug developers, patient and disease organizations, academics, FDA regulators and reviewers, and relevant staff from other federal agencies. All workshops include coordination between the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) and address the Centers' approaches to the relevant issues. The workshops also include a discussion of the role of patients and patient/disease organizations in the design and implementation of innovative solutions. The workshops primarily focus on cross-cutting or common issues and will not be focused on any specific product under review by the Agency. Preference will be given to submissions that are germane to multiple disease states and/or that are submitted jointly by two or more entities.

The Agency requests that submissions include:

—a description of the proposed topic;
—suggested speakers and/or subject matter experts;
—a description of the impact of the topic on the development and regulatory science of rare disease therapies;
—the disease state(s) affected by the challenge highlighted in the submission;

—if relevant, related FDA guidances or existing programs addressing the challenge highlighted in the submission.

Notice of this meeting series is given pursuant to 21 CFR 10.65.

Dated: June 9, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–10801 Filed 6–12–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Sudden Unexpected Infant Death Prevention

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

ACTION: Announcing period of performance extension with funding for the Sudden Unexpected Infant Death (SUID) Prevention Program.

SUMMARY: HRSA will provide additional award funds to the one recipient of the SUID Prevention Program with period of performance ending in fiscal year 2025 to extend the current period of performance by 12 months to continue the activities of the program related to reducing infant deaths.

FOR FURTHER INFORMATION CONTACT: Diane Pilkey, Senior Nurse Consultant, Division of Child Adolescent and Family Health, Maternal and Child Health Bureau, Health Resources and Services Administration, at *dpilkey@hrsa.gov* and 301–500–9637.

SUPPLEMENTARY INFORMATION:

Intended Recipient(s) of the Award: American Academy of Pediatrics (AAP).

Amount of Non-Competitive Award(s): One Award of $500,000.

Project Period: July 1, 2025, through June 30, 2026.

Assistance Listing (CFDA) Number: 93.110.

Award Instrument: Cooperative Agreement.

Authority: This non-competitive supplemental funding is authorized by 42 U.S.C. 701(a)(2) (title V, sec. 501(a)(2) of the Social Security Act).

Purpose/Justification: HRSA will provide a non-competitive supplement of $500,000 to the SUID Prevention Program recipient, AAP, to extend the period of performance by an additional year, July 1, 2025, to June 30, 2026, to connect families with the resources that they need and to help improve family capacity to practice safe sleep. This Program was awarded on July 1, 2022, for a 3-year period (HRSA 22–082). The purpose of the program is to reduce overall rates of SUID by supporting pediatric health care practitioners to provide evidence-based counseling and education to infant caregivers and families; to guide system improvements; and to identify and support policy changes that address state- and community-specific SUID risks. The awardee has demonstrated progress during this period and will be able to expand that progress if extended by 1 year.

Funds are available for award for this non-competitive supplement. A non-competitive supplement is necessary to ensure on time, high-quality implementation of best practices for reducing infant deaths that the current recipient is uniquely positioned to continue. The recipient is in good standing with current HRSA grant requirements and has been a leader in Sudden Infant Death Syndrome (SIDS) and SUID prevention for decades, starting with the initial Back to Sleep campaign in the 1990s that urged parents and caregivers to place infants to sleep supine following the emergence of data that supported this recommendation. More recently, the AAP Task Force on SIDS has published comprehensive recommendations for the prevention of SIDS, Accidental Suffocation and Strangulation in Bed, and other sleep-related deaths, based on a detailed and impartial analysis of all available evidence. In addition, AAP directs several initiatives aimed at improving child health outcomes.

The current recipient will use their existing infrastructure to maintain implementation without disruption and they are the only organization with a unique existing network of practicing pediatricians and related professionals who are part of a National Safe Sleep Champion Network, a network of pediatrician experts in safe sleep to promote safe sleep recommendations and education for providers to better serve families.

The recipient will be expected to ensure continued efforts around reducing infant deaths by disseminating and implementing best practices, increasing connections with state and local infant fatality review teams and AAP Chapters, supporting implementation of a community engagement toolkit, and expanding their National Safe Sleep Champion Network.

Thomas J. Engels,

Administrator.

[FR Doc. 2025–10738 Filed 6–12–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0278]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before July 14, 2025.

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 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Natalie Klein, *Natalie.Klein@hhs.gov* or (240) 453–6900. When submitting comments or requesting information, please include the document identifier 0990–0278–30D and project title, Federalwide Assurance (FWA) Form, for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

Title of the Collection: Federalwide Assurance (FWA) Form.

Type of Collection: Revision.

OMB No.: 0990–0278.

Abstract: The Office of the Assistant Secretary for Health, Office for Human