I. Background

In the United States, approximately 5.5 million pregnancies occur each year (Ref. 1). Half of individuals who are pregnant use at least one drug or biological product to treat chronic (*e.g.,* diabetes, seizure disorders, or asthma), acute (*e.g.,* infection) or serious medical conditions (Ref. 2). Typically at the time of initial market approval, there are limited to no human data on the safety of drug or biological products used during pregnancy. As a result, for most products, human pregnancy safety data are collected after a product is available on the market (*i.e.,* postapproval).

In May 2019, FDA published a draft Guidance for Industry entitled ''Postapproval Pregnancy Safety Studies'' (available at *https://www.fda.gov/media/124746/download*), which discusses the strengths and limitations of postapproval study types including studies based on registry data and cohort studies using electronic health records or claims data. However, more research is needed to better understand the key considerations for determining the optimal postapproval study designs to obtain timely evidence to ensure the safe use of drug and biological products in pregnant individuals. The public workshop is a preliminary discussion with stakeholders to inform FDA's further development of a framework and also meets a performance goal under the FDA User Fee Reauthorization Act of 2022, in accordance with the Prescription Drug User Fee Act (PDUFA) Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027 letter (PDUFA VII Commitment Letter), which is available at *https://www.fda.gov/media/151712/download.* Specifically, the PDUFA VII Commitment Letter outlines the commitment of a public workshop to discuss postapproval pregnancy safety studies to facilitate determination of ideal study designs.

II. Topics for Discussion at the Public Workshop

The public workshop will include the following topics for discussion:

1. FDA's considerations for constructing a framework describing how data from different types of post-market pregnancy safety studies might optimally be used.
2. Stakeholders' perspectives on opportunities to optimize postapproval pregnancy safety study types and designs.
3. Design considerations and potential approaches to bridge knowledge gaps in developing the framework, including understanding how the Sentinel Initiative (*i.e.,* Sentinel System and Biologics Effectiveness and Safety (BEST)) may address these gaps.
4. Stakeholders' perspectives on considerations for FDA's proposed framework.

Meeting updates, the agenda, and background materials (if any) will be made available at *https://duke.is/nj5kg* prior to the workshop.

III. Participating in the Public Workshop

Registration: To register for this hybrid public workshop, please visit the following website: *https://duke.is/nj5kg.* Please provide complete contact information for each attendee, including attendance format (in-person or virtual), name, title, affiliation, and email. Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by 10 a.m. Eastern Daylight Time, September 18, 2023. Early registration is recommended due to limited seating; therefore, FDA may limit the number of participants from each organization. Registrants will receive a confirmation email when they have been registered.

If you need special accommodations due to a disability, please contact Luke Durocher, Duke-Margolis Center for Health Policy, 202–621–2800, *margolisevents@duke.edu,* no later than 5 p.m. Eastern Time, September 5, 2023.

Requests for Oral Comments: During online registration, you may indicate if you wish to speak during a public comment session. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and request a time for joint commentary. All requests to make oral comments must be received by 11:59 p.m. Eastern Time on September 5, 2023. FDA will determine the amount of time allotted to each commenter and the approximate time each comment is to begin and will select and notify participants by September 11, 2023.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed by the Dockets Management Staff.

IV. References

The following references marked with an asterisk (*) have been placed on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

*1. Centers for Disease Control and Prevention, National Center for Health Statistics. ''U.S. Pregnancy Rates Drop During Last Decade.'' Hyattsville (MD); 2023 April 12, Available from: *https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2023/20230412.htm.*

2. Mitchell, A.A, S.M. Gilboa, M.M. Werler, et al. ''Medication Use During Pregnancy, with Particular Focus on Prescription Drugs: 1976–2008.'' *American Journal of Obstetrics & Gynecology* 2011;205:51.e1–8.

Dated: August 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17718 Filed 8–16–23; 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; Biographical Sketch Form for Use With Applications to the Maternal and Child Health Bureau Research Grants OMB No. 0906—Reinstatement

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 September 18, 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 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 Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Forms for Use with Applications to the Maternal and Child Health Bureau Research Grants, OMB 0906—Reinstatement

Abstract: HRSA is requesting reinstatement of the Biographical Sketch Form for use with applications to the Maternal and Child Health Bureau Research Grants (Biographical Sketch) for HRSA's SF424 Research & Related application package. These grants are funded by a number of authorities such as 42 U.S.C. 701(a)(2) (title V, 501(a)(2) of the Social Security Act) and by 42 U.S.C. 280i–1(f) (title III, section 399BB(f) of the Public Health Service Act. The purpose of these grants is to advance the health and well-being of Maternal and Child Health populations and children and adolescents with autism spectrum disorder by supporting innovative, applied, and translational intervention research studies on critical issues affecting these populations.

A 60-day notice published in the **Federal Register** on March 1, 2023, vol. 88, No. 40; pp. 12953–54. There were no public comments.

Need and Proposed Use of the Information: HRSA plans to use the Biographical Sketch as a required element of the SF424 Research & Related application package. The applicants use the Biographical Sketch form to summarize the qualifications of each key personnel on their proposed research team, including education/training, positions and honors, contributions to science, and related experience. The grant reviewers will use this information to assess the capabilities of the research team to carry out the planned research project. The Biographical Sketch form also collects demographic data for the Principal Investigator and key program staff. HRSA is considering several changes for the Biographical Sketch:

- *Clarifying instructions:* Provides the applicant more information on what should and should not be included on the biographical sketch.
- *Removal of Section D:* Section D: Related Experience has been removed.
- *Removal of Section E:* Section E: Additional Information: Research Support and/or Scholastic Performance Awards has been removed.
- ''*Some Other Race*'' *Category:* At the request of our applicants, this category was added.

Likely Respondents: Respondents are applicants to HRSA's Maternal and Child Health Bureau research programs.

Burden Statement: Burden includes 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, disclosing and providing information. It also accounts for time to train personnel, respond to a collection of information, search data sources; complete and review the collection of information, and 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 burden hours
Biographical Sketch Form	200	5	1,000	1.75	1,750
Total	200	5	1,000	1.75	1,750

Amy P. McNulty,

Deputy Director, Executive Secretariat.

[FR Doc. 2023–17636 Filed 8–16–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice; Licensing and Collaboration Opportunity

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is directed to potential peptidyl therapeutics that counteract with amyloid forming IAPP and amyloid-β in treatments of diabetes and Alzheimer's disease and serve as blood-based biomarkers for Alzheimer's disease. This technology was discovered and is being developed by the National Institute on Aging (NIA). The NIA is currently seeking a licensee and/or collaborator to further develop this technology.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this licensing and collaboration opportunity should be directed to: Zarpheen Jinnah, Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702 Telephone: (240) 276–5530; Facsimile: (240) 276–5504 Email: *zarpheen.jinnah@nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to this invention.

SUPPLEMENTARY INFORMATION: The following patent application is available for licensing and/or collaboration under a Cooperative Research and Development Agreement (CRADA):

U.S. Provisional Application No. 63/417,582.

Achieving expeditious commercialization of federally funded research and development is consistent with the goals of the Bayh-Dole Act, codified as 35 U.S.C. 200–212.

Background and Description of Technology: Over 34 million Americans are living with diabetes and an estimated 6.5 million Americans are living with Alzheimer's disease (AD). A