Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 301–796–6985, *CBERVRBPAC@fda.hhs.gov; or* FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting. For press inquiries, please contact the Office of Media Affairs at 301–796–4540 or *fdaoma@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 4, 2024 (89 FR 15590), FDA announced that a meeting of the Vaccines and Related Biological Products Advisory Committee would be held on May 16, 2024. On page 15590, in the second column, the **SUMMARY** and **DATES** portions of the document are changed to read as follows:

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. On June 5, 2024, the Committee will meet in open session to discuss and make recommendations on the selection of the 2024 to 2025 formula for COVID–19 vaccines. The meeting will be open to the public.

DATES: The meeting will be held virtually on June 5, 2024, from 8:30 a.m. to 4:30 p.m. EST. This notice is issued under the Federal Advisory Committee Act 5 U.S.C. 1001 *et seq*. and 21 CFR part 14, relating to the advisory committees.

Dated: May 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–11216 Filed 5–21–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0001]

Evaluating Immunosuppressive Effects of In Utero Exposure to Drug and Biologic Products; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Evaluating Immunosuppressive Effects of In Utero Exposure to Drug and Biologic Products.'' The purpose of the public workshop is to discuss transplacental transfer of drug and biological products with immunosuppressive properties and the potential clinical impact on the developing fetus and newborn infant, understand the gaps in knowledge, and consider innovative approaches to improve collection of relevant data.

DATES: The public workshop will be held on July 11, 2024, from 9 a.m. to 5 p.m. Eastern Time and on July 12, 2024, from 9 a.m. to 1 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus and online. Entrance for the registered public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.*

FOR FURTHER INFORMATION CONTACT: Meshaun Payne and Michelle Pollack, Office of New Drugs Public Meeting Support Team, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6466, Silver Spring, MD 20993–0002, 301–796–6668, *ONDPublicMTGSupport@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Drug and biological products are widely used in various therapeutic areas during pregnancy to treat various conditions. Some products can be actively or passively transported across the placenta from a pregnant individual to their fetus. When this occurs for products with immunosuppressive properties, it is biologically plausible that these products can exert immunosuppressive effects on the developing fetus and newborn infant. Historically, pregnant individuals have generally been excluded from clinical trials, resulting in a paucity of data available on transplacental transfer and its potential consequences to the developing fetus and newborn infant. This lack of data poses challenges in providing adequate information in product labeling to help prescribers and patients make informed decisions about use of these products during pregnancy.

II. Topics for Discussion at the Public Workshop

Pregnant individuals may have chronic and/or acute conditions that need to be treated, and published data show that most pregnant individuals take at least one medication (excluding vitamins) during pregnancy. Therefore, understanding the safety of medications when used during pregnancy is important. The main objective of the ''Evaluating Immunosuppressive Effects of In Utero Exposure to Drug and Biologic Products'' workshop is to discuss the available data on the placental transfer of drug and biological products with immunosuppressive effects and the potential clinical impact on infants exposed in utero, identify gaps in knowledge, and explore innovative and practical approaches for collection of relevant data. In addition, the workshop will allow for an open dialogue among regulators, academia, industry, and patient organizations regarding the potential safety concerns of medicines that may need to be used during pregnancy and approaches to data collection.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://lu.ma/5vdmbibm.* Please register by July 10, 2024, at 11:59 p.m. Eastern time. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by July 10, 2024, at 11:59 p.m. Eastern time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Brittany Witcher, OND Public Meeting Support Team at *ONDPublicMTGSupport@fda.hhs.gov* no later than July 1, 2024.

Streaming Webcast of the Public Workshop: This public workshop will also be streamed virtually via Zoom. Virtual attendees may register at the following website to receive the Zoom link: *https://lu.ma/5vdmbibm.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

Transcripts and Recordings: Please be advised that as soon as transcripts and recordings of the public workshop are available, they will be accessible on the FDA event web page *https://www.fda.gov/drugs/news-events-*

human-drugs/evaluating-immunosuppressive-effects-utero-exposure-drug-and-biologic-products-07112024. The transcripts and recordings will also be accessible at *https://www.regulations.gov* and may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: May 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–11228 Filed 5–21–24; 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 Request: National Survey of Organ Donation Attitudes and Practices, OMB No. 0915–0290

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 June 21, 2024.

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 a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: National Survey of Organ Donation Attitudes and Practices, OMB No. 0915–0290—Revision.

Abstract: The overall purpose of this study is to conduct an independent multi-mode (web and telephone) survey of public opinion regarding various issues related to organ donation. The survey will measure public opinion on issues such as willingness to become an organ donor, financial incentives for donation, living donation, impediments to donation, and level of public knowledge about donation. Previous National Survey of Organ Donation Attitudes and Practices were conducted during 1993, 2005, 2012, and 2019. Similar to the 2019 survey, the goal is to complete 10,000 interviews with adults (18 years of age or older) nationwide. Specifically, this will include 1,000 equal-probability of selection method computer-assisted telephone interviewing (CATI) interviews, 1,000 ethnic oversamples CATI interviews, and a supplemental web panel of 8,000 respondents. The final sample will include 1,000 interviews each with Black or African Americans, Asian Americans, Hispanic/Latino Americans, and American Indian/Alaskan Natives, and a statistically sufficient sample for meaningful comparisons across demographic levels of age group, education, and income groups. A total sample of 10,000 is necessary to achieve sufficiently large subgroups for statistical analysis across demographic groups.

A 60-day notice published in the **Federal Register** on January 18, 2024, vol. 89, No. 12; pp. 3409–3410. There were no public comments.

Need and Proposed Use of the Information: The Division of Transplantation, within the Health Systems Bureau of HRSA at the Department of Health and Human Services, is the primary federal entity responsible for oversight of the solid organ and blood stem cell transplant systems in the United States and for initiatives to increase organ donor registration and donation. Sponsorship of a national survey on the American public's donation attitudes and practices is one of the services that Division of Transplantation provides for the larger donation community, consistent with its legal authority to establish a public education and awareness program (Section 377A of the Public Health Service Act, 42 U.S.C. 274f–1).

Patients in need of organ transplantation in the United States face a longstanding critical shortage of organs. Approximately 103,000 Americans were on the waiting list for transplantation by the end of 2022, but only 42,000 transplants were performed, which only meets two-fifths of the national need. While this represents an increase from the number of transplants performed in 2021, the organ shortage remains in the United States. Understanding public attitudes about organ donation and how the attitudes change over time is critical to addressing organ shortage through public awareness and education efforts.

The information from this survey will facilitate appropriate tailoring and targeting of donation outreach messages and strategies and provide an overall assessment of the impact of previous outreach messages and strategies. The data will also inform the development of policy related to organ donation and transplantation.

Likely Respondents: A nationally representative sample of adults over the age of 18 with a higher number of responses from populations of interest such as racial-ethnic minorities, including Black or African American, Asian American, American Indian/Alaskan Native, and Hispanic/Latino American respondents, as well as respondents of all age groups and education levels.

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.