

a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for a particular device panel. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

IV. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Nomination must include a current, complete résumé or curriculum vitae for each nominee including current business address and telephone number, email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). Nominations must also specify the advisory panel for which the nominee is recommended. Nominations

must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the particular device panels listed in table 1. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees, and therefore encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*), relating to advisory committees.

Dated: May 16, 2024.

Lauren K. Roth,
Associate Commissioner for Policy.

[FR Doc. 2024–11178 Filed 5–21–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2021–N–0403, FDA–2023–N–4181, and FDA–2021–N–0584]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRASStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB Control No.	Date approval expires
Food Additives; Food Contact Substances Notification System	0910–0495	4/30/2027
Cattle Materials Prohibited From Use in Animal Food or Feed	0910–0627	4/30/2027
Standardized Reporting Forms for Federally Funded Public Health Projects and Agreements	0910–0909	4/30/2027

Dated: May 16, 2024.

Lauren K. Roth,
Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0970]

Vaccines and Related Biological Products Advisory Committee; Amendment of Notice—Selection of the 2024 to 2025 Formula for COVID–19 Vaccines

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Vaccines and Related Biological Products Advisory Committee. This meeting was announced in the **Federal Register** of March 4, 2024. The amendment is being made to reflect a change in the meeting date in the **SUMMARY** and **DATES** portions of the document from May 16, 2024, to June 5, 2024. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Kathleen Hayes or Prabhakara Atreya, Center for Biologics Evaluation and

Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993-0002, 301-796-6985, CBERVBPAC@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]

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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: Meshawn 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/5vdmibim>. 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/5vdmibim>. 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->