4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0001]

Scientific and Ethical Considerations for the Inclusion of Pregnant Women in Clinical Trials; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing a public meeting that will be convened by Duke University's Robert J. Margolis Center for Health Policy and supported by a cooperative agreement with FDA. The meeting, entitled "Scientific and Ethical Considerations for the Inclusion of Pregnant Women in Clinical Trials," is intended to gather industry, patient, clinician, researcher, institutional review board, ethicist, professional society and other stakeholder input on the scientific and ethical issues that surround the inclusion of pregnant women in clinical trials for drug development.

DATES: The public meeting will be held on February 2, 2021, from 12 p.m. to 4 p.m. Eastern Time and February 3, 2021, from 12 p.m. to 3 p.m. Eastern Time. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be a Zoom virtual meeting.

FOR FURTHER INFORMATION CONTACT: Jasmine Smith, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, at ONDPublicMTGSupport@fda.hhs.gov or 301-796-0621; or Catherine Sewell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5360, Silver Spring, MD 20993-0002, Fax: 301-796-9897.

SUPPLEMENTARY INFORMATION:

I. Background

FDA endorses an informed and balanced approach to gathering data informing the safe and effective use of drugs and biological products in pregnancy through judicious inclusion of pregnant women in clinical trials and careful attention to potential fetal risk. Input from this meeting will help provide information on the development of therapies for pregnancy-specific conditions and for general medical conditions that occur in women of childbearing age and who require treatment during pregnancy. This meeting supports the objectives of The Task Force on Research Specific to Pregnant Women and Lactating Women, which was established by section 2041 of the 21st Century Cures Act (Pub. L. 114-255), to provide advice and guidance on activities related to identifying and addressing gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.[1] Input from this meeting may also help further inform the finalization of FDA's draft guidance entitled "Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials" (https://www.fda.gov/media/112195/download, also see 83 FR 15161 (April 9, 2018)).

II. Topics for Discussion at the Public Meeting

The meeting will allow participants (including industry, clinicians, patients, researchers, institutional review boards, ethicists, professional societies and other stakeholders) to provide input on key topics, including:

- Key areas of unmet needs for therapeutic development or clinical data in obstetrics
- The regulatory, scientific, and ethical considerations and challenges in the enrollment of pregnant women in clinical research

For more information on the meeting topics and discussion questions, visit https://healthpolicy.duke.edu/events/scientific-and-ethical-considerations-inclusion-pregnant-women-clinical-trials. FDA will publish a discussion guide outlining background information on the topic areas to this website approximately 2 weeks before the meeting date. FDA will also

[1] https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf

post the agenda and other meeting materials to this website approximately 5 business days before the meeting.

The format of the public meeting will consist of a series of presentations, panel discussions, and open discussion.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: https://healthpolicy.duke.edu/events/scientific-and-ethical-considerations-inclusion-pregnant-women-clinical-trials. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free. Persons interested in attending this public meeting must register. Registrants will receive confirmation once they have been accepted. Registered participants will be sent technical system requirements in advance of the event. We recommend that you review these technical system requirements prior to joining the virtual public meeting. The meeting will be recorded, and the recording will be available after the meeting.

There will be live closed captioning for the event. If you need other special accommodations due to a disability, by January 25, 2021, please contact Jasmine Smith, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, at ONDPublicMTGSupport@fda.hhs.gov or 301-796-0621; or Catherine Sewell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5360, Silver Spring, MD 20993-0002, Fax: 301-796-9897.

FDA has verified the website addresses in this document as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that transcripts of the public meeting will be available by February 8, 2021, at the event page https://healthpolicy.duke.edu/events/scientific-and-ethical-considerations-inclusion-pregnant-women-clinical-trials.

Dated: December 14, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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