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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled "Scientific and Ethical Considerations for the Inclusion of Pregnant Women in Clinical Trials." The meeting will be convened by Duke University's Robert J. Margolis, Center for Health Policy (Duke-Margolis) and supported by a cooperative agreement with FDA. The meeting 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 April 16, 2020, from 9 a.m. to 5 p.m. See the SUPPLEMENTARY INFORMATION section for registration information.

ADDRESSES: The public meeting will be held at the National Press Club Main Ballroom, 529 14th St NW, Washington, DC 20045.

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 such information on the development of therapies for pregnancy-specific conditions and for general medical conditions that occur in women of childbearing age and require treatment during pregnancy. This meeting supports the objectives of The Task Force on Research Specific to Pregnant Women and Lactating Women ("Task Force" or "PRGLAC") 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 FDA's work toward the finalization of the Agency's draft guidance: Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials (83 FR 15161, April 6, 2018).

II. Topics for Discussion at the Public Meeting

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

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 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 and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation once they have been accepted. If

time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, 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.

Persons attending FDA's meetings are advised that FDA is not responsible for providing access to electrical outlets.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast and archived video footage will be available at the event website. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. Persons interested in viewing the live webcast are encouraged to register in advance. You will be asked to indicate in your registration if you plan to attend in person or via the webcast. Please register for the webcast by visiting https://healthpolicy.duke.edu/events/scientific-and-ethical-considerations-inclusion-pregnant-women-clinical-trials.

Registered webcast participants will be sent technical system requirements in advance of the event. It is recommended that you review these technical system requirements prior to joining the streaming webcast of the public meeting.

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 not be available.

Dated: March 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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