nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: December 14, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28054 Filed 12–18–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1866]

Wockhardt Ltd., et al.; Withdrawal of Approval of Nine Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice entitled ''Wockhardt Ltd., et al.; Withdrawal of Approval of Nine Abbreviated New Drug Applications'' that appeared in the **Federal Register** on October 9, 2020. The document announced the withdrawal of approval (as of November 9, 2020) of nine abbreviated new drug applications (ANDAs) from multiple applicants. The document indicated that FDA was withdrawing approval of the following ANDA after receiving a withdrawal request from VistaPharm, Inc., 7265 Ulmerton Rd., Largo, FL 33771: ANDA 077788, Albuterol Sulfate Syrup, Equivalent to 2 milligrams base/5 milliliters. Before FDA withdrew the approval of this ANDA, VistaPharm, Inc., informed FDA that it did not want the approval of the ANDA withdrawn. Because VistaPharm, Inc., timely requested that approval of this ANDA not be withdrawn, the approval of ANDA 077788 is still in effect.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 9, 2020 (85 FR 64150), in FR Doc. 2020–22403, the following correction is made:

On page 64150, in the table, the entry for ANDA 077788 is removed.

Dated: December 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28081 Filed 12–18–20; 8:45 am]

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

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