

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]

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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FDA withdrew the approval of this ANDA, VistaPharm, Inc., informed FDA that it did not want the approval of the ANDA withdrawn. Because VistaPharm, Inc., timely requested that approval of this ANDA not be withdrawn, the approval of ANDA 077788 is still in effect.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]

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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.

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.

[FR Doc. 2020-28069 Filed 12-18-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Scientific Registry of Transplant Recipients; Information Collection Effort for Potential Donors for Living Organ Donation OMB No. 0906-0034—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has 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 January 20, 2021.

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 30-day 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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Scientific Registry of Transplant Recipients Information Collection Effort for Potential Donors for Living Organ Donation, OMB No. 0906-0034—Extension.

Abstract: The Scientific Registry of Transplant Recipients (SRTR) is administered under contract with HRSA, a sub agency of HHS. HHS is

authorized to establish and maintain mechanisms to evaluate the long-term effects associated with living organ donations (42 U.S.C. 273a) and is required to submit to Congress an annual report on the long-term health effects of living donation (42 U.S.C. 273b). In 2018, the SRTR contractor implemented a pilot living donor registry in which transplant programs registered all potential living organ donors who provide informed consent to participate in the pilot registry. The SRTR's authority to collect information concerning potential living organ donors is set forth in the HHS organ procurement and transplantation network regulation, 42 CFR part 121, requiring organ procurement organizations and transplant hospitals to submit to the SRTR, as appropriate, information regarding "donors of organs" and "other information that the Secretary deems appropriate" (42 CFR 121.11(b)(2)).

In 2018, an updated version of the data collection instrument was approved. The data collection modifications improve the quality of the data and reduce the administrative burden for respondents.

A 60-day notice published in the **Federal Register** on September 8, 2020, vol. 85, No. 174; pp. 55464-65. There were no public comments.

Need and Proposed Use of the Information: The transplant programs submit health information collected at the time of donation evaluation through a secure web-based data collection tool developed by the contractor. The SRTR contractor maintains contact with registry participants and collects data on long-term health outcomes through surveys. The data collection includes outcomes of evaluation, including reasons for non-donation. The living donor registry is an ongoing effort, and the goal is to continue to collect data on living organ donor transplant programs in the United States over time. Monitoring and reporting of long-term health outcomes of living organ donors post-donation will continue to provide useful information to transplant programs in their future donor selection process and aid potential living organ donors in their decision to pursue living donation.

There were minor revisions to the burden per response as it has decreased from the current amount due to improvements to the efficiency of the processes used by programs for data submission, as well as the tools provided for program use by SRTR.

Likely Respondents: Potential living donors, transplant programs, medical