(dobutamine hydrochloride), eq 12.5 mg base/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that DOBUTREX (dobutamine hydrochloride), eq 12.5 mg base/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of DOBUTREX (dobutamine hydrochloride), eq 12.5 mg base/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list DOBUTREX (dobutamine hydrochloride), eq 12.5 mg base/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28080 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–2018–N–0417]

Request for Nominations of Voting Members on a Public Advisory Committee; National Mammography Quality Assurance Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the National Mammography Quality Assurance Advisory Committee in the Center for Devices and Radiological Health. Nominations will be accepted for upcoming vacancies effective February 1, 2021, with this notice. 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.

DATES: Nominations received on or before February 19, 2021, will be given first consideration for membership on the National Mammography Quality Assurance Advisory Committee. Nominations received after February 19, 2021, will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be submitted electronically by logging into the FDA Advisory Nomination Portal at *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: *Regarding all nomination questions for membership:* Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993, 301–796–0400, *Aden.Asefa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members to fill upcoming vacancies on the National Mammography Quality Assurance Advisory Committee.

I. General Description of the Committee Duties

The National Mammography Quality Assurance Advisory Committee advises the Commissioner of Food and Drugs (the Commissioner) or designee on: (1) Developing appropriate quality standards and regulations for mammography facilities; (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (3) developing regulations with respect to sanctions; (4) developing procedures for monitoring compliance with standards; (5) establishing a mechanism to investigate consumer complaints; (6) reporting new developments concerning breast imaging that should be considered in the oversight of mammography facilities; (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

II. Criteria for Voting Members

The committee consists of a core of 15 members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among physicians, practitioners, and other health professionals, whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography. Almost all non-Federal members of this committee serve as Special Government Employees. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address, telephone number, and email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the

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.*