IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance have been approved under OMB control numbers 0910–0284 and 0910–0645.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

VI. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: October 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24152 Filed 10–8–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Science Advisory Board to the National Center for Toxicological Research Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Science Advisory Board (SAB) to the National Center for Toxicological Research (NCTR).

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 6, 2014, from 8:15 a.m. to 4:15 p.m. and on November 7, 2014, from 8 a.m. to 2 p.m.

Location: NCTR SAB, 3900 NCTR Rd., Conference Room B–12, Jefferson, AR 72079.

Contact Person: Donna Mendrick, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 2208, Silver Spring, MD 20993–0002, 301–796–8892, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On November 6, 2014, the NCTR Director will welcome the participants and provide a Center-wide update on scientific initiatives and accomplishments during the past year. The SAB will be presented with an overview of the Division of Microbiology Subcommittee and the Subcommittee Site Visit Report. Following the public session, the SAB will hear an update from each of NCTR's research Divisions, the Office of Science Coordination, followed by an update on NCTR's Global Interactions.

On November 7, 2014, the Office of the Chief Scientist will update the SAB on their research needs, and discuss opportunities for collaboration to help address these needs, followed by a report from the National Toxicology Program of the National Institutes of Environmental Health Sciences on current and future collaboration.

The Center for Biological Evaluation and Research, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, the Center for Veterinary Medicine, the Center for Tobacco Products, the Office of Regulatory Affairs, and the Center for Food Safety and Applied Nutrition will each briefly discuss their Center-specific research strategic needs.

Following an open discussion of all the information presented, the open session of the meeting will close so that SAB members can discuss personnel issues at NCTR.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 30, 2014. Oral presentations from the public will be scheduled between approximately 12 noon to 1 p.m. on November 6, 2014. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 22, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 23, 2014.

Closed Committee Deliberations: On November 7, 2014, from 12 noon to 2 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

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

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Donna

Mendrick at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Date: September 30, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–24039 Filed 10–8–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 6, 2014, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Caleb Briggs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31 Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: During the morning session, the committee will discuss new drug application (NDA) 205353, panobinostat capsules, application submitted by Novartis Pharmaceuticals Corporation. The proposed indication (use) for this product is in combination with bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy.

During the afternoon session, the committee will discuss NDA 206317, ferric pyrophosphate solution, for administration via hemodialysis dialysate, application submitted by Rockwell Medical, Inc. The proposed indications (uses) for this product are for the treatment of iron loss or iron deficiency to maintain hemoglobin in adult patients with hemodialysis-dependent stage 5 chronic kidney disease and to reduce the prescribed dose of erythropoiesis stimulating agent required to maintain desired hemoglobin levels.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 23, 2014. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 3:30 p.m. to 4 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 15, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 16, 2014.

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

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Caleb Briggs at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

September 30, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–24038 Filed 10–8–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0394]

Request for Nominations for Voting Members on a Public Advisory Committee; Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.