ntp.niehs.nih.gov/, select "Nominations to the Testing Program").

The NTP invites interested parties to submit written comments, provide supplementary information, or present oral comments at the BSC meeting on the nominated substances and preliminary study recommendations (*see* "Request for Comments" below). The NTP welcomes toxicology study information from completed, ongoing, or anticipated studies, as well as information on current U.S. production levels, use or consumption patterns, human exposure, environmental occurrence, or public health concerns for any of the nominated substances. The NTP is interested in identifying appropriate animal and non-animal experimental models for mechanistic-based research, including genetically modified rodents and high-throughput *in vitro* test methods, and as such, solicits comments regarding the use of specific *in vivo* and *in vitro* experimental approaches to address questions relevant to the nominated substances and issues under consideration. Although the deadline for submission of written comments to be considered at the BSC meeting is November 16, 2010 (*see* "Request for Comments" above), the NTP welcomes comments or additional information on these study nominations at any time.

To facilitate review of the proposed research project by the BSC and the public, NTP staff developed a draft research concept document for the nomination recommended for study. A research concept is a brief document outlining the nomination or study rationale, and the significance, study approach, and expected outcome of a proposed research program tailored for each nomination. The purpose of a research concept is to outline the general elements of a program of study that would address the specific issues that prompted the nomination and the preliminary study recommendations. A research concept may also encompass larger public health issues or topics in toxicology that could be appropriately addressed through studies on the nominated substance(s). Draft research concepts should be available on the BSC meeting page (*http://ntp.niehs.nih.gov/go/165*) by October 19, 2010.

Background Information on the NTP Board of Scientific Counselors

The BSC is a technical advisory body comprised of scientists from the public and private sectors that provides primary scientific oversight to the NTP. Specifically, the BSC advises the NTP on matters of scientific program content, both present and future, and conducts periodic review of the program for the purpose of determining and advising on the scientific merit of its activities and their overall scientific quality. Its members are selected from recognized authorities knowledgeable in fields such as toxicology, pharmacology, pathology, biochemistry, epidemiology, risk assessment, carcinogenesis, mutagenesis, molecular biology, behavioral toxicology, neurotoxicology, immunotoxicology, reproductive toxicology or teratology, and biostatistics. Members serve overlapping terms of up to four years. The BSC usually meets biannually.

Dated: October 5, 2010.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2010–26023 Filed 10–18–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Endocrinologic and Metabolic 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: Endocrinologic and Metabolic 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 December 7, 2010, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 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 "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings".

Contact Person: Paul Tran, 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: 301–847–8540, e-mail: *paul.tran@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512536. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On December 7, 2010, the committee will discuss the safety and efficacy of new drug application (NDA) 20–0063, proposed tradename CONTRAVE (naltrexone HCl/bupropion HCl) extended-release tablets, manufactured by Orexigen Therapeutics, Inc., for the treatment of obesity and weight management, including weight loss and maintenance of weight loss in patients with an initial body mass index (BMI) of equal to or greater than 30 kilograms (kg) per square meter, or a BMI equal to or greater than 27 kg per square meter with one or more risk factors (*e.g.* diabetes, dyslipidemia, or hypertension). The BMI is a measure of body weight (mass) based on a person's weight and height, and is a widely-used tool for doctors in assessing optimum weights for a patient.

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 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 November 22, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make 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 November 12, 2010. 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 November 15, 2010.

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 Paul Tran 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).

Dated: October 14, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–26251 Filed 10–18–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–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 December 2, 2010, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 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 "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings".

Contact Person: Nicole Vesely, 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, e-mail: *Nicole.vesely@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 301–451–2542. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On December 2, 2010, during the morning session, the committee will discuss biologics license application (BLA) 125377, with the proposed trade name Yervoy (ipilimumab), manufactured by Bristol-Myers Squibb Company. The proposed indication (use) for this product is for the treatment of advanced melanoma in patients who have received prior therapy. During the afternoon session, the committee will discuss new drug application (NDA) 022–405, with the proposed trade name Zictifa (vandetanib) Tablets, manufactured by iPR Pharmaceuticals, Inc., represented by AstraZeneca Pharmaceuticals LP (authorized U.S. agent). The proposed indication (use) for this product is for the treatment of patients with unresectable (non-operable) locally advanced or metastatic medullary thyroid cancer.

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 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 November 16, 2010. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m. and between approximately 3:30 p.m. and 4 p.m. Those desiring to make 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 November 8, 2010. 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 November 9, 2010.

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 Nicole Vesely 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).

Dated: *October 14, 2010.*

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–26247 Filed 10–18–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0487]

Product Development Program for Interventions in Patients With Severe Bleeding Due to Trauma or Other Causes; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a 2-day public workshop entitled "Product Development Program for Interventions in Patients with Severe Bleeding Due to Trauma or Other Causes." The purpose of this public workshop is to discuss possible paradigms for the evaluation of products indicated for use to stop severe bleeding. The workshop has been planned in partnership with the Department of Health and Human Services, Office of Public Health and Science; the National Heart, Lung and Blood Institute; and the Department of Defense. The public workshop will include presentations and panel discussions by experts from academic institutions, government agencies, and industry.

Dates and Times: The public workshop will be held on December 9, 2010, from 8 a.m. to 5:30 p.m. and December 10, 2010, from 8 a.m. to 1 p.m.

Location: The public workshop will be held at the Masur Auditorium, 10 Center Dr., Bldg. 10, Clinical Center, National Institutes of Health, Bethesda, MD 20892.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike,