

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]

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## 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](mailto: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]

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## 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,

suite 200N, Rockville, MD 20852-1448, 301-827-6129, FAX: 301-827-2843, e-mail: rhonda.dawson@fda.hhs.gov.

**Registration:** Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person (see *Contact Person*) by November 19, 2010. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space-available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *CONTACT PERSON*) at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** Severe bleeding may be encountered in both traumatic and non-traumatic clinical situations. New products for the treatment of severe bleeding are needed to reduce the need for blood transfusions, minimize complications resulting from blood loss, and improve patient outcomes. The development and approval of new products for use in treatment of severe bleeding, particularly severe bleeding resulting from trauma, has been complicated by the lack of a consensus definition of severe bleeding as well as the need to identify appropriate clinical endpoints for assessment of product safety and efficacy. Clinical endpoints may vary depending on the product indications, patient characteristics, nature of injury, whether the product acts locally or systemically, the nature of the product (e.g., device, drug, biologic, or combination), and conditions of use.

Because it may not always be feasible to obtain standard informed consent, clinical trials of products used for the treatment of life-threatening severe bleeding resulting from trauma may raise significant ethical and legal considerations. Researchers studying products for use in such circumstances may need guidance to carry out appropriate consultation with representatives of the communities in which the clinical investigation will be conducted and from which the study participants will be selected. Clinical trials on products intended for use in trauma are also complicated by the difficulty of identifying patients who may meet study inclusion criteria. Given these challenges, further discussion is needed about how products approved for use for treatment of severe bleeding occurring during surgery or due to non-surgical conditions may best be evaluated for use

in treatment of severe bleeding in trauma.

The first day of the workshop will include presentations and panel discussions on the following topics: (1) Current clinical scientific knowledge concerning the pathophysiology of trauma and assessment of severe bleeding; (2) currently available locally acting and systemic products used to treat severe bleeding in trauma and non-trauma settings; (3) animal models for pre-clinical evaluation of products; (4) ethical considerations for clinical trials to evaluate products used in treatment of severe bleeding in trauma; and (5) clinical evaluation of products for bleeding interventions, including clinical trials and endpoints. The second day of the workshop will include a discussion of whether products with an indication for use in severe bleeding due to trauma can be evaluated in clinical settings other than a trauma clinical trial and a summary of the sessions presented at the workshop.

**Transcripts:** Please be advised that as soon as a transcript is available, it can be obtained in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm>.

Dated: October 13, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-26212 Filed 10-18-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial

property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Institute of Neurological Disorders and Stroke Special Emphasis Panel, SPOTRIAS.

**Date:** December 15, 2010.

**Time:** 8 a.m. to 5 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call.)

**Contact Person:** Richard D. Crosland, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Room 3208, MSC 9529, Bethesda, MD 20892-9529. 301-496-0635. [Rc218u@nih.gov](mailto:Rc218u@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: October 13, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-26321 Filed 10-18-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Medicinal Chemistry.

**Date:** November 9-10, 2010.

**Time:** 8 a.m. to 5 p.m.

**Agenda:** To review and evaluate contract proposals.