

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Subcommittee for Dose Reconstruction Reviews (SDRR), Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention, announces the following meeting for the aforementioned subcommittee:

*Time and Date:* 9:30 a.m.–5 p.m., January 7, 2010.

*Place:* Cincinnati Airport Marriott, 2395 Progress Drive, Hebron, Kentucky 41018. Telephone (859) 334-4611, Fax (859) 334-4619.

*Status:* Open to the public, but without a public comment period. To access by conference call dial the following information at 1 (866) 659-0537, Participant Pass Code 9933701.

*Background:* The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2011.

*Purpose:* The Advisory Board is charged with (a) Providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have

endangered the health of members of this class. The Subcommittee for Dose Reconstruction Reviews was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction.

*Matters To Be Discussed:* The agenda for the Subcommittee meeting includes: discussion of dose reconstruction cases under review (sets 6–9); OCAS dose reconstruction quality management and assurance activities.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

*Contact Person for More Information:* Theodore Katz, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road, Mailstop E-20, Atlanta GA 30333, Telephone (513) 533-6800, Toll Free 1 (800) CDC-INFO, E-mail [ocas@cdc.gov](mailto:ocas@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: December 3, 2009.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. E9-29976 Filed 12-16-09; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0664]

#### 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 February 10, 2010, from 8 a.m. to 5 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy, Gaithersburg, MD. The hotel phone number is 301-977-8900.

*Contact Person:* Nicole Vesely, Pharm.D., Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-6793, FAX: 301-827-6776, 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 3014512542. 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 February 10, 2010, during the morning session, the committee will discuss new drug application (NDA) 022-481, proposed trade name PIXUVRI (pixantrone dimaleate) injection, manufactured by Cell Therapeutics, Inc. The proposed indication (use) for this product is as a single agent treatment for patients with recurring or refractory (difficult to treat), aggressive non-Hodgkin's lymphoma (NHL) who have received two or more prior lines of therapy.

During the afternoon session, the committee will discuss NDA 022-374, proposed trade name OMAPRO (omacetaxine mepesuccinate) for injection, manufactured by ChemGenex Pharmaceuticals. The proposed indication (use) for this product is for the treatment of adults with chronic myeloid leukemia (CML) bearing a genetic alteration known as the Bcr-Abl T315I mutation, and who have failed prior therapy with the drug IMATINIB.

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 January 27, 2010. 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 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 January 19, 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 January 20, 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: December 11, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9-29989 Filed 12-16-09; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Notice of Meeting: Secretary's Advisory Committee on Genetics, Health, and Society

Pursuant to Public Law 92-463, notice is hereby given of the twenty-first meeting of the Secretary's Advisory

Committee on Genetics, Health, and Society (SACGHS), U.S. Public Health Service. The meeting will be held from 8:30 a.m. to approximately 5:30 p.m. on Thursday, February 4, 2010, and from 8 a.m. to approximately 3 p.m. on Friday, February 5, 2010, at the Omni Shoreham Hotel, 2500 Calvert Street, NW., Washington, DC 20008. The meeting will be open to the public with attendance limited to space available. The meeting also will be Web cast.

The main agenda items involve the review of a revised report on gene patents and licensing practices, the review of a public consultation draft report on genetics education and training, and an information-gathering session on the mechanisms and policies related to genomic data sharing. Other agenda items include a preliminary discussion to help plan a future session on implications of an affordable genome; a report on activities of the Clinical Utility and Comparative Effectiveness Task Force; and updates from Federal agencies on activities related to the implementation of the Genetic Information Nondiscrimination Act, the coverage and reimbursement of genetic tests, the oversight of genetic testing, and the retention and use of residual dried blood spot specimens after newborn screening.

As always, the Committee welcomes hearing from anyone wishing to provide public comment on any issue related to genetics, health, and society. Individuals who would like to provide public comment should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301-496-9838 or e-mail at [carrs@od.nih.gov](mailto:carrs@od.nih.gov). The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892. Anyone planning to attend the meeting who needs special assistance, such as sign language interpretation or other reasonable accommodations, is also asked to contact the Executive Secretary.

Under authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic and genomic technologies and, as warranted, to provide advice on these issues. The draft meeting agenda and other information about SACGHS, including information about access to the Web cast, will be available at the following Web site: [http://oba.od.nih.gov/SACGHS/sacghs\\_meetings.html](http://oba.od.nih.gov/SACGHS/sacghs_meetings.html).

Dated: December 10, 2009.

**Jennifer Spaeth,**

*Director, NIH Office of Federal Advisory Committee Policy.*

[FR Doc. E9-30023 Filed 12-16-09; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

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 meetings.

The meetings 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 material, 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 Allergy and Infectious Diseases Special Emphasis Panel, Transplant and Viruses.

*Date:* January 11, 2010.

*Time:* 1 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817. (Telephone Conference Call.)

*Contact Person:* Priti Mehrotra, PhD, Chief, Immunology Review Branch, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700B Rockledge Drive, Room 3138, Bethesda, MD 20892-7616, 301-435-9369, [pm158b@nih.gov](mailto:pm158b@nih.gov).

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel, "B Lymphocyte Responses."

*Date:* January 12, 2010.

*Time:* 12:30 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817. (Telephone Conference Call.)

*Contact Person:* Wendy F. Davidson, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIH/NIAID/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892-7616, 301-402-8399, [davidsonw@niaid.nih.gov](mailto:davidsonw@niaid.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)