

notify PCPID Policy Analyst, Madjid (MJ) Karimi, via email at [MJ.Karimie@acf.hhs.gov](mailto:MJ.Karimie@acf.hhs.gov), or via telephone at 202-619-0634. Special accommodations needed must be received no later than Friday, August 03, 2012. PCPID will attempt to meet requests for accommodations made after that date, but cannot guarantee ability to grant requests received after this deadline.

**Agenda:** Discussion plans for developing the PCPID 2012 Report to the President.

**Additional Information:** For further information, please contact Laverdia Taylor Roach, Senior Advisor, President's Committee for People with Intellectual Disabilities, The Aerospace Center, Second Floor West, 370 L'Enfant Promenade SW., Washington, DC 20447. Telephone: 202-619-0634. Fax: 202-205-9519. Email: [Laverdia.Roach@acf.hhs.gov](mailto:Laverdia.Roach@acf.hhs.gov).

**SUPPLEMENTARY INFORMATION:** PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services, through the Administration on Intellectual and Developmental Disabilities, on a broad range of topics relating to programs, services, and supports for persons with intellectual disabilities. The PCPID Executive Order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (a) Expansion of educational opportunities; (b) promotion of homeownership; (c) assurance of workplace integration; (d) improvement of transportation options; (e) expansion of full access to community living; and (f) increasing access to assistive and universally designed technologies.

Dated: July 6, 2012.

**Sharon Lewis,**

*Commissioner, Administration on Intellectual and Developmental Disabilities.*

[FR Doc. 2012-17450 Filed 7-20-12; 8:45 am]

**BILLING CODE 4184-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

### Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** 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:** Cardiovascular and Renal Drugs Advisory Committee.

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

**DATES:** The meeting will be held on September 14, 2012, from 8 a.m. to 5 p.m.

**ADDRESSES:** **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 "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

**FOR FURTHER INFORMATION CONTACT:**

**Contact Person:** Kalyani Bhatt, 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: [CRDAC@fda.hhs.gov](mailto:CRDAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. 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.

**SUPPLEMENTARY INFORMATION:**

**Agenda:** The committee will discuss new drug application (NDA) 203446, imatinib mesylate, submitted by Novartis Pharmaceuticals Corp., as adjunctive therapy for the treatment of pulmonary arterial hypertension (WHO Diagnostic Group 1), to improve exercise capacity and cardiopulmonary hemodynamics in patients who remain

symptomatic despite treatment with two or more approved vasodilator therapies ("vasodilator therapies" refer to medicines used to dilate blood vessels and thereby reduce resistance to blood flow).

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 August 29, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 August 21, 2012. 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 August 22, 2012.

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 Kalyani Bhatt 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: July 17, 2012.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2012-17881 Filed 7-20-12; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Advisory Committee on Organ Transplantation; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

*Name:* Advisory Committee on Organ Transplantation (ACOT).

*Date and Time:* August 28, 2012, 8:00 a.m. to 4:30 p.m. Eastern Daylight Time.  
*Place:* Rockville Hilton Hotel, 1750 Rockville Pike, Rockville, MD 20852.

*Status:* The meeting will be open to the public.

*Purpose:* Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12 (2000), ACOT was established to assist the Secretary in enhancing organ donation, ensuring that the system of organ transplantation is grounded in the best available medical science, and assuring the public that the system is as effective and equitable as possible, and, thereby, increasing public confidence in the integrity and effectiveness of the transplantation system. ACOT is composed of up to 25 members, including the Chair. Members are serving as Special Government Employees and have diverse backgrounds in fields such as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members.

*Agenda:* The Committee will hear reports including those from the three ACOT Work Groups: Declining Rates of Donation/Geographical and Other Variations in Organ Distribution, Alignment of CMS Regulatory Requirements with OPTN and HRSA, and Brain Death Determination. Agenda items are subject to change as priorities indicate.

After Committee discussion, members of the public will have an opportunity to comment. Because of the Committee's full agenda and timeframe in which to cover the

agenda topics, public comment will be limited. All public comments will be included in the record of the ACOT meeting. Meeting summary notes will be posted on the Department's donation Web site at <http://www.organdonor.gov/legislation/advisory.html#meetings>.

The draft meeting agenda will be posted on <https://www.team-psa.com/ACOT/Summer2012/>. In order to register for this meeting, please visit the Meeting Registration Page. The deadline to register is August 13, 2012. For all logistical questions and concerns, please contact Brittany Carey of PSA at 703-889-9033 or [bcarey@exploreprsa.com](mailto:bcarey@exploreprsa.com).

*Public Comment:* Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Passy Tongele, DoT, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 12C-06, 5600 Fishers Lane, Rockville, Maryland 20857 or email at [ptongele@hrsa.gov](mailto:ptongele@hrsa.gov). Requests should contain the name, address, telephone number, email address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative.

The allocation of time may be adjusted to accommodate the level of expressed interest. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may request it at the time of the public comment period. Public participation and ability to comment will be limited to space and time as it permits.

*For Further Information Contact:* Patricia Stroup, Executive Secretary, ACOT, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 12C-06, Rockville, Maryland 20857; telephone (301) 443-1127.

Dated: July 13, 2012.

**Jennifer Riggle,**

*Deputy Director, Office of Management.*

[FR Doc. 2012-17830 Filed 7-20-12; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Public Comment Period Extension for the Final Supplementary Risk Assessment for the Boston University (BU) National Emerging Infectious Diseases Laboratories (NEIDL)

**SUMMARY:** A Notice of Availability for the Final Supplementary Risk Assessment for the Boston University (BU) National Emerging Infectious Diseases Laboratories (NEIDL) was published in the **Federal Register** on July 6, 2012. Upon the publication of the Notice of Availability, a required comment period of at least 30 day began in which the National Institutes of

Health would accept and consider comments from the public on the final supplementary risk assessment. This comment period was set to end on August 6, 2012. In order to provide the public with additional time to review and comment on the final supplementary risk assessment, the National Institutes of Health (NIH) has decided to extend the public comment period for the final supplementary risk assessment until August 24, 2012.

**ADDRESSES:** Written comments on the final supplementary risk assessment must be postmarked no later than August 24, 2012. Comments should be sent to The National Institutes of Health, Office of Biotechnology Activities, Attn: NEIDL Risk Assessment, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland, 20892. Email comments should be sent to [NIH\\_BRP@od.nih.gov](mailto:NIH_BRP@od.nih.gov). Please note that comments sent by email must be received by 11:59 p.m. on the last day of the comment period, August 24, 2012.

#### FOR FURTHER INFORMATION CONTACT:

National Institutes of Health Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland, 20892. Telephone number: (301) 496-9838. Electronic mail address: [NIH\\_BRP@od.nih.gov](mailto:NIH_BRP@od.nih.gov).

*Availability of Copies and Electronic Access:* Copies of the Final Supplementary Risk Assessment for the Boston University National Emerging Infectious Diseases Laboratory and the accompanying reader's guide may be obtained at no cost by calling (301) 496-9838, or by emailing requests to [NIH\\_BRP@od.nih.gov](mailto:NIH_BRP@od.nih.gov). The documents are also available electronically at: <http://nihblueribbonpanel-bumc-neidl.od.nih.gov/default.asp>.

A copy of the final supplementary risk assessment and the reader's guide has also been made available for review at each of the following locations: Central Branch of the Boston Public Library, 700 Boylston Street, Boston, MA; South End Library, 685 Tremont Street, Boston, MA; Grove Hall Library, 42 Geneva Avenue; and Dudley Library, 65 Warren Street, Boston, MA.

Dated: July 18, 2012.

**Ryan T. Bayha,**

*Science Policy Analyst, Office of Science Policy, National Institutes of Health.*

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