

(FDA). The meeting will be open to the public.

*Name of Committee:* Pediatric 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 Wednesday, September 16, 2015, from 8:30 a.m. to 5:30 p.m.

*Location:* Double Tree by Hilton, 8727 Colesville Rd., Silver Spring, MD 20910, 301-589-5200. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://doubletree3.hilton.com/en/hotels/maryland/doubletree-by-hilton-hotel-washington-dc-silver-spring-DCASSDT/index.html>.

*Contact Person:* Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 301-796-0885, email: [walter.ellenberg@fda.hhs.gov](mailto:walter.ellenberg@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:* On September 16, 2015, the Pediatric Advisory Committee (PAC) will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107-109) and the Pediatric Research Equity Act (Pub. L. 108-155). The PAC will meet to discuss the following products:

1. DUREZOL (difluprednate ophthalmic emulsion) 0.05%, Phenylephrine Hydrochloride Ophthalmic Solution,
2. ZYLET (loteprednol etabonate and tobramycin ophthalmic suspension),
3. BETHKIS (tobramycin Inhalation Solution),
4. INTELENCE (etravirine),
5. PREZISTA (darunavir),
6. VIRAMUNE XR (nevirapine),
7. EPIDUO (adapalene and benzoyl peroxide),
8. EXJADE (deferasirox),
9. DOTAREM (gadoterate meglumine),
10. FYCOMPA (perampanel),

11. RECOTHROM (thrombin, topical [recombinant]),

12. PREVNAR 13 (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM<sub>197</sub> Protein]),

13. PLEXIMMUNE,

14. ELANA SURGICAL KIT (HUD),

15. BERLIN HEART EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE (VAD),

16. ENTERRA THERAPY SYSTEM, and

17. CONTEGRA Pulmonary Valved Conduit.

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 September 8, 2015. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.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 September 1, 2015. 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 September 8, 2015.

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 Walter Ellenberg 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: August 5, 2015.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2015-19729 Filed 8-11-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; 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:* Center for Scientific Review Special Emphasis Panel; Hypertension and Microcirculation.

*Date:* September 15, 2015.

*Time:* 10:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Katherine M. Malinda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7814, Bethesda, MD 20892, 301-435-0912, [Katherine\\_Malinda@csr.nih.gov](mailto:Katherine_Malinda@csr.nih.gov).

*Name of Committee:* Digestive, Kidney and Urological Systems Integrated Review Group; Clinical, Integrative and Molecular Gastroenterology Study Section.

*Date:* September 28, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

*Contact Person:* Mushtaq A. Khan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2176, MSC 7818, Bethesda, MD 20892, 301-435-1778, [khanm@csr.nih.gov](mailto:khanm@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 7, 2015.

**Anna Snouffer,**

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

[FR Doc. 2015-19802 Filed 8-11-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; 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 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 on Aging Special Emphasis Panel; Male Osteoporosis.

*Date:* September 9, 2015.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Ave., Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Alicja L. Markowska, Ph.D., DSC, Scientific Review Branch, National Institute On Aging, 7201 Wisconsin Avenue, Suite 2c212, Bethesda, MD 20892, 301-496-9666, [markowska@nia.nih.gov](mailto:markowska@nia.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 7, 2015.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-19784 Filed 8-11-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; 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:* Vascular and Hematology Integrated Review Group; Hypertension and Microcirculation Study Section.

*Date:* September 14-15, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Marriott Wardman Park Washington DC Hotel, 2660 Woodley Road NW., Washington, DC 20008

*Contact Person:* Ai-Ping Zou, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301-408-9497, [zouai@csr.nih.gov](mailto:zouai@csr.nih.gov).

*Name of Committee:* Cardiovascular and Respiratory Sciences Integrated Review Group; Lung Injury, Repair, and Remodeling Study Section.

*Date:* September 21-22, 2015.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

*Contact Person:* Ghenima Dirami, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7814, Bethesda, MD 20892, 240-498-7546, [diramig@csr.nih.gov](mailto:diramig@csr.nih.gov).

*Name of Committee:* Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Sensorimotor Integration Study Section.

*Date:* September 22, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Embassy Suites DC Convention Center, 900 10th Street NW., Washington, DC 20001.

*Contact Person:* John Bishop, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408-9664, [bishopj@csr.nih.gov](mailto:bishopj@csr.nih.gov).

*Name of Committee:* Genes, Genomes, and Genetics Integrated Review Group; Molecular Genetics B Study Section.

*Date:* September 28-29, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

*Contact Person:* Richard A Currie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892, (301) 435-1219, [currieri@csr.nih.gov](mailto:currieri@csr.nih.gov).

*Name of Committee:* Vascular and Hematology Integrated Review Group; Atherosclerosis and Inflammation of the Cardiovascular System Study Section.

*Date:* September 28-29, 2015.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

*Contact Person:* Natalia Komissarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, 301-435-1206, [komissar@mail.nih.gov](mailto:komissar@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 6, 2015.

**Carolyn Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-19735 Filed 8-11-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; 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