

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 FDA's website at <https://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 committees will discuss new drug application 022324, oxycodone extended-release capsules, submitted by Pain Therapeutics, with the proposed indication of the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The product is intended to have abuse-deterrent properties based on its physicochemical properties. The committees will be asked to discuss whether the data submitted by the Applicant are sufficient to support labeling of the product with the properties expected to deter abuse.

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 website 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 website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* On June 26, 2018, from 9:30 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before June 12, 2018, will be provided to the committees. Oral presentations from the public will be scheduled between approximately between 1:30 p.m. and 2:30 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 June 4, 2018. 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 June 5, 2018.

*Closed Committee Deliberations:* On June 26, 2018, from 8 a.m. to 9:30 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). During this session, the committees will discuss the drug development program of an investigational opioid formulation with properties designed to deter abuse.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Yinghua Wang (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://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: May 21, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-11166 Filed 5-23-18; 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, 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; Small Business: Cancer Biotherapeutics Development.

*Date:* June 18, 2018.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.  
*Contact Person:* Nicholas J. Donato, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040, Bethesda, MD 20892, 301-827-4810, [nick.donato@nih.gov](mailto:nick.donato@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Neuromusculoskeletal Injury Rehabilitation.

*Date:* June 19, 2018.

*Time:* 2:00 p.m. to 4:00 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:* Srikanth Ranganathan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7802, Bethesda, MD 20892, 301-435-1787, [srikanth.ranganathan@nih.gov](mailto:srikanth.ranganathan@nih.gov).

*Name of Committee:* Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Cellular Aspects of Diabetes and Obesity Study Section.

*Date:* June 20-21, 2018.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Sheraton Orlando North, 600 N Lake Destiny Drive, Maitland, FL 32751.

*Contact Person:* Antonello Pileggi, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6166, Bethesda, MD 20892-7892, (301) 402-6297, [pileggia@csr.nih.gov](mailto:pileggia@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Cellular Aspects of Diabetes and Obesity.

*Date:* June 20, 2018.

*Time:* 11:30 a.m. to 12:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Sheraton Orlando North, 600 N Lake Destiny Drive, Maitland, FL 32751.

*Contact Person:* Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, EMNR IRG, Center

for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6182 MSC 7892, Bethesda, MD 20892, 301 435-2514, [riverase@csr.nih.gov](mailto:riverase@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Infectious Diseases and Microbiology.

*Date:* June 20, 2018.

*Time:* 2:00 p.m. to 4:00 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:* John C. Pugh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7808, Bethesda, MD 20892, (301) 435-2398, [pughjohn@csr.nih.gov](mailto:pughjohn@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA-CA-17-036: HTAN Data Coordination Center (U24).

*Date:* June 20, 2018.

*Time:* 12:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Craig Giroux, Ph.D., Scientific Review Officer, BST IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5150, Bethesda, MD 20892, 301-435-2204, [girouxcn@csr.nih.gov](mailto:girouxcn@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR15-315: CounterAct Exploratory Grants.

*Date:* June 21, 2018.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Monaco Baltimore, 2 North Charles Street, Baltimore, MD 21201.

*Contact Person:* Geoffrey G. Schofield, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040-A, MSC 7850, Bethesda, MD 20892, 301-435-1235, [geoffreys@csr.nih.gov](mailto:geoffreys@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Review of Neuroscience AREA Grant Applications.

*Date:* June 21-22, 2018.

*Time:* 8:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Westin Georgetown, 2350 M Street NW, Washington, DC 20037.

*Contact Person:* Richard D. Crosland, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7850, Bethesda, MD 20892, 301-694-7084, [crosland@nih.gov](mailto:crosland@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Computational, Modeling and Biodata Management.

*Date:* June 21, 2018.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Allen Richon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7892, Bethesda, MD 20892, 301-379-9351, [allen.richon@nih.hhs.gov](mailto:allen.richon@nih.hhs.gov).

*Name of Committee:* Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurotransmitters, Receptors, and Calcium Signaling Study Section.

*Date:* June 21-22, 2018.

*Time:* 8:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* St. Gregory Hotel, 2033 M Street NW, Washington, DC 20036.

*Contact Person:* Peter B. Guthrie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4182, MSC 7850, Bethesda, MD 20892, (301) 435-1239, [guthriep@csr.nih.gov](mailto:guthriep@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Physiology and Pathobiology of Cardiovascular and Respiratory Systems.

*Date:* June 21-22, 2018.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites Alexandria Old Town, 1900 Diagonal Road, Alexandria, VA 22314.

*Contact Person:* Eugene Carstea, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4130, MSC 7818, Bethesda, MD 20892, (301) 408-9756, [carsteae@csr.nih.gov](mailto:carsteae@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Biomedical Sensing, Measurement and Instrument.

*Date:* June 21, 2018.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

*Contact Person:* Inna Gorshkova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-435-1784, [gorshkoi@csr.nih.gov](mailto:gorshkoi@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Societal and Ethical Issues in Research.

*Date:* June 21, 2018.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Karin F. Helmers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7770, Bethesda, MD 20892, 301-254-9975, [helmersk@csr.nih.gov](mailto:helmersk@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: May 18, 2018.

**Sylvia L. Neal,**

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

[FR Doc. 2018-11080 Filed 5-23-18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting of the NHLBI Heart, Lung, and Blood Program Project Review Committee.

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:* Heart, Lung, and Blood Initial Review Group; Heart, Lung, and Blood Program Project Review Committee.

*Date:* June 15, 2018.

*Time:* 8:00 a.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:* Jeffrey H. Hurst, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7208, Bethesda, MD 20892, 301-435-0303, [hurstj@nhlbi.nih.gov](mailto:hurstj@nhlbi.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 17, 2018.

**Michelle D. Trout,**

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

[FR Doc. 2018-11081 Filed 5-23-18; 8:45 am]

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