

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 25, 2013, the committee will discuss optimal strategies for the evaluation, interpretation, and communication of drug-drug interaction (DDI) information. FDA will seek input on: (1) Best practices in DDI communication through prescription drug product labels (i.e., "package inserts"), namely: (a) Appropriate format for presentation (e.g. tables, graphs, text) of DDI information; (b) level of detail of DDI study results; and (c) appropriate wording for clinical recommendations based on empirical data versus anticipated interactions; (2) appropriate criteria for determining whether or not to describe DDI information derived from the literature in product labels; and (3) how package insert information on DDIs is used by various end-users (e.g., prescribers, dispensers, DDI database curators) in decision making and/or communication.

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 11, 2013. Oral presentations from the public will be scheduled between approximately 12:45 p.m. and 1:45 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 September 3, 2013. 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 4, 2013.

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 Yvette Waples 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 12, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

## 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 (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 Heart, Lung, and Blood Institute Special Emphasis Panel; Research Dissemination and Implementation & Sleep Education Projects.

**Date:** August 26, 2013.

**Time:** 12:30 p.m. to 6:00 p.m.

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

**Place:** Crystal Gateway Marriott, 1700 Jefferson Davis Highway, Arlington, VA 22202.

**Contact Person:** Keith A. Mintzer, Ph.D., Scientific Review Officer, Office of Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7186, Bethesda, MD 20892-7924, 301-594-7947 [mintzerk@nhlbi.nih.gov](mailto:mintzerk@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: July 12, 2013.

**Michelle Trout,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

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**Name of Committee:** National Heart, Lung, and Blood Institute Special Emphasis Panel; Pediatric Pulmonary Vascular Disease Bioinformatics Clinical Coordinating Center.

**Date:** August 29, 2013.

**Time:** 9:30 a.m. to 12:00 p.m.

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

**Place:** National Institutes of Health, 7182, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

**Contact Person:** Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge