

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-0001]

#### Cardiovascular and Renal 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:* Cardiovascular and Renal 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 April 15, 2015, from 8 a.m. to 4 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

*Contact Person:* Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20903-0002, 301-796-9001, FAX: 301-847-8533, [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). 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:* The committee will discuss new drug application New Drug Application 204958, cangrelor injection, submitted by The Medicines Company, for the proposed indication of reduction of thrombotic cardiovascular events

including stent thrombosis (events related to blood clots in a stent, a device inserted to keep the artery open) in patients with coronary artery disease undergoing percutaneous coronary intervention (PCI). PCI refers to the opening of narrowed blood vessels supplying the heart muscle by a balloon inserted through an artery puncture with or without a stent.

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 meeting 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 April 1, 2015. 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 March 24, 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 March 25, 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 Kristina Toliver 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: February 24, 2015.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2015-04128 Filed 2-26-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-0001]

#### The 2015 Office of Regulatory Science and Innovation Science Symposium

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

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: The 2015 Office of Regulatory Science and Innovation (ORSI) Science Symposium.

The purpose of the public workshop is to increase scientific collaborations with government institutions, academia, industry and other stakeholders, working to improve science, training, and networking in accordance with the FDA mission of the advancement of regulatory science. This venue will also enhance knowledge and awareness of the FDA ORSI resources and provide guidance of its available services.

*Date and Time:* The public workshop will be held on Monday, April 27, 2015, from 8:15 a.m. to 5:30 p.m.

*Location:* The public workshop will be held at the FDA White Oak Campus located at 10903 New Hampshire Ave., Bldg. 31, Great Room, Silver Spring, MD 20903. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm> or contact us at [2015ORSIScienceSymposium@fda.hhs.gov](mailto:2015ORSIScienceSymposium@fda.hhs.gov).

**Contact Person:** Diane Rose, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 1, Rm. 4233, Silver Spring, MD 20993. 301-796-9600, [diane.rose@fda.hhs.gov](mailto:diane.rose@fda.hhs.gov).

**Registration:** On-line registration is required (including name, title, affiliation, address, email, telephone and FAX numbers) by April 15, 2015. Those without Internet access should contact Diane Rose (see **Contact Person**) to register. There is no fee for the public workshop. Early registration is recommended as seating is limited to the first 300 registrants. Registration on the day of the public workshop will be provided on a space available basis from 7:45 a.m. to 8:15 a.m. provided the 300-person registration limit has not been met. Please register at: [https://www.eventbrite.com/e/2015-orsi-science-symposium-tickets-14591440391?utm\\_campaign=new\\_event\\_email&utm\\_medium=email&utm\\_source=eb\\_email&utm\\_term=viewmyevent\\_button](https://www.eventbrite.com/e/2015-orsi-science-symposium-tickets-14591440391?utm_campaign=new_event_email&utm_medium=email&utm_source=eb_email&utm_term=viewmyevent_button) or email us at [2015ORSIScienceSymposium@fda.hhs.gov](mailto:2015ORSIScienceSymposium@fda.hhs.gov) if you have additional questions. A lite breakfast and lunch are available for pre-purchase.

If you need special accommodations due to a disability, please contact Diane Rose (see **Contact Person**) at least 7 days in advance.

**Streaming Webcast of the Public Workshop:** This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online or call us at 301-796-9600 by April 15, 2015. Early registration is recommended because Webcast lines are limited. Organizations are required to register all participants, but to view the Webcast using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after April 23, 2015. If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit <http://inside.fda.gov:9003/ora/southwestregion/dallas/ucm234468.htm>. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Dated: February 20, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-04123 Filed 2-26-15; 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; Member Conflict: Pathways, Biomarkers in Addiction and Schizophrenia.

**Date:** March 12, 2015.

**Time:** 2:00 p.m. to 5:30 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:** Julius Cinque, MS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7846, Bethesda, MD 20892, (301) 435-1252, [cinquej@csr.nih.gov](mailto:cinquej@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

**Name of Committee:** Center for Scientific Review Special Emphasis Panel; Member Conflict: Synaptic Development and Function.

**Date:** March 13, 2015.

**Time:** 12:00 p.m. to 2:30 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:** Deborah L. Lewis, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4183, MSC 7850, Bethesda, MD 20892, 301-408-9129, [lewisdeb@csr.nih.gov](mailto:lewisdeb@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

**Name of Committee:** AIDS and Related Research Integrated Review Group; AIDS Discovery and Development of Therapeutics Study Section.

**Date:** March 19, 2015.

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

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

**Place:** The Fairmont Washington, DC, 2401 M Street NW., Washington, DC 20037.

**Contact Person:** Shiv A. Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301-443-5779, [prasads@csr.nih.gov](mailto:prasads@csr.nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel; Fellowships: Endocrinology, Metabolism, Nutrition and Reproductive Sciences.

**Date:** March 24, 2015.

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

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

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

**Contact Person:** Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301-435-1154, [dianne.hardy@nih.gov](mailto:dianne.hardy@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: February 23, 2015.

**Melanie J. Gray,**

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

[FR Doc. 2015-04057 Filed 2-26-15; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood 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 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; Cardiovascular Development Consortium.

**Date:** March 19, 2015.

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

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