

schedule of meetings, is posted on FDA's Web site at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm>.

## II. Public Meeting Information

### A. Purpose and Scope of the Meeting

As part of Patient-Focused Drug Development, FDA will obtain patient and patient stakeholder input on symptoms of pulmonary arterial hypertension that matter most to patients and on current approaches to treating pulmonary arterial hypertension. Pulmonary arterial hypertension is a rare, progressive condition that affects the heart and lungs. It is characterized by abnormally high blood pressure in the pulmonary artery and may be accompanied by shortness of breath, chest pain, fatigue, dizziness, fainting, lightheadedness, and swollen ankles and legs. There are several treatment options for pulmonary arterial hypertension, including medications, surgery, and lifestyle changes.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief patient panel discussion will begin the dialogue, followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through written comments that can be submitted to the public docket (see **ADDRESSES**).

### Topic 1: Disease Symptoms and Daily Impacts That Matter Most to Patients

1. Of all the symptoms that you experience because of your condition, which one to three symptoms have the most significant impact on your life? (Examples may include symptoms such as chest pain, shortness of breath, difficulty concentrating, and others.)

2. Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your condition? (Examples may include activities such as household chores, walking up the stairs.)

- How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days?

3. How have your condition and its symptoms changed over time?

### Topic 2: Patients' Perspectives on Current Approaches to Treating Pulmonary Arterial Hypertension

1. What are you currently doing to help treat your condition or its symptoms? (Examples may include prescription medicines, over-the-counter products, other therapies including non-drug therapies such as diet modification.)

- How has your treatment regimen changed over time, and why?
- How well does your current treatment regimen treat the most significant symptoms of your disease?
- Have the medications for pulmonary arterial hypertension made a difference to you? If so, in what ways?

2. What are the most significant downsides to your current treatments, and how do they affect your daily life? (Examples may include downsides such as bothersome side effects, going to the hospital for treatment, and others.)

3. Assuming there is no complete cure for your condition, what specific things would you look for in an ideal treatment for your condition?

### B. Meeting Attendance and Participation

If you wish to attend this meeting, visit <https://patientfocusedpulmonaryarterialhypertension.eventbrite.com>. Please register by April 30, 2014. Those who are unable to attend the meeting in person can register to view a live Webcast of the meeting. You will be asked to indicate in your registration whether you plan to attend in person or via the Webcast. Your registration should also contain your complete contact information, including name, title, affiliation, address, email address, and phone number.

Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of disability, please contact Graham Thompson (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients will also be asked to send a brief summary of responses to the topic questions to [PatientFocused@fda.hhs.gov](mailto:PatientFocused@fda.hhs.gov). We will notify panelists of their selection soon after the close of registration on April 30, 2014. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

*Comments:* Regardless of attendance at the public meeting, you can submit electronic or written responses to the questions pertaining to Topics 1 and 2 to the public docket (see **ADDRESSES**) by July 14, 2014. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

*Transcripts:* As soon as a transcript is available, FDA will post it at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm379694.htm>.

Dated: January 30, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-02629 Filed 2-6-14; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of General Medical Sciences; 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 Institute of General Medical Sciences Initial Review Group; Training and Workforce Development Subcommittee—C.

*Date:* March 3, 2014.

*Time:* 8:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

*Contact Person:* Mona R. Trempe, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical

Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12A, Bethesda, MD 20892-4874, 301-594-3998, [trempe@mail.nih.gov](mailto:trempe@mail.nih.gov).

*Name of Committee:* National Institute of General Medical Sciences Initial Review Group; Training and Workforce Development Subcommittee—D.

*Date:* March 13–14, 2014.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

*Contact Person:* Rebecca H. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.18C, Bethesda, MD 20892-4874, 301-594-2771, [JohnsoRe@nigms.nih.gov](mailto:JohnsoRe@nigms.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS).

Dated: February 3, 2014.

**Melanie J. Gray,**

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

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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/contract proposals 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 Cancer Institute Special Emphasis Panel; Omnibus R03/R21: Tumor Immunology.

*Date:* March 5–6, 2014.

*Time:* 6:30 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Robert Bird, Ph.D., Chief, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W110, Bethesda, MD 20892-8328, 240-276-6344, [birdr@mail.nih.gov](mailto:birdr@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; NCI Omnibus—Cancer Biology 1.

*Date:* March 6–7, 2014.

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

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Zhiqiang Zou, MD, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W242, Bethesda, MD 20892-9750, 240-276-6372, [zouzhiq@mail.nih.gov](mailto:zouzhiq@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Collaborative Research in Integrative Cancer Biology.

*Date:* March 13, 2014.

*Time:* 11:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W242, Rockville, MD 20850, (Telephone Conference Call).

*Contact Person:* Zhiqiang Zou, MD, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W242, Bethesda, MD 20892-9750, 240-276-6372, [zouzhiq@mail.nih.gov](mailto:zouzhiq@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Awards for Research on Imaging and Biomarkers for Early Cancer Detection.

*Date:* March 17, 2014.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 2W914, Rockville, MD 20850, (Telephone Conference Call).

*Contact Person:* Thomas A. Winters, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W412, Rockville, MD 20892-2750, 240-276-6386, [twinters@mail.nih.gov](mailto:twinters@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Cancer Prevention.

*Date:* March 19, 2014.

*Time:* 7:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Clifford Schweinfest, Ph.D., Scientific Review Officer, Special

Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W108, Bethesda, MD 20892-9750, 240-276-6343, [schweinfest@mail.nih.gov](mailto:schweinfest@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Biosensor-Based Core Needles for Tumor Biopsy.

*Date:* March 19, 2014.

*Time:* 12:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 4W032, Rockville, MD 20850, (Telephone Conference Call).

*Contact Person:* Donald L. Coppock, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center, Room 7W260, Bethesda, MD 20892, 240-276-6382, [donald.coppock@mail.nih.gov](mailto:donald.coppock@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Omnibus—Drug Delivery/Imaging/Biotechnology.

*Date:* March 20–21, 2014.

*Time:* 7:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Courtyard Marriott Washingtonian Center, 204 Boardwalk Place, Gaithersburg, MD 20878.

*Contact Person:* Gerald G. Lovinger, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W266, Rockville, MD 20850-9750, 240-276-6385, [lovingeg@mail.nih.gov](mailto:lovingeg@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel, Cancer Therapy (Omnibus).

*Date:* March 27–28, 2014.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

*Contact Person:* Caron A Lyman, Ph.D., Chief, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W126, Bethesda, MD 20892-9750, 240-276-6348, [lymanc@mail.nih.gov](mailto:lymanc@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Drug Reformulation.

*Date:* March 27, 2014.

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

*Agenda:* To review and evaluate contract proposals.

*Place:* Hilton Garden Inn Washington DC/Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

*Contact Person:* Thomas M. Vollberg, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W412, Bethesda, MD 20892-9750, 240-276-6341, [vollbert@mail.nih.gov](mailto:vollbert@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Career