

to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients, or the drug is compounded in accordance with all applicable conditions identified on the list as conditions that are necessary to prevent the drug or category of drugs from presenting such demonstrable difficulties (see section 503B(a)(6)(A) and (B) of the FD&C Act).

FDA will discuss with the committee drugs proposed for inclusion on the section 503A bulk drug substances list and on the demonstrably difficult to compound list under sections 503A and 503B of the FD&C Act.

*Agenda:* On March 8, 2016, the committee will discuss six bulk drug substances nominated for inclusion on the section 503A bulk drug substances list. FDA will discuss the following nominated bulk drug substances: Quinacrine hydrochloride, boswellia, aloe vera 200:1 freeze dried, D-ribose, chondroitin sulfate, and acetyl-L-carnitine. The nominators of these substances will be invited to make a short presentation supporting the nomination.

On March 9, 2016, the committee will discuss two categories of drug products nominated for the list of drug products that present demonstrable difficulties for compounding. These categories of drug products are metered dose inhalers and dry powder inhalers. The nominators who nominated the category of drugs or specific drug products in the category will be invited to make a short presentation supporting the nomination.

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 March 1, 2016. Oral presentations from the public will be scheduled between approximately 11 a.m. to 11:15 a.m. and 3:15 p.m. to 3:30 p.m. on March 8, 2016, and between approximately 11:30 a.m. to 12 noon on March 9, 2016. 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 February 24, 2016. 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 February 25, 2016.

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 disabilities. If you require accommodations due to a disability, please contact Cindy Hong 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 8, 2016.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Biomedical Imaging and Bioengineering; 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 Biomedical Imaging and Bioengineering Special Emphasis Panel; Career Award and Conference Grant Review (2016/05).

*Date:* March 18, 2016.

*Time:* 9:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Mark Martin, Ph.D., Scientific Review Officer, 6707 Democracy Boulevard, Suite 920, Bethesda, MD 20892, (240) 447-2148, [mark.martin@mail.nih.gov](mailto:mark.martin@mail.nih.gov).

*Name of Committee:* National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; P41 BTRC review (2016/05).

*Date:* March 23-25, 2016.

*Time:* 6:00 p.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Wyndham Boston Beacon Hill, 5 Blossom Street, Boston, MA 02114.

*Contact Person:* Dennis Hlasta, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Bethesda, MD 20892, (301) 451-4794, [dennis.hlasta@nih.gov](mailto:dennis.hlasta@nih.gov).

Dated: February 4, 2016.

**David Clary,**

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

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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.