

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 link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the efficacy and safety of new drug application (NDA) 22219, AVEED (testosterone undecanoate) intramuscular injection, submitted by Endo Pharmaceutical Solutions, Inc., for the proposed indication of replacement therapy in adult males for conditions associated with a deficiency or absence of testosterone. The safety discussion will focus on postmarketing reports of oil embolism in the lungs and potential anaphylactic reactions. In addition to AVEED, other approved testosterone injectable products will be referenced, especially in regard to oil embolism and potential anaphylactic reactions reported for those products.

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 4, 2013. 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 27, 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 March 28, 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 Kalyani Bhatt 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: March 8, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-05861 Filed 3-13-13; 8:45 am]

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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 and/or 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 or the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, NCI Provocative Questions.

Date: March 28, 2013.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Peter J. Wirth, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8131, Bethesda, MD 20892-8328 301-496-7565 pw2q@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, Nanotechnology RNA Therapeutics.

Date: April 18-19, 2013.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, 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, 6116 Executive Boulevard, Room 7142, Bethesda, MD 20892, 301-594-9582, vollbert@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 8, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-05847 Filed 3-13-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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.