

about possible modifications before coming to the meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application, sponsored by TherOx, Inc., for the TherOx Aqueous Oxygen System (AO System). The system is intended for use in acute myocardial infarction (AMI) patients, who have undergone successful revascularization less than or equal to 6 hours from symptom onset. These patients were randomized to AO Therapy or not. The endpoint is reduction in the final size of the infarct. The system draws blood from the patient, hyperoxygenates it with the AO cartridge component of the system, and reinfuses the blood via the infusion catheter directly to the infarction site of the heart. This therapy is intended to be performed for 90 minutes post percutaneous coronary intervention/stenting.

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/ohrms/dockets/ac/acmenu.htm>, click on the year 2009 and 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 March 4, 2009. Oral presentations from the public will be scheduled approximately 30 minutes at the beginning of committee deliberations and approximately 30 minutes near the end of the deliberations. Those desiring to make 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 25, 2009. 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 26, 2009.

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 AnnMarie Williams, Conference Management Staff, at 240-276-8932, 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/oc/advisory/default.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 10, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9-3488 Filed 2-18-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Allergy and Infectious Diseases Special Emphasis Panel, Sexually Transmitted Infections Cooperative Research Centers.

Date: March 3-5, 2009.

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

Agenda: To review and evaluate grant applications.

Place: The Crowne Plaza Hotel, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Michelle M. Timmerman, PhD, Scientific Review Officer, Scientific Review Program, NIH/NIAID/DHHS, Room 3147, 6700B Rockledge Drive, MSC-7616, Bethesda, MD 20892-7616, 301-451-4573, timmermanm@niaid.nih.gov.

NAME OF COMMITTEE: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Review of Unsolicited P01 Application.

Date: March 10, 2009.

Time: 11 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Eleazar Cohen, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, Room 3129, 6700B Rockledge Drive, Bethesda, MD 20892, (301) 435-3564, ec17w@nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Review of Unsolicited P01 Application.

Date: March 12, 2009.

Time: 11 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Eleazar Cohen, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, Room 3129, 6700B Rockledge Drive, Bethesda, MD 20892, (301) 435-3564, ec17w@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: February 11, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-3437 Filed 2-18-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment; Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Center for Substance Abuse Treatment (CSAT) National Advisory Council on March 19, 2009.

The meeting is open to the public and will include discussion of the Center's policy issues, and current administrative, legislative, and program developments.