

Date and Time: The meeting will be held on December 16, 2009, from 9 a.m. to 3 p.m.

On page 59195, in the second column, the *Agenda* portion of the document is changed to read as follows:

Agenda: On December 16, 2009, the committee will discuss supplemental new drug application (sNDA) 021-743/S-016, TARCEVA (erlotinib) tablets, by OSI Pharmaceuticals, Inc. The proposed indication (use) for this product is first-line maintenance, monotherapy (first-choice, single drug) treatment in patients with a form of lung cancer called non-small cell lung cancer (NSCLC) that is either locally advanced (has spread regionally within the lung and/or within chest lymph nodes) or metastatic (has spread beyond the lung), and who have not progressed (including those patients with stable disease) on first-line treatment with platinum-based chemotherapy (a regimen including a platinum drug (cisplatin or carboplatin) plus another chemotherapy drug).

On page 59195, in the third column, the third sentence in the *Procedure* portion of the document is changed to read as follows:

Procedure: Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: December 3, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-29208 Filed 12-7-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

Anesthetic and Life Support 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: Anesthetic and Life Support 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 January 28, 2010, from 8 a.m. to 4:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD. The hotel telephone number is 301-977-8900.

Contact Person: Kalyani Bhatt, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail:

Kalyani.Bhatt@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in Washington, DC area), code 3014512529. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hotline/phone line to learn about possible modifications before coming to the meeting.

Agenda: On January 28, 2010, the committee will discuss the available safety and efficacy data for new drug application (NDA) 22516, CYMBALTA (duloxetine HCL) Capsules, by Eli Lilly and Co., as they relate to the proposed indication of treatment of chronic pain.

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 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 January 13, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. 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 January 5, 2010. 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 January 6, 2010.

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: December 3, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-29211 Filed 12-7-09; 8:45 am]

BILLING CODE 4160-01-S

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.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Inflammation, Hypersensitivity, Autoimmunity, Tolerance, and Transplantation and Tumor Immunity.

Date: December 15, 2009.

Time: 9:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Jian Wang, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4095D, MSC 7812, Bethesda, MD 20892, (301) 435-2778, wangjia@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.

(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: December 2, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-29254 Filed 12-7-09; 8:45 am]

BILLING CODE 4140-01-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; Topics in Virology.

Date: January 6, 2010.

Time: 1 p.m. to 3 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: Liangbiao Zheng, PhD, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892, 301-402-5671, zhengli@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Clinical Cardiovascular Studies 09A.

Date: January 7, 2010.

Time: 2:30 p.m. to 4 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: Joseph Thomas Peterson, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301-443-8130.

(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: December 2, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-29252 Filed 12-7-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Clinical and Preventive Services; Division of Behavioral Health; the Methamphetamine and Suicide Prevention Initiative for American Indian and Alaska Native Urban Programs

Announcement Type: New.

Funding Announcement Number: HHS-2010-IHS-METHU-0001.

Catalog of Federal Domestic Assistance Number(s): 93.933.

KEY DATES: *Application Deadline Date:* January 5, 2010. *Review Date:* January 12-13, 2010. *Earliest Anticipated Start Date:* February 1, 2010.

I. Funding Opportunity Description

The Indian Health Service (IHS) announces competitive grant applications for the Methamphetamine & Suicide Prevention Initiative (MSPI) for American Indian and Alaska Native (AI/AN) Urban Program communities. This program is authorized under the Snyder Act, 25 U.S.C. 13, as amended, and Indian Health Care Improvement Act (IHCIA), 25 U.S.C. 1653(e). This program is described at 93.933 in the Catalog of Federal Domestic Assistance. The purpose of the Methamphetamine & Suicide Prevention Initiative for AI/AN

Urban Programs (MSPI-U) is to expand community-level access to effective, urban AI/AN methamphetamine and/or suicide prevention and treatment programs. Resources will enhance evidence-based or practice-based methamphetamine and/or suicide prevention or treatment programs and/or community mobilization programs. The methamphetamine and suicide prevention or treatment funding will be used to:

- Provide community-focused responses that enhance evidence-based or practice based methamphetamine and/or suicide prevention or treatment services or education programming.
- Coordinate services for communities to respond to their local methamphetamine and/or suicide crises.
- Participate in a nationally coordinated program focusing specifically on increasing access to methamphetamine and/or suicide prevention or treatment related activities among the Federal partners, Areas, Tribes, States, and academic or not-for-profit programs.
- Provide communities with needed resources to develop their own community-focused programs with preference for coordinated programming that maximizes the impact across communities and Tribal groups.
- Establish baseline data information related to methamphetamine abuse/suicides in the local communities.
- Adequately document the level of need for the community.
- Promote programs that will ensure measurable impact.
- Awardees' activities for this program are as follows:
 - Develop a three (3) year action plan. Applicants must document how their methamphetamine and/or suicide prevention or treatment activities will be implemented as soon as possible but no later than six (6) months after award. The remainder of Year One, Year Two, and Year Three will focus on implementation. The primary intent of the action plan should be to illustrate how the applicant will enhance community access to or support community delivery of evidence-based or practice-based methamphetamine and/or suicide prevention or treatment services. The action plan should describe the project implementation process. The action plan should include objectives that are specific, measurable, achievable, relevant, and time-phased. Objectives should demonstrate adherence to the Government Performance and Results Act of 1993 (GPRA), where applicable. The implementation process may be guided