

Loestrin Fe (norethindrone acetate and ethinyl estradiol ethinyl estradiol and ferrous fumarate), Aridol (mannitol inhalation powder), Augmentin XR (amoxicillin/clavulanate potassium), Afinitor (everolimus), Moxeza (moxifloxacin hydrochloride), and Lastacast (alcaftadine).

As mandated by the Food and Drug Administration Amendments Act, Title III, Pediatric Medical Device Safety and Improvement Act of 2007 (Public Law 110–85), the committee will discuss the safety of and the ongoing propriety of the humanitarian device exemption for the Melody Transcatheter Pulmonary Valve and Ensemble Delivery System and the Elana Surgical Kit.

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 September 4, 2012. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. on September 11, 2012. 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 August 24, 2012. 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 August 27, 2012.

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 Walter Ellenberg (walter.ellenberg@fda.hhs.gov) or 301–796–0885 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: July 24, 2012.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–18509 Filed 7–27–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel Rodent Testing to Identify Pharmacotherapies for Substance Dependence (8908).

Date: August 23, 2012.

Time: 9:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4227, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20892–9550. (301) 435–1439, lf33c.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and

Addiction Research Programs, National Institutes of Health, HHS)

Dated: July 24, 2012.

Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–18475 Filed 7–27–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood 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 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 Heart, Lung, and Blood Institute Special Emphasis Panel Clinical Trials at the NHLBI.

Date: August 20, 2012.

Time: 11:00 a.m. to 4:00 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: Charles Joyce, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892–7924, 301–435–0288, cjoyce@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Pathogen Inactivation for Blood Components.

Date: August 20, 2012.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Giuseppe Pintucci, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892, 301–435–0287, Pintuccig@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases