

anti-inflammatory drug indicated for the treatment of arthritis. On August 4, 1982, Lilly voluntarily withdrew ORAFLEX (benoxaprofen) Tablets from the market because of postmarketing reports of severe liver toxicity in patients who took ORAFLEX. In a letter dated February 6, 2013, Lilly requested that FDA withdraw approval of NDA 18-250 for ORAFLEX (benoxaprofen) Tablets under § 314.150(d) (21 CFR 314.150(d)). In that letter, Lilly waived any opportunity for a hearing otherwise provided under § 314.150(a). In FDA's letter of February 15, 2013, the Agency acknowledged Lilly's agreement to permit FDA to withdraw approval of ORAFLEX (benoxaprofen) Tablets under § 314.150(d) and waive its opportunity for a hearing.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner of Food and Drugs to the Director, Center for Drug Evaluation and Research, approval of NDA 18-250, and all amendments and supplements thereto, is withdrawn (see DATES). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: May 28, 2013.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2013-13053 Filed 6-3-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Children's Study Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Registration is required since space is limited and will begin at 8:00 a.m. Please visit the conference Web site for information on meeting logistics and to register for the meeting at meeting <http://www.cvent.com/d/3cq6zz>. Individuals who plan to attend and need special assistance, such as sign language interpretation or other

reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Children's Study Advisory Committee.

Date: July 23, 2013.

Time: 9:00 a.m. to 4:30 p.m.

Agenda: The Committee will receive an update on the current status of Vanguard Study and will discuss general data collection methods and retention strategy and methods.

Place: National Institutes of Health, Natcher Conference Center, Room E1/E2, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Kate Winseck, MSW, Executive Secretary, National Children's Study, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5C01, Bethesda, MD 20892, (703) 902-1339, ncs@circlesolutions.com.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. For additional information about the Federal Advisory Committee meeting, please contact Circle Solutions at ncs@circlesolutions.com.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 29, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-13123 Filed 6-3-13; 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; Systemic Injury by Environmental Exposure.

Date: June 11, 2013.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Bonnie L Burgess-Beusse, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, 301-435-1783, beusseb@mail.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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Stroke, Spinal Cord Injury, and Neuroimmunology.

Date: June 14, 2013.

Time: 2:00 p.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: Samuel C Edwards, Ph.D., IRG CHIEF, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435-1246, edwardss@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: May 29, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-13124 Filed 6-3-13; 8:45 am]

BILLING CODE 4140-01-P