

digitalis toxicity, the two approved indications for the drug (35 FR 437, January 13, 1970).

In a letter dated September 17, 2007, FDA informed Hospira that the agency was reevaluating the safety and efficacy of ENDRATE (edetate disodium) Injection based on reports of fatal medication errors and reports of serious adverse reactions associated with this product. In its September 17, 2007, letter, FDA asked Hospira for additional information related to the safety of ENDRATE (edetate disodium) Injection.

On September 19, 2007, FDA sent letters to Apotex and Bioniche for ANDAs 40-376 and 40-437, respectively, requesting the same information for generic versions of edetate disodium. In a letter dated October 1, 2007, Hospira provided the postmarketing safety information FDA requested on ENDRATE (edetate disodium). In its October 1, 2007, letter, Hospira stated that “[b]ased on the limited indications for ENDRATE (edetate disodium) and the availability of alternate medical products that offer a superior risk-benefit profile,” Hospira determined that “the product is not medically necessary.”

In a letter dated December 7, 2007, under § 314.150(d), FDA asked Hospira to waive its opportunity for a hearing (otherwise provided for under part 314 (21 CFR part 314)) to permit FDA to withdraw approval of NDA 11-355, and to voluntarily remove ENDRATE (edetate disodium) from the market. In a letter dated December 20, 2007, Hospira concurred with FDA’s determination to withdraw approval of NDA 11-355, ENDRATE (edetate disodium), under § 314.150(d); waived its opportunity for a hearing; and agreed to voluntarily remove ENDRATE from the market. Hospira initiated a recall of the product.

In separate telephone conversations on April 8, 2008, FDA asked Apotex and Bioniche, under § 314.150(d), to permit FDA to withdraw approval of ANDAs 40-376 and 40-437, respectively, for generic versions of edetate disodium, and to waive their opportunity for a hearing. Apotex and Bioniche, in letters dated April 9, 2008, and April 17, 2008, respectively, agreed to withdraw their ANDAs under § 314.150(d). Both Apotex and Bioniche indicated that alternative drug products that offer a superior risk-benefit profile are currently available for the approved indications for edetate disodium injection. Both Apotex and Bioniche waived their opportunity for a hearing (otherwise provided under part 314). In its April 9, 2008, letter, Apotex stated it has never marketed ANDA 40-376. In

its April 17, 2008, letter, Bioniche agreed to voluntarily remove its edetate disodium product from the market.

Therefore, under section 505(e) of the act (21 U.S.C. 355(e)), § 314.150(d), and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner of Food and Drugs, approval of the applications listed in the table of this document, and all amendments and supplements thereto, is withdrawn (see **DATES**). Distribution of these products in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the act (21 U.S.C. 355(a) and 331(d)). On the basis of the circumstances described in this document that led to the withdrawal of approval of the applications listed in the table of this document, the agency will remove these products from the list of drug products with effective approvals published in FDA’s “Approved Drug Products With Therapeutic Equivalence Evaluations,” referred to as the “Orange Book.”

Dated: May 15, 2008.

Douglas C. Throckmorton,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. E8-13273 Filed 6-11-08; 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 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: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Musculoskeletal Tissue Engineering.

Date: June 16, 2008.

Time: 10 a.m. to 12:30 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: John P. Holden, PhD, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301-496-8551, holdenjo@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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Orthopaedic Device-associated Immunology.

Date: June 20, 2008.

Time: 8 a.m. to 9:30 a.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: John P. Holden, PhD, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301-496-8551, holdenjo@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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: CNS Disorders and Clinical Neuroscience.

Date: July 8, 2008.

Time: 3 p.m. to 5 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: Alexander Yakovlev, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5206, MSC 7846, Bethesda, MD 20892, 301-435-1254, yakovleva@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Minority Fellowships in Neurobiology and Development.

Date: July 14, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Cathy J. Wedeen, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3213, MSC 7808, Bethesda, MD 20892, 301-435-1191, wedeenc@csr.nih.gov.

(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: June 4, 2008.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-13017 Filed 6-11-08; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, July 8, 2008, 8 a.m. to July 8, 2008, 5:30 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, which was published in the **Federal Register** on June 2, 2008, 73 FR 31493-31495.

The meeting title has been changed to "Tomography for Chronic Diseases". The meeting is closed to the public.

Dated: June 4, 2008.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-13020 Filed 6-11-08; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 Neurological Disorders and Stroke Initial Review Group; Neurological Sciences and Disorders K.

Date: June 19, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Willard InterContinental Washington, 1401 Pennsylvania Avenue, NW., Washington, DC 20004.

Contact Person: Shanta Rajaram, PhD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC9529, Bethesda, MD 20852, (301) 435-6033, rajarams@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: National Institute of Neurological Disorders and Stroke Initial Review Group; Neurological Sciences and Disorders B.

Date: June 19, 2008.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Avenue, NW., Washington, DC 20037.

Contact Person: Ernest W. Lyons, PhD, Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-4056.

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: National Institute of Neurological Disorders and Stroke Initial Review Group; Neurological Sciences and Disorders C.

Date: June 20, 2008.

Time: 8 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Avenue, NW., Washington, DC 20037.

Contact Person: William C. Benzing, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892, (301) 496-0660, benzingw@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: National Institute of Neurological Disorders and Stroke Initial Review Group; Neurological Sciences and Disorders A.

Date: June 26, 2008.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Washington DC Downtown, 815 14th Street, NW., Washington, DC 20005.

Contact Person: Richard D. Crosland, PhD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223.

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. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: June 4, 2008.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-13021 Filed 6-11-08; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; The NIDDK Special Emphasis Panel Telephone Review.

Date: July 21, 2008.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Xiaodu Guo, MD, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 761, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-4719, guox@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Ancillary Studies.

Date: July 29, 2008.

Time: 1:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).