

site. The BE recommendations identified in this document were developed using the process described in that guidance.

DATES: Submit written or electronic comments on the draft product-specific BE recommendations by January 23, 2008. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the individual BE guidances to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft product-specific BE recommendations to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Doan T. Nguyen, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0495.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 31, 2007 (72 FR 30388), FDA announced the availability of a draft guidance for industry, "Bioequivalence Recommendations for Specific Products," that explained the "process" that would be used to make product-specific BE recommendations available to the public on FDA's Web site at <http://www.fda.gov/CDER/GUIDANCE/bioequivalence/default.htm>. As described in that draft guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations.

In that same issue of the **Federal Register** (72 FR 30386), FDA also announced that 200 product-specific BE recommendations were being made available on FDA's Web site at <http://www.fda.gov/CDER/GUIDANCE/bioequivalence/default.htm>. However, a number of the recommendations listed in that notice were not posted on the Web site. In addition, some of the

recommendations posted on the Web site were omitted from the **Federal Register** notice. Finally, four recommendations announced in the May 31, 2007, notice and posted on the Web site were incorrect and have now been corrected. This document clarifies the notice of May 31, 2007 (72 FR 30386), as follows:

A. Recommendations Listed in the May 31, 2007, Federal Register Notice That Were Not Posted on the Web Site

- (1) Ganciclovir
- (2) Ibuprofen; Pseudoephedrine HCl
- (3) Felbamate (multiple dosage forms)
- (4) Leflunomide

These drugs are now available on the Web site.

B. Recommendations Posted on the Web Site That Were Not Listed in the May 31, 2007, Federal Register Notice

- (1) Fosinopril Sodium
- (2) Hydrochlorothiazide and Irbesartan
- (3) Levonorgestrel
- (4) Lidocaine
- (5) Loratadine
- (6) Phenytoin Sodium (multiple RLDs)
- (7) Phenytoin
- (8) Terazosin HCl

C. Recommendations Listed in the May 31, 2007, Federal Register Notice and Posted on the Web Site That Were Incorrect

- (1) Mycophenolate mofetil tablet 50723, corrected the analytes to measure
- (2) Mycophenolate mofetil capsule 50722, corrected the analytes to measure
- (3) Erlotinib HCl tablet, deleted the IND requirement
- (4) Hydrochlorothiazide and losartan potassium tablets, added waiver strength 12.5 mg/100mg

The recommendations listed in sections I.A, B, and C of this document are available for comment by (see **DATES**).

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on any of the specific BE recommendations posted on FDA's Web site. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance, notices, and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain these BE recommendations at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: October 19, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-21062 Filed 10-24-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel, Reverse Site Visit.

Date: November 26-27, 2007.

Time: 5 p.m. to 4 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: Louise L. Hsu, PhD, Health Scientist Administrator, Scientific Review Office, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue/Suite 2C212, Bethesda, MD 20892, (301) 496-7705, hsul@exmur.nia.nih.gov.

Name of Committee: National Institute on Aging Special Emphasis Panel, "Aging Brain Vasculature".

Date: November 30, 2007.

Time: 12 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, 2C212, Bethesda, MD 20814, (Telephone Conference Call).

Contact Person: William Cruce, PhD, Health Scientist Administrator, Scientific Review Office, National Institute on Aging, National Institutes of Health, Room 2C212,

7201 Wisconsin Avenue, Bethesda, MD 20814, 301-402-7704, crucew@nia.nih.gov.

Name of Committee: National Institute on Aging Special Emphasis Panel, Comparative Longitudinal Studies.

Date: December 6-7, 2007.

Time: 6 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Wilbur C. Hadden, PhD, Health Scientist Administrator, National Institute on Aging, Gateway Building, Room 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, haddenw@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: October 19, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07-5285 Filed 10-24-07; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; 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 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: National Institute of Child Health and Human Development Special Emphasis Panel Training Program in Social Development.

Date: November 13, 2007.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01E, Rockville, MD 20852. (Virtual Meeting)

Contact Person: Carla T. Walls, PhD., Scientific Review Administrator, Division of Scientific Review National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, (301) 435-6898, wallsc@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.

(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: October 19, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07-5287 Filed 10-24-07; 8:45am]

BILLING CODE 4140-01-M

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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, 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 of Allergy and Infectious Diseases Special Emphasis Panel NHP Models for HIV Therapeutics and Microbiocides.

Date: November 16, 2007.

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

Agenda: To review and evaluate contract proposals.

Place: Holiday Inn Capitol, 550 C Street, SW., Saturn/Venus Room, Washington, DC 20024.

Contact Person: Lucy A. Ward, DVM, PhD., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID/DHHS, 6700B Rockledge Drive, Bethesda, MD 20892-7616, 301-496-2550, lward@niaid.nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel Clinical Pharmacology Quality Assurance and Quality Control.

Date: November 16, 2007.

Time: 11 a.m. to 4 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, 3147, Bethesda, MD 20817. (Telephone Conference Call)

Contact Person: Mary J. Homer, PhD., Scientific Review Administrator, Scientific Review Program, National Institute of Allergy and Infectious Diseases, DEA/NIH/DHHS, 6700-B Rockledge Drive MSC 7616 Room 3147, Bethesda, MD 20892, 301-496-7042, mjhomer@niaid.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: October 19, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07-5289 Filed 10-24-07; 8:45 am]

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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, Review of HIV/AIDS SBIR Applications.

Date: November 13, 2007.

Time: 12 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Mark P. Rubert, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, (301) 435-1775, rubertm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Neural Control of Cardiovascular Function.

Date: November 14, 2007.

Time: 10 a.m. to 12 p.m.