

document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget,
Paperwork Reduction Project, Fax: 202-395-6974, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: April 28, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8-9762 Filed 5-2-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0257]

Draft Prescription Drug User Fee Act IV Drug Safety Five-Year Plan; Availability for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for public comment of the draft drug safety 5-year plan entitled "Prescription Drug User Fee Act (PDUFA) IV Drug Safety Five-Year Plan." This plan is intended to communicate FDA's strategy for meeting the commitments for enhancing and modernizing the drug safety system within the context of the PDUFA IV program.

DATES: Submit written or electronic comments on the draft drug safety 5-year plan by June 19, 2008.

ADDRESSES: Submit written requests for single copies of the draft plan to the Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6100, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft drug safety 5-year plan to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

FOR FURTHER INFORMATION CONTACT: Jayne C. Ware, Food and Drug

Administration, Center for Drug Evaluation and Research, Office of Executive Programs, 10903 New Hampshire Ave., Bldg. 51, rm. 6100, Silver Spring, MD 20993-0002, 301-796-3200.

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007, which includes the reauthorization and expansion of PDUFA. The reauthorization of PDUFA will significantly broaden and modernize the agency's drug safety program and facilitate more efficient development of safe and effective new medications for the American public. During the user fee negotiation process leading up to the renewal of PDUFA, FDA and the relevant regulated industries mutually agreed to certain commitments that the FDA will carry out during fiscal years 2008 through 2012. Congress signaled its agreement with the commitments by authorizing PDUFA funds for them. Among those commitments is the responsibility of the FDA to develop and periodically update a 5-year plan describing activities that will lead to enhancing and modernizing FDA's drug safety system.

FDA is announcing for public comment the availability of the draft drug safety 5-year plan entitled "Prescription Drug User Fee Act (PDUFA) IV Drug Safety Five-Year Plan." This plan is intended to communicate FDA's strategy for meeting the commitments for enhancing and modernizing the drug safety system within the context of the PDUFA IV program. The plan describes the agency's strategy for achieving the commitments defined in section VIII, Enhancement and Modernization of the FDA Drug Safety System, and section IX, Review of Proprietary Names to Reduce Medication Errors, of the PDUFA IV Performance Goals (<http://www.fda.gov/oc/pdufa4/pdufa4goals.html>). At the end of the comment period, FDA will review the comments, update the "PDUFA IV Drug Safety Five-Year Plan," and publish the final version.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the

docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/pdufa/PDUFA_IV_5yr_plan_draft.pdf.

Dated: April 25, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-9726 Filed 5-2-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

The 11th Annual Food and Drug Administration-Orange County Regulatory Affairs Educational Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following conference: 11th Annual Educational Conference co-sponsored with the Orange County Regulatory Affairs Discussion Group (OCRA). The conference is intended to provide the Drug, Device, and Biologics industries with an opportunity to interact with FDA reviewers and compliance officers from the Centers and District Offices, as well as other industry experts. The main focus of this interactive conference will be product approval, compliance, and risk management in the three medical product areas. Industry speakers, interactive questions and answers, and workshop sessions will also be included to assure open exchange and dialogue on the relevant regulatory issues.

Date and Time: The conference will be held on June 11 and 12, 2008, from 7:30 a.m. to 5 p.m.

Location: The conference will be held at the Irvine Marriott Hotel, 18000 Von Karman Ave., Irvine, CA 92612.

Contact: Linda Hartley, Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612, 949-608-4413, FAX: 949-608-4417, or OCRA, Attention to Detail (ATD), 5319 University Dr., suite 641, Irvine, CA 92612, 949-387-9046, FAX: 949-387-9047, Web site: www.ocra-dg.org.

Registration and Meeting Information: See OCRA Web site, www.ocra-dg.org. Contact ATD at 949-387-9046.

Before May 9, 2008, registration fees are as follows: \$675.00 for members, \$725.00 for non-members and \$475.00 for FDA/Govt/Students.¹ After May 9, 2008, \$725.00 for members, \$775.00 for non-members, and \$475.00 for FDA/Govt/Students.

The registration fee will cover actual expenses including refreshments, lunch, materials, and speaker expenses. If you need special accommodations due to a disability, please contact Linda Hartley at least 10 days in advance.

Dated: April 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-9728 Filed 5-2-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, NICHD.

The meeting will be open to the public as indicated below, with attendance limited to space available. 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.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Child Health and Human Development, including consideration of personnel qualifications and performance, and the

competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NICHD.

Date: June 6, 2008.

Open: 8 a.m. to 11:30 a.m.

Agenda: A report by the Scientific Director, NICHD, on the status of the NICHD Division of Intramural Research.

Place: National Institutes of Health, Building 31, 9000 Rockville Pike, Room 2A48, Bethesda, MD 20892.

Closed: 11:30 a.m. to 5 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 31, 9000 Rockville Pike, Room 2A48, Bethesda, MD 20892.

Contact Person: Owen M. Rennert, MD, Scientific Director, National Institute of Child Health and Human Development, 9000 Rockville Pike, Building 31, Room 2a50, Bethesda, MD 20892, (301) 496-2133, rennerto@mail.nih.gov.

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.

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.

Information is also available on the Institute's/Center's home page: <http://www.nichd.nih.gov/about/bsd/html>, where an agenda and any additional information for the meeting will be posted when available. (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: April 25, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-9639 Filed 5-2-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Division of Intramural Research Board of Scientific Counselors, NIAID. The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Allergy and Infectious Diseases, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Division of Intramural Research Board of Scientific Counselors, NIAID.

Date: June 2-4, 2008.

Time: June 2, 2008, 8 a.m. to 5:10 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 50, 50 Center Drive, Conference Rooms 1227/1233, Bethesda, MD 20892.

Time: June 3, 2008, 8 a.m. to 4:50 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 50, 50 Center Drive, Conference Rooms 1227/1 233, Bethesda, MD 20892.

Time: June 4, 2008, 8 a.m. to 11:20 a.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 50, 50 Center Drive, Conference Rooms 1227/1 233, Bethesda, MD 20892.

Contact Person: Kathryn C. Zoon, PhD, Director, Division of Intramural Research, National Institute of Allergy and Infectious Diseases, NIH, Building 31, Room 4A30, Bethesda, MD 20892, 301-496-3006, kzoon@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: April 28, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-9756 Filed 5-2-08; 8:45 am]

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¹Applied to full-time students with the proper identification.