

academic (but not government or industry) speakers, and other expenses. The fee for the 2-day meeting for registrants from industry is \$350, and the fee for academic or government registrants is \$175. Fees will be waived for invited speakers and moderators.

The registration process will be handled by AASLD, which has extensive experience in planning, executing, and organizing educational meetings. Register online at <http://www.aasld.org>. Although the NLC facility is spacious, registration will be on a first-come, first-served basis. If you would like to make an oral presentation during the open hour of the conference on March 27, 2008, you must register with Lana Pauls (see **FOR FURTHER INFORMATION CONTACT**) by close of business on March 14, 2008. To make a presentation, you will be asked to provide your name, title, business affiliation (if applicable), address, and type of organization you represent (e.g., industry, consumer organization). Persons registered to make an oral presentation should check in before the conference. If you need special accommodations because of a disability, please contact Lana Pauls at least 7 days before the conference.

#### *D. Where Can I Find Out More About This Public Conference?*

Background information on the conference, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at <http://www.fda.gov/cder/livertox> and <http://www.aasld.org>.

#### *E. Conference Transcripts*

We will prepare a transcript of the conference presentations and discussions and will post it online along with copies of slides shown. The transcript will be available for review on the Internet at <http://www.fda.gov/cder/livertox> approximately 30 days after the conference.

### III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance and the issues and questions presented in this document or at the conference. 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 Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

### IV. Electronic Access

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

Dated: February 29, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E8-4361 Filed 3-5-08; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Summaries of Medical and Clinical Pharmacology Reviews of Pediatric Studies; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for BETOPTIC (betaxolol), LAMICTAL (lamotrigine), LEVAQUIN (levofloxacin), RISPERDAL (risperidone), and TIMOLOL (timolol). These summaries are being made available consistent with the Best Pharmaceuticals for Children Act (the BPCA). For all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of the pediatric studies conducted for the supplement.

**ADDRESSES:** Submit written requests for single copies of the summaries to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please specify by product name which summary or summaries you are requesting. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries.

### FOR FURTHER INFORMATION CONTACT:

Grace Carmouze, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6460, Silver Spring, MD 20993-0002, 301-796-0700, e-mail: [grace.carmouze@fda.hhs.gov](mailto:grace.carmouze@fda.hhs.gov).

### SUPPLEMENTARY INFORMATION:

#### I. Background

FDA is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies conducted for BETOPTIC (betaxolol), LAMICTAL (lamotrigine), LEVAQUIN (levofloxacin), RISPERDAL (risperidone), and TIMOLOL (timolol). The summaries are being made available consistent with section 9 of the BPCA (Public Law 107-109). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the pediatric exclusivity program described in section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a). Section 505A of the act permits certain applications to obtain 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

One of the provisions the BPCA added to the pediatric exclusivity program pertains to the dissemination of pediatric information. Specifically, for all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement (21 U.S.C. 355a(m)(1)). The summaries are to be made available not later than 180 days after the report on the pediatric study is submitted to FDA (21 U.S.C. 355a(m)(1)). Consistent with this provision of the BPCA, FDA has posted on the Internet at <http://www.fda.gov/cder/pediatric/index.htm> summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for BETOPTIC (betaxolol), LAMICTAL (lamotrigine), LEVAQUIN (levofloxacin), RISPERDAL (risperidone), and TIMOLOL (timolol). Copies are also available by mail (see **ADDRESSES**).

#### II. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/pediatric/index.htm>.

Dated: February 29, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E8-4426 Filed 3-5-08; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Research Resources; 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 Center for Research Resources Special Emphasis Panel; Comparative Medicine SEP-1 (08).

*Date:* March 27, 2008.

*Time:* 2 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 1 Democracy Plaza, 6701 Democracy Blvd., Room 1078, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Steven Birken, PhD, Scientific Review Officer, National Center for Research Resources, or National Institutes of Health, 6701 Democracy Boulevard, One Democracy Plaza, Room 1078, MSC 4874, Bethesda, MD 20892-4874, 301-435-0815, [birkens@mail.nih.gov](mailto:birkens@mail.nih.gov).

*Name of Committee:* National Center for Research Resources Special Emphasis Panel; 2008 NCRR Loan Repayment Review.

*Date:* April 24, 2008.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Bonnie Dunn, PhD, Scientific Review Officer, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd., 1 Dem. Blvd., Rm. 1074, Bethesda, MD 20892-4874, (301) 435-0824, [dunnbo@mail.nih.gov](mailto:dunnbo@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical

Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: February 28, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 08-963 Filed 3-5-08; 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 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 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, Time Perception and Timed Performance in Autism.

*Date:* March 11, 2008.

*Time:* 3:15 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, 5B01, Rockville, MD 20852 (Telephone Conference Call).

*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, [wallsct@mail.nih.gov](mailto:wallsct@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. 93.964, 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: February 28, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 08-957 Filed 3-5-08; 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 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 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; Innovation Therapies and Clinical Studies For Screenable Disorders.

*Date:* March 28, 2008.

*Time:* 12 p.m. to 1:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, 5B01, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Norman Chang, 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) 496-1485, [changn@mail.nih.gov](mailto:changn@mail.nih.gov).

(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: February 28, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 08-958 Filed 3-5-08; 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 Meetings

Pursuant to section 10(a) of the Federal Advisory Committee Act, as