

ADDRESSES) written or electronic comments on the draft guidance. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/guidelines.htm>.

Dated: February 6, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-3166 Filed 2-13-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-S-0002]

Phonetic Orthographic Computer Analysis Software Program for Review of Proprietary Drug and Biologic Names; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the source code and supporting technical documentation for the Phonetic Orthographic Computer Analysis (POCA) software program. POCA is an analytic tool designed to help identify drug and biologic names and medical terminology that are phonetically and orthographically similar to one another. POCA is one analytic tool that FDA uses to review proposed proprietary drug and biologic names.

ADDRESSES: Requests for single copies of the POCA software should be submitted to the following e-mail address: pocasourcecoderequest@fda.hhs.gov. Communications other than requests for POCA software should be directed to the Division of Medication Error Prevention and Analysis, Center for Drug Evaluation and Research, 10903 New Hampshire Ave. Bldg. 22, Mail Stop 4447, Silver Spring, MD 20993-0002, 301-796-2360.

FOR FURTHER INFORMATION CONTACT:

Carol Holquist, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4416, Silver Spring, MD 20993-0002, 301-796-2360.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of the source code and supporting technical documentation for the POCA software program, an analytic tool designed to help identify drug and biologic names and medical terminology that are phonetically and orthographically¹ similar to one another. POCA is one analytic tool that FDA uses in its review of proposed proprietary drug and biologic names to help FDA identify proprietary names that look alike or sound alike. FDA is not providing technical support for the software program.

In title I of the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85), Congress reauthorized and expanded the Prescription Drug User Fee Act (PDUFA IV). As part of the PDUFA IV performance goals, FDA agreed to provide the full source code and supporting technical documentation for the POCA tool and make it available on disk for use by industry and others from the general public (see section IX.C.2. at <http://www.fda.gov/oc/pdufa4/pdufa4goals.html>).

The POCA software was produced under a U.S. Government contract, and the United States has unlimited rights in the software. The United States has determined that it is in its best interest to provide it royalty-free to the public to use or modify the software for any purpose. Thus, the software is hereby provided free of any restriction on use or distribution. The software is furthermore provided “as is” without warranty of any kind or any guarantee that the software will work for any purpose. Project Performance Corp. developed the software under a U.S. Government contract.

Single copies of the POCA software are available from FDA upon request (see **ADDRESSES**).

¹ Merriam-Webster Online defines the term “orthography” in part as: (1) The representation of the sounds of a language by written or printed symbols or (2) a part of language study that deals with letters and spelling. Complete definitions of “orthography” and “orthographic” are available at <http://www.merriam-webster.com/dictionary.htm>.

Dated: February 6, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9-3170 Filed 2-13-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, March 11, 2009, 8 a.m. to March 12, 2009, 6 p.m., National Cancer Institute/NIH, 6116 Executive Blvd., Room 8053, Rockville, MD 20852 which was published in the **Federal Register** on January 29, 2009, 74FR5170.

The meeting notice is changed to reflect the date change from March 11-12, 2009 to March 18-19, 2009. The meeting is closed to the public.

Dated: February 11, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-3309 Filed 2-13-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & 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; Limited Competition for Data Sharing for Demographic Research Infrastructure.

Date: March 2, 2009.

Time: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 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, 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: February 9, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-3192 Filed 2-13-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & 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 10, 2009.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 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, wallsc@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 9, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-3195 Filed 2-13-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & 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, Chondrocyte Maturation and Chondrodysplasias.

Date: March 11, 2009.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Peter Zelazowski, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Rm. 5B01, Bethesda, MD 20892-7510, 301-435-6902, peter.zelazowski@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 9, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-3212 Filed 2-13-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, March 16, 2009, 8 a.m. to March 17, 2009, 6 pm, Hilton Washington DC North/Gaithersburg, 620 Perry Parkway, Gaithersburg, MD, 20877 which was published in the **Federal Register** on December 17, 2008, 73 FR76669.

This notice is amended to change the date from March 16-17, 2009 to March 10-11, 2009, 6 pm. The meeting is closed to the public.

Dated: February 9, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-3200 Filed 2-13-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, March 26, 2009, 8:30 a.m. to March 26, 2009, 6 p.m., Bethesda Marriott-Pooks Hill, 5151 Pooks Hill Road, Bethesda, MD 20814 which was published in the **Federal Register** on January 12, 2009, 74 FR71219.

This notice is amended to change the Scientific Review Officer from Rhonda J. Moore, PhD to Gerald Lovinger, PhD. The meeting is closed to the public.

Dated: February 9, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-3201 Filed 2-13-09; 8:45 am]

BILLING CODE 4140-01-P