

prescription drug and biological products. This guidance is intended to help applicants select information for inclusion in the "Dosage and Administration" section of labeling and to help them organize that information.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the guidance 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 guidance document.

**FOR FURTHER INFORMATION CONTACT:** Joseph P. Griffin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4204, Silver Spring, MD 20993-0002, 301-796-2270; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled "Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and Format." The guidance provides recommendations on how to select information for inclusion in the "Dosage and Administration" section of labeling and how to organize information within the section. This guidance is one of a series of guidances FDA is developing, or has developed, to assist applicants with the format and content of certain sections of the labeling for prescription drugs. In the **Federal Register** of January

24, 2006 (71 FR 3998), FDA issued final guidances on the format and content of the "Adverse Reactions" and "Clinical Studies" sections of labeling and draft guidances on implementing the new labeling requirements for prescription drugs and the format and content of the "Warnings and Precautions," "Contraindications," and "Boxed Warning" sections of labeling. In the **Federal Register** of March 3, 2009 (74 FR 9250), FDA issued a draft guidance on the format and content of the "Clinical Pharmacology" section of labeling. The labeling requirements (71 FR 3922) and these guidances are intended to make information in prescription drug labeling easier for health care practitioners to access, read, and use.

On April 9, 2007, FDA issued a draft of this guidance on the dosage and administration section of labeling to obtain public comment (72 FR 17561). FDA received 10 comments—9 from the pharmaceutical industry (individual companies, a trade association, and a consultant) and 1 from an academic medical center. The comments offered generally favorable impressions of the guidance and its goals. The bulk of the comments focused on clarifications and further illustrations of issues discussed in individual sections and subsections of the guidance. FDA made an effort to address as many of the identified concerns as possible. A recurring general concern in many industry comments was that the guidance should more clearly differentiate content that is required when relevant to a given drug from content that is recommended. FDA has attempted to make the distinction as clear as possible by using the word "must" and citing the relevant section of the regulation whenever the guidance is discussing required content and using the word "should" when discussing recommended content.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the content and format of the "Dosage and Administration" section of labeling for human prescription drug and biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**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.

**III. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 201.57 have been approved under OMB control number 0910-0572.

**IV. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.regulations.gov>.

Dated: March 18, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**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. App.), 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; Small

Business: AIDS/HIV Small Business Innovative Research Applications.

*Date:* April 1, 2010.

*Time:* 11:59 a.m. to 3:30 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 Officer, 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](mailto:rubertm@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: Insulin Signaling and Diabetes.

*Date:* April 6-7, 2010.

*Time:* 9 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Ann A. Jerkins, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6154, MSC 7892, Bethesda, MD 20892, 301-435-4514, [jerkinsa@csr.nih.gov](mailto:jerkinsa@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: Exploratory Research in AIDS Immunology and Pathogenesis.

*Date:* April 7, 2010.

*Time:* 2 p.m. to 4 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:* Shiv A. Prasad, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301-443-5779, [prasads@csr.nih.gov](mailto:prasads@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Molecular Signaling.

*Date:* April 13, 2010.

*Time:* 2 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:* Russell T. Dowell, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4128, MSC 7814, Bethesda, MD 20892, (301) 435-1850, [dowellr@csr.nih.gov](mailto:dowellr@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: March 16, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-6299 Filed 3-22-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Conference Grants (R13's).

*Date:* April 5-6, 2010.

*Time:* 11 a.m. to 10 a.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Robert T. Su, Ph.D., Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892-7924. 301-435-0297. [sur@mail.nih.gov](mailto:sur@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 16, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-6301 Filed 3-22-10; 8:45 am]

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## 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. App.), 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 Special Emphasis Panel R25 Initiative.

*Date:* April 1, 2010.

*Time:* 11:15 a.m. to 12:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

*Contact Person:* Phillip F. Wiethorn, Scientific Review Administrator, DHHS/NIH/NINDS/DER/SRB, 6001 Executive Boulevard; MSC 9529, Neuroscience Center; Room 3203, Bethesda, MD 20892-9529, (301) 496-5388, [wiethorp@ninds.nih.gov](mailto:wiethorp@ninds.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 Special Emphasis Panel Udall Centers.

*Date:* April 20-21, 2010.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Monaco Alexandria, 480 King Street, Alexandria, VA 22314.

*Contact Person:* Ernest W Lyons, PhD., Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-4056, [lyonse@ninds.nih.gov](mailto:lyonse@ninds.nih.gov).

(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: March 15, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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