

the pharmacologic class first because: (1) It is important for the safe use of drugs; (2) it is necessary for making future indexing meaningful (e.g., drug interactions); and (3) this choice leverages existing FDA resources. After pharmacologic class, we will be seeking public input on which indexing elements should be added in future phases.

The guidance also recommends that applicants submit any questions regarding existing indexing, including any requests to add or revise an indexing element, to FDA by e-mail at spl@fda.hhs.gov. Inquiries and requests will be forwarded to the appropriate FDA personnel, who will consider them and make any appropriate change in the SPL.

In the **Federal Register** of March 19, 2007, FDA announced a draft version of this guidance entitled "Indexing Structured Product Labeling" (72 FR 12807). A number of comments were received, and FDA considered them carefully during finalization of the guidance. For example, applicants expressed a desire to recommend indexing terms to FDA; the guidance now provides advice on this topic. Applicants also indicated that they would like to see the indexing terms that FDA has selected prior to indexing. The guidance describes a high level process for sharing indexing terms before FDA actually indexes the SPL decision for a specific element, e.g., pharmacologic class. The guidance also clarifies various points set forth in the draft guidance that the public suggested needed clarification. This guidance is being issued as a joint CDER-CBER guidance in preparation for CBER to implement SPL in the future.

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 indexing SPL. 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

Comments on agency guidances are welcome at any time. 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 either <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.regulations.gov>.

Dated: May 23, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-12158 Filed 5-30-08; 8:45 am]

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. 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; Host Interactions with Bacterial Pathogens.

Date: June 12, 2008.

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

Agenda: To review and evaluate grant applications.

Place: Latham Hotel, 3000 M Street, NW., Washington, DC 20007.

Contact Person: Richard G. Kostriken, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 301-402-4454, kostrkr@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; CASE and KNOD SRG Member Conflict Panel.

Date: June 16, 2008.

Time: 10 a.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: Fungai F. Chanetsa, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, 301-435-1262, chanetsaf@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, Urology Overflow Applications.

Date: June 17, 2008.

Time: 4 p.m. to 6 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: Ryan G. Morris, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4205, MSC 7814, Bethesda, MD 20892, 301-435-1501, morrisr@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, Neurobiophysical Topics.

Date: June 18, 2008.

Time: 1 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: Mary Custer, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4148, MSC 7850, Bethesda, MD 20892-7850, (301) 435-1164, custerterm@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, Fungal Pathogens.

Date: June 23, 2008.

Time: 1 p.m. to 3 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: Richard G. Kostriken, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 301-402-4454, kostrikr@csr.nih.gov.

Name of Committee: Center for Scientific Review, Special Emphasis Panel, Molecular Cardiology.

Date: June 24, 2008.

Time: 1:30 p.m. to 3:30 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.

Name of Committee: AIDS and Related Research Integrated Review Group; Behavioral and Social Science Approaches to Preventing HIV/AIDS Study Section.

Date: July 7-8, 2008.

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

Agenda: To review and evaluate grant applications.

Place: Grand Hyatt Seattle, 721 Pine Street, Seattle, WA 90101.

Contact Person: Jose H. Guerrier, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5222, MSC 7852, Bethesda, MD 20892, 301-435-1137, guerriej@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Biomedical Devices and Bioengineering.

Date: July 7, 2008.

Time: 8 a.m. to 5 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: Guo Feng Xu, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, 301-435-1032, xuguofen@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; SAT Member Conflict.

Date: July 7, 2008.

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, (Virtual Meeting).

Contact Person: Roberto J. Matus, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7854, Bethesda, MD 20892, (301) 435-2204, matusr@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel;

Dissemination and Implementation Research in Healthcare Special Emphasis Panel.

Date: July 8, 2008.

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

Agenda: To review and evaluate grant applications.

Place: Sir Francis Drake Hotel, 450 Powell Street, San Francisco, CA 94102.

Contact Person: Melinda Tinkle, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3141, MSC 7770, Bethesda, MD 20892, (301) 594-6594, tinklem@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; AIDS SBIR/STTR Biological Sciences.

Date: July 8, 2008.

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

Agenda: To review and evaluate grant applications.

Place: The Allerton Hotel, 701 N. Michigan Avenue, Chicago, IL 60611.

Contact Person: Kenneth A. Roebuck, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, MSC 7852, Bethesda, MD 20892, (301) 435-1166, roebuckk@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; ELSI of Human Microbiome Research.

Date: July 8, 2008.

Time: 8 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, NW., Washington, DC 20037.

Contact Person: Richard A. Currie, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1108, MSC 7890, Bethesda, MD 20892, (301) 435-1219, currieri@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Radioligands.

Date: July 8, 2008.

Time: 8 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Raya Mandler, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217, MSC 7840, Bethesda, MD 20892, 301-402-8228, rayam@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Molecular, Cellular and Developmental Neurobiological Small Business Applications.

Date: July 8, 2008.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Embassy Suites, 1250 22nd Street, NW., Washington, DC 20037.

Contact Person: Michael A. Lang, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140,

MSC 7850, Bethesda, MD 20892, (301) 435-1265, langm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Diabetes, Obesity and Nutrition.

Date: July 8, 2008.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Krish Krishnan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, (301) 435-1041, krishnak@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RIBT Member Conflicts.

Date: July 8, 2008.

Time: 1 p.m. to 3 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: George M. Barnas, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2180, MSC 7818, Bethesda, MD 20892, 301-435-0696, barnasg@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Diversity Program.

Date: July 8, 2008.

Time: 12 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: Bonnie L. Burgess-Beusse, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2191C, MSC 7818, Bethesda, MD 20892, 301-435-1783, beusseb@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Lipids and Lipoproteins.

Date: July 9-10, 2008.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Michael Knecht, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6176, MSC 7892, Bethesda, MD 20892, (301) 435-1046, knechtm@csr.nih.gov.

Name of Committee: Biology of Development and Aging Integrated Review Group; International and Cooperative Projects—I Study Section.

Date: July 10, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, D.C., 2401 M Street, NW., Washington, DC 20037.

Contact Person: Manana Sukhareva, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892, 301-435-1116, sukharem@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Cell Biology.

Date: July 10-11, 2008.

Time: 8 a.m. to 5 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: Jonathan Arias, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7840, Bethesda, MD 20892, 301-435-2406, ariasj@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Roadmap-R21 HTS Assays.

Date: July 10, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: James J. Li, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7849, Bethesda, MD 20892, 301-435-2417, lijames@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Nature's Solutions.

Date: July 10, 2008.

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: Joyce C. Gibson, DSC, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4130, MSC 7814, Bethesda, MD 20892, (301) 435-4522, gibsonj@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Musculoskeletal Rehabilitation SBIR.

Date: July 10-11, 2008.

Time: 8 a.m. to 5 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: Jo Pelham, BA, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4102, MSC 7814, Bethesda, MD 20892, (301) 435-1786, pelhamj@csr.nih.gov.

Name of Committee: AIDS and Related Research Integrated Review Group; AIDS Immunology and Pathogenesis Study Section.

Date: July 11, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Hotel, 2401 M Street, NW., Washington, DC 20037.

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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business Hematology.

Date: July 11, 2008.

Time: 8 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Lombardy, 2019 Pennsylvania Avenue, NW., Washington, DC 20006.

Contact Person: Delia Tang, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4126, MSC 7802, Bethesda, MD 20892, 301-435-2506, tangd@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Predoctoral Fellowship to Promote Diversity in Health-Related Research (DCPS).

Date: July 11, 2008.

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

Agenda: To review and evaluate grant applications.

Place: Savoy Suites, 2505 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Gabriel B. Fosu, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3215, MSC 7808, Bethesda, MD 20892, (301) 435-3562, fosug@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cognition, Language, and Perception Fellowship Study Section.

Date: July 11, 2008.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, D.C., 2401 M Street, NW., Washington, DC 20037.

Contact Person: Dana Jeffrey Plude, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301-435-2309, pluded@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Alzheimer's Disease Pilot Clinical Trials.

Date: July 11, 2008.

Time: 11 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Alfonso R. Latoni, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7848, Bethesda, MD 20892, 301-435-0913, latonia@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: May 20, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-11790 Filed 5-30-08; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Project: Methamphetamine Use Prevention Initiative—NEW

Prevention of Methamphetamine Abuse grants are authorized under Section 519E of the Public Health Service Act, as amended. This program addresses the growing problem of methamphetamine abuse and addiction by assisting localities to expand prevention interventions that are effective and evidence-based and/or to increase capacity through infrastructure development. According to the 2005 National Survey on Drug Use and Health, 10.4 million Americans age 12 and older had tried methamphetamine at least once in their lifetime. In addition, the number of methamphetamine users who were dependent on or abused some kind of illicit drug rose significantly from 164,000 in 2002 to 257,000 in 2005. The goal of the Methamphetamine Abuse Prevention grants is to intervene effectively to prevent, reduce, or delay the use and/or spread of methamphetamine abuse.

Proposed Methamphetamine Prevention and Abuse grants will focus on conducting community-based prevention programs targeting those populations within the community that are most at risk for methamphetamine abuse and addiction. In addition, grants may be used for assisting local government entities to conduct appropriate methamphetamine prevention activities in rural and urban areas that are experiencing increases in methamphetamine abuse and addiction. This can be documented by local and