

Dated: April 6, 2009.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E9-10818 Filed 5-7-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Board of Scientific Counselors, National Center for Public Health Informatics (BSC, NCPHI)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the CDC announces the following meeting of the aforementioned committee:

Time and Date: 8:30 a.m.–5 p.m., May 26, 2009.

Place: Swan & Dolphin Hotel, 1500 Epcot Resorts Boulevard, Lake Buena Vista, Florida 32830. Audio conference call via FTS conferencing. The USA toll free dial number is 1-866-713-5586, with a participant pass code of 4624038.

Status: Open to the public, limited only by the space available.

Purpose: The committee will meet to conduct BSC, NCPHI business.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 4, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

Matters To Be Discussed: To discuss BSC, NCPHI-related matters including: update on BioSense; re-formation of three BSC working groups; and various other BSC-related activities. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Scott McNabb, Ph.D., Designated Federal Officer, NCPHI, CDC, 1600 Clifton Road, NE., Mailstop E-78, Atlanta, Georgia 30333, Telephone: (404)498-6427, Fax (404)498-6235.

[FR Doc. E9-10738 Filed 5-7-09; 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 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: Neurological Sciences Training Initial Review Group; NST-1 Subcommittee.

Date: May 11–12, 2009.

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

Agenda: To review and evaluate grant applications.

Place: The Tuscan Inn, 495 Jefferson Street, San Francisco, CA 94109.

Contact Person: Raul A. Saavedra, PhD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, NSC; 6001 Executive Blvd., Ste. 3208, Bethesda, MD 20892-9529, 301-496-9223, saavedrr@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.

(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: May 4, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-10803 Filed 5-7-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Arthritis Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 16, 2009, from 8:30 a.m. to 4 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is 301-589-5200.

Contact Person: Nicole Vesely, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-6793, FAX: 301-827-6776, e-mail:

nicole.vesely@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512532. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Agenda: The committee will discuss biologics license application (BLA) 125293, KRYSTEXXA (pegloticase), Savient Pharmaceuticals, Inc., as a therapy for patients with refractory gout.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2009 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 2, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief

statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 22, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 26, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Nicole Vesely at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 30, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9-10729 Filed 5-7-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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 Center for Research Resources Special Emphasis Panel; BioTechnology 2 SEP.

Date: June 25, 2009.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lee Warren Slice, PhD, Scientific Review Officer, Office of Review, National Center for Research Resources, 6701 Democracy Blvd. Room 1068, Bethesda, MD 20892, 301-435-0965.

(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; 93.702, ARRA Related Construction Awards., National Institutes of Health, HHS).

Dated: May 4, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-10804 Filed 5-7-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NIH-Sponsored Workshop: "Soy Protein and Isoflavones Research: Challenges in Designing and Evaluating Intervention Studies"; Notice

The National Institutes of Health (NIH) Office of Dietary Supplements (ODS) is co-sponsoring a workshop entitled "Soy Protein and Isoflavones Research: Challenges in Designing and Evaluating Intervention Studies" with other NIH Institutes and Centers (National Center for Complementary and Alternative Medicine, National Cancer Institute, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute on Aging, and the Division of Nutrition Research Coordination). The workshop will be held on July 28-29 at the Bethesda North Marriott Hotel and Conference Center, Bethesda, Maryland.

Summary

NIH has been supporting research on soy in its many forms for a range of outcomes. Questions concerning which forms of soy might be better for studies of specific health outcomes and at what doses led the National Center for Complementary and Alternative

Medicine and the Office of Dietary Supplements to commission an evidence-based review of the literature. The resulting report (<http://www.ahrq.gov/clinic/tp/soytp.htm>) found a large, but weak, literature with equivocal findings. Moreover, the National Institute of Environmental Health Sciences provided some troubling data about soy products used in research, which included confounding produced by unanticipated levels of phytoestrogens in animal feed (Heindel *et al. Environmental Health Perspectives* 2008:116(3);389-393). Hence, components of the NIH became concerned about the quality of data from human studies.

The purpose of this workshop, therefore, is to provide guidance for the next generation of soy protein and isoflavone human research. Specifically, the workshop objectives are to identify (1) methodological issues relative to exposures and interventions that may confound study results and interpretation and (2) scientifically sound and useful options and solutions for dealing with these issues in the design, conduct, reporting of results, and interpretation of ongoing and future studies. NIH is seeking input from scientists from multiple disciplines, including nutritionists, physicians, analytical chemists, epidemiologists, biochemists, and clinical trialists from academia, industry, and government. This highly participatory workshop will address issues related to population exposure to soy and other phytoestrogens, factors influencing variability of response to soy interventions and negative consequences of exposure, methods and tools to assess exposure, product composition, and analytic methods to assess soy product constituents and metabolites.

Registration

Seating at this workshop is very limited. To register, please e-mail by June 1, 2009, your name, complete contact information (including phone number, e-mail address, and street address), and the dates that you plan to attend to Ms. Tricia Wallich at wallich@csionweb.com. If you do not have access to e-mail, please call Ms. Wallich at 301-670-0270 (not a toll-free number). Ms. Wallich will be coordinating the registration for this workshop.

Dated: May 4, 2009.

Raynard S. Kington,

Acting Director, National Institutes of Health.

[FR Doc. E9-10788 Filed 5-7-09; 8:45 am]

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