

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]

BILLING CODE 4160-01-S

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]

BILLING CODE 4140-01-P

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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