

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 materials, 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 Mental Health Special Emphasis Panel; Fellowships and Dissertations.

*Date:* July 13, 2010.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Serena P. Chu, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892-9609, 301-443-0004, [sechu@mail.nih.gov](mailto:sechu@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: May 27, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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## 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. 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 Institute of Child Health and Human Development Special Emphasis Panel; Race-Based Social Stress and Health in the MADICS Longitudinal Study, University of Michigan at Ann Arbor.

*Date:* June 25, 2010.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

*Contact Person:* Michele C. Hindi-Alexander, PhD, Division of Scientific Review, National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 1600 Executive Boulevard, Rm. 5B01, Bethesda, MD 20892, (301) 435-8382, [hindiadm@mail.nih.gov](mailto:hindiadm@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: May 27, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0215]

#### Substances Generally Recognized as Safe Added to Food for Animals; Notice of Pilot Program

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is seeking participants for a voluntary pilot program whereby persons submit to FDA notices of claims that a particular use of a substance in food for animals is exempt from the statutory premarket approval requirements based on the notifier's determination that such use is generally recognized as safe (GRAS). FDA intends to evaluate these notices and will inform each participant (notifier) in writing either that the notice provides a sufficient basis for the GRAS determination or that FDA has identified questions as to whether the intended use of the substance is GRAS.

**DATES:** Submit written requests to participate in the pilot program beginning June 4, 2010.

**ADDRESSES:** Submit written requests to participate in the pilot program to the Division of Animal Feeds (HFV-224), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.

**FOR FURTHER INFORMATION CONTACT:**

Geoffrey K. Wong, Center for Veterinary Medicine (HFV-224), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6879, [Geoffrey.wong@fda.hhs.gov](mailto:Geoffrey.wong@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

### I. Background

#### A. The 1958 Amendment

In 1958, in response to public concern about the increased use of chemicals in foods and food processing, Congress enacted the Food Additives Amendment (the 1958 amendment) to the Federal Food, Drug, and Cosmetic Act (the act). The 1958 amendment required that, before a new additive could be used in food, its producer must demonstrate the safety of the additive to FDA. The 1958 amendment defined the terms "food additive" (section 201(s) of the act (21 U.S.C. 321(s))) and "unsafe food additive" (section 409(a) of the act (21 U.S.C. 348(a))), established a premarket approval process for food additives (section 409(b) through (h)), and amended the food adulteration provisions of the act to deem adulterated any food that is, or bears or contains, any food additive that is unsafe within the meaning of section 409 (section 402(a)(2)(C) of the act (21 U.S.C. 342(a)(2)(C))).

In enacting the 1958 amendment, Congress recognized that many substances intentionally added to food would not require formal premarket review by FDA to assure their safety. Congress thus adopted, in section 201(s) of the act, a two-step definition of "food additive." The first step broadly includes any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of food. The second step, however, excludes from the definition of "food additive" substances that are generally recognized, among experts qualified by scientific training and experience to evaluate their safety ("qualified experts"), as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or through