

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Gerie Voss, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 877-287-1373, gerie.voss@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 22, 2011 (76 FR 36628), FDA issued a final rule regarding required warnings for use on cigarette packages and in cigarette advertisements. FDA examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612) and determined that the rule would have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121), FDA is making available this SECG stating in plain language the legal requirements of the June 22, 2011, final rule, set forth in 21 CFR part 1141, establishing requirements for graphic health warnings on cigarette packages and in cigarette advertisements.

FDA is issuing this SECG as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the Agency's current thinking on this topic. 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**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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. Electronic Access

Persons with access to the Internet may obtain an electronic version of this guidance document at either <http://>

www.regulations.gov or <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: October 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-27530 Filed 10-24-11; 8:45 am]

BILLING CODE 4160-01-P

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: Non-HIV Diagnostics, Food Safety, Sterilization/Disinfection and Bioremediation.

Date: November 17-18, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Hotel, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Gagan Pandya, PhD, Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, RM 3200, MSC 7808, Bethesda, MD 20892, 301-435-1167, pandyaga@mai.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Respiratory Sciences.

Date: November 17-18, 2011.

Time: 9 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: Ghenima Dirami, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7814, Bethesda, MD 20892, 301-594-1321, diramig@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, DA-12-004:

The Placebo Effect: Mechanisms and Methodology (R21).

Date: November 30, 2011.

Time: 9 a.m. to 11:30 a.m.

Agenda: To review and evaluate grant applications.

Place: Legacy Hotel and Meeting Center, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Melissa Gerald, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3172, MSC 7848, Bethesda, MD 20892, (301) 408-9107, geraldmel@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, DA-12-003: The Placebo Effect: Mechanisms and Methodology (R01).

Date: November 30, 2011.

Time: 11:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Legacy Hotel and Meeting Center, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Melissa Gerald, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3172, MSC 7848, Bethesda, MD 20892, (301) 408-9107, geraldmel@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: October 19, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-27545 Filed 10-24-11; 8:45 am]

BILLING CODE 4140-01-P

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 Fellowships: AIDS Predoctoral and Postdoctoral.

Date: November 14, 2011.

Time: 11 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Westin Georgetown, 2350 M Street, NW., Washington, DC 20037.

Contact Person: Mary Clare Walker, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435-1165, walkermc@csr.nih.gov.

Name of Committee: AIDS and Related Research Integrated Review Group HIV/AIDS Vaccines Study Section.

Date: November 18, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Mary Clare Walker, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435-1165, walkermc@csr.nih.gov.

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

Date: November 29–30, 2011.

Time: 8 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: Rass M Shayiq, PhD, Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 435-2359, shayiqr@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Early Embryo Development Pluripotency.

Date: November 29–30, 2011.

Time: 8 a.m. to 8 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 H. Chaitin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7850, Bethesda, MD 20892, (301) 435-0910, chaitinm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Antimicrobials and Resistance.

Date: November 29–30, 2011.

Time: 8:30 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: John C Pugh, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7808, Bethesda, MD 20892, (301) 435-2398, pughjohn@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer Biology and Signaling.

Date: November 30–December 1, 2011.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Rolf Jakobi, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7806, Bethesda, MD 20892, 301-495-1718, jakobir@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Stroke, Spinal Cord and Brain Injury.

Date: November 30–December 1, 2011.

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: Seetha Bhagavan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237-9838, bhagavas@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowship: Oncological Sciences Overflow.

Date: November 30, 2011.

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, (Telephone Conference Call).

Contact Person: Alexander Gubin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4196, MSC 7812, Bethesda, MD 20892, 301-435-2902, gubina@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: October 19, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-27544 Filed 10-24-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research 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: Center for Inherited Disease Research Access Committee.

Date: November 10, 2011.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Camilla E. Day, PhD, Scientific Review Officer, CIDR, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Suite 4075, Bethesda, MD 20892, 301-402-8837, camilla.day@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. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: October 19, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-27542 Filed 10-24-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases 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 Diabetes and Digestive and Kidney Diseases