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.

BILLYING 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, DA–12–003: 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, geraldme@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, DA–12–004: Predoctoral and Postdoctoral.

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, geraldme@csr.nih.gov.


Dated: October 19, 2011.

Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

BILLYING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Notice of Closed Meetings

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Dated: October 19, 2011.

Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

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