Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.


SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “What You Need to Know About Administrative Detention of Foods,” which replaces the guidance of the same title issued in November 2004. The guidance is intended to provide individuals in the human and animal food industries with an understanding of FDA’s authority to order the administrative detention of human or animal food under section 304(h)(1)(A) of the FD&C Act (21 U.S.C. 334(h)), as amended by section 207 of FSMA, to section 304(h)(1)(A) of the FD&C Act to provide FDA the authority to order administrative detention if there is reason to believe that an article of food is adulterated or misbranded. On May 5, 2011, in accordance with FSMA, FDA published an interim final rule in the Federal Register amending its regulations in part 1, subpart K (21 CFR part 1, subpart K), (76 FR 25538), that pertain to the criteria for ordering administrative detention. This interim final rule became effective on July 3, 2011.

The guidance represents the Agency’s current thinking on its authority to order the administrative detention of human or animal foods. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). We conclude that the collections of information in §§1.381(d) and 1.402 are exempt from OMB review under 44 U.S.C. 18(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. The regulations in 5 CFR 1320(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit, or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the decision to detain an article of food.

III. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/RegulatoryInformation/Guidances/default.htm or http://www.regulations.gov. Always access an FDA guidance document by using the FDA’s Web site listed previously to find the most current version of the guidance.

Dated: October 20, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.

[FR Doc. 2011–27529 Filed 10–24–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0568]

Small Entity Compliance Guide: Required Warnings for Cigarette Packages and Advertisements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Required Warnings for Cigarette Packages and Advertisements—Small Entity Compliance Guide” for a final rule published in the Federal Register on June 22, 2011. This small entity compliance guide (SECG) is intended to set forth in plain language the requirements of the regulation and to help small businesses understand and comply with the regulation.

DATES: Submit either electronic or written comments on the SECG at any time.

ADDRESSES: Submit written requests for single copies of the SECG entitled “Required Warnings for Cigarette Packages and Advertisements—Small Entity Compliance Guide” to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.
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 314.73). 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, 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, 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 (R21).

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.


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, Predoctoral and Postdoctoral Fellowships: AIDS Predoctoral and Postdoctoral.

Dated: October 20, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.

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