

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

**FOR FURTHER INFORMATION CONTACT:**

William A. Correll, Jr., Office of Compliance (HFS-607), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1611.

**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) of the FD&C Act (21 U.S.C. 334(h)), as amended by section 207 of FSMA. It provides practical information, including who can approve an administrative detention order, what food may be subject to administrative detention, who receives a copy of an administrative detention order, and the process for appealing an administrative detention order. Additionally, the guidance identifies references that contain more information regarding FDA's authority to order administrative detention.

This guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation § 10.115 (21 CFR 10.115) as a level 1 guidance. The Agency will accept comments, but it is implementing this document immediately, in accordance with § 10.115(g)(2) because the Agency has determined that prior public participation is not feasible or appropriate. The Agency made this determination because much of this guidance remains the same as the guidance issued in November 2004. In addition, this guidance simply reflects the statutory changes made by section 207 of FSMA to section 304(h)(1)(A) of the FD&C Act (21 U.S.C. 334(h)(1)(A)) and seeks to remove any confusion that might arise due to the existence of a guidance document that is inconsistent with the FD&C Act and its implementing regulations. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's GGPs regulation.

FSMA was signed into law on January 4, 2011. Section 207 of FSMA amended the criteria for ordering administrative detention in 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](mailto: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](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](mailto: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](mailto: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](mailto: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](mailto: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.