

10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 8, 2010.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229.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self-addressed adhesive label to assist that office in processing your requests or include a fax number to which the draft guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Carol Drew, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 877-287-1373.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled “Harmful and Potentially Harmful Constituents’ in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act.” This draft guidance, when finalized, will discuss the meaning of the term “harmful and potentially harmful constituent” for use in implementing section 904(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 387d(e)) as amended by the Tobacco Control Act.

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111-310) into law. The Tobacco Control Act amended the act (21 U.S.C. 301 *et seq.*) by, among other things, adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 904(e) of the act, as added by the Tobacco Control Act, requires FDA to establish, and periodically revise as appropriate, “a list of harmful and potentially harmful constituents, including smoke constituents, to health

in each tobacco product by brand and by quantity in each brand and subbrand.” The draft guidance discusses the meaning of the term “harmful and potentially harmful constituent” in the context of implementing the listing requirements of section 904(e) of the act.

**II. Significance of Guidance**

This draft guidance is being issued as a level 1 guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on certain provisions of the Tobacco Control Act. 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.

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

Dated: June 7, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-14046 Filed 6-8-10; 4:15 pm]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-D-0282]

**Guidance for Industry and Food and Drug Administration Staff; Use of “Light,” “Mild,” “Low,” or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Use of ‘Light,’ ‘Mild,’ ‘Low,’ or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products.” This guidance provides information on the Family Smoking Prevention and Tobacco Control Act’s (Tobacco Control Act) requirements related to the use of “light,” “mild,” “low,” or similar descriptors in the label, labeling, or advertising of tobacco products. This guidance document will be implemented immediately, but it remains subject to comment in accordance with the agency’s good guidance practices.

**DATES:** Submit either electronic or written comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled “Use of ‘Light,’ ‘Mild,’ ‘Low,’ or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products” 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 information on electronic access to the guidance.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments concerning this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Beth Buckler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373, e-mail: [beth.buckler@fda.hhs.gov](mailto:beth.buckler@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111-31) into law. The Tobacco Control Act grants FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 911(b)(2)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Tobacco Control Act, prohibits the use of the descriptors "light," "mild," or "low," or similar descriptors on tobacco product labels, labeling, or advertising unless an FDA order is in effect for the product under section 911(g) of the act. Section 911(b)(3) of the act, as amended by the Tobacco Control Act, provides that section 911(b)(2)(A)(ii) shall take effect on June 22, 2010, and the effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 911(b)(2)(A)(ii). The guidance provides information in response to specific questions related to this provision. In accordance with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)), you may comment on this guidance at any time. The agency will consider your comments and determine whether to revise the guidance at a later date.

## II. Significance of Guidance

FDA is issuing this guidance document as a level 1 guidance consistent with FDA's good guidance practices regulation (§ 10.115). This guidance document is being implemented immediately without prior public comment, under § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. This guidance document provides information on statutory requirements that take effect on June 22, 2010 (section 911(b)(3) of the act). It is important that FDA provide this information before that date.

## 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

An electronic version of the guidance document is available on the Internet at <http://www.regulations.gov> and <http://www.fda.gov/TobaccoProducts/>

## GuidanceComplianceRegulatory Information/default.htm.

Dated: June 7, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-13986 Filed 6-7-10; 4:15 pm]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; 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:* National Institute on Aging Special Emphasis Panel; Work Levels, Disease, and Death.

*Date:* June 23-24, 2010.

*Time:* 3 p.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Guest Suites Santa Monica, 1707 Fourth Street, Santa Monica, CA 90401.

*Contact Person:* Jeannette L. Johnson, PhD, Scientific Review Officer, National Institutes on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301-402-7705, [johnsonj9@nia.nih.gov](mailto:johnsonj9@nia.nih.gov).

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Health and Survival.

*Date:* June 23-24, 2010.

*Time:* 3 p.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications

*Place:* Doubletree Guest Suites Santa Monica, 1707 Fourth Street, Santa Monica, CA 90401.

*Contact Person:* Jeannette L. Johnson, PhD, Scientific Review Officer, National Institutes on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301-402-7705, [johnsonj9@nia.nih.gov](mailto:johnsonj9@nia.nih.gov).

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Exercise, Motor Deficits, and Aging.

*Date:* July 1, 2010.

*Time:* 1 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Rebecca J. Ferrell, PhD, Scientific Review Officer, National Institute on Aging, Gateway Building Rm. 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-402-7703, [ferrellrj@mail.nih.gov](mailto:ferrellrj@mail.nih.gov).

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Nutrition effects on Aging Brain.

*Date:* July 23, 2010.

*Time:* 11 a.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* William Cruce, PhD, Scientific Review Officer, National Institute on Aging, Scientific Review Branch, Gateway Building 2C-212, 7201 Wisconsin Ave., Bethesda, MD 20814, 301-402-7704, [crucew@nia.nih.gov](mailto:crucew@nia.nih.gov).

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Antecedent Markers for Alzheimer's Disease.

*Date:* July 26, 2010.

*Time:* 2 p.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* William Cruce, PhD, Scientific Review Officer, National Institute on Aging, Scientific Review Branch, Gateway Building 2C-212, 7201 Wisconsin Ave., Bethesda, MD 20814, 301-402-7704, [crucew@nia.nih.gov](mailto:crucew@nia.nih.gov).

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Frontotemporal Dementias.

*Date:* July 29, 2010.

*Time:* 2 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, 7201 Wisconsin Avenue, RM 2C212, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* William Cruce, PhD, Scientific Review Officer, National Institute on Aging, Scientific Review Branch, Gateway Building 2C-212, 7201 Wisconsin Ave., Bethesda, MD 20814, 301-402-7704, [crucew@nia.nih.gov](mailto:crucew@nia.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: June 4, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-13948 Filed 6-9-10; 8:45 am]

**BILLING CODE 4140-01-P**