I. Background

In the **Federal Register** of March 19, 2010 (75 FR 13225), FDA published final regulations restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents. This guidance document discusses FDA's intended enforcement policies with respect to two provisions of the final regulations restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents.

One provision, § 1140.16(a) (21 CFR 1140.16(a)), specifies that manufacturers may not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product unless the trade or brand name was on both the tobacco product and a nontobacco product sold in the United States on January 1, 1995. FDA is aware of concerns regarding this provision and is considering what changes, if any, would be appropriate to address those concerns.[1] While FDA has this issue under consideration, it intends to exercise its enforcement discretion concerning § 1140.16(a) (21 CFR 1140.16(a)) not to commence enforcement actions under this provision for the duration of its consideration where:

(1) The trade or brand name of the cigarettes or smokeless tobacco product was registered, or the product was marketed, in the United States on or before June 22, 2009; or

(2) The first marketing or registration in the United States of the tobacco product occurs before the first marketing or registration in the United States of the nontobacco product bearing the same name; provided, however, that the tobacco and nontobacco product are not owned, manufactured, or distributed by the same, related, or affiliated entities (including as a licensee).

The second provision is § 1140.32(a) (21 CFR 1140.32(a)). Under this section of the final rule, manufacturers, distributors, and retailers must use only black text on a white background for labeling or advertising (with certain exceptions). The United States District Court for the Western District of Kentucky recently issued an order permanently enjoining FDA from enforcing § 1140.32(a) (formerly 21 CFR 897.32(a) of the 1996 final rule that published in the **Federal Register** of August 28, 1996 (61 FR 44396)) (*Commonwealth Brands, Inc.* v. *United States*, No. 1:09-CV-117-M (W.D. Ky. Jan. 4, 2010)). As required by section 102 of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), the effective date for § 1140.32(a) is June 22, 2010. At this time, however, in light of the court's order in *Commonwealth Brands*, FDA intends to exercise its enforcement discretion concerning § 1140.32(a) not to commence enforcement actions under this provision during the pendency of the litigation irrespective of whether the entity is a party to the pending lawsuit or located in the Western District of Kentucky.

FDA intends that the exercise of enforcement discretion expressed in this guidance document for §§ 1140.16(a) and 1140.32(a) begin upon the effective date of the final rule (June 22, 2010). In accordance with FDA's GGP 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 GGP 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 document provides guidance on regulations that are required by statute (section 102 of the Tobacco Control Act); moreover, the statute directs that the regulations take effect on June 22, 2010 (section 102(a)(2)(F) of the Tobacco Control Act). It is important that FDA explain its enforcement policy for these two provisions before that date.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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/GuidanceComplianceRegulatoryInformation/default.htm*.

Dated: May 4, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–10934 Filed 5–5–10; 11:15 am]

BILLING CODE 4160–01–S

[1] Under section 102(a)(3)-(4) of the Family Smoking Prevention and Tobacco Control Act (21 U.S.C. 387a-1(a)(3)-(4)), FDA may amend the final rule after issuing a proposed rule for notice and comment.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Advisory Committee for Women's Services; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the Substance Abuse and Mental Health Services Administration's (SAMHSA) Advisory Committee for Women's Services (ACWS) on May 26–27 at SAMHSA.

The meeting is open to the public. It will include reports from the SAMHSA Administrator and the ACWS Chair, Updates from ACWS members, and a discussion of SAMHSA's strategic initiatives.

Attendance by the public will be limited to space available. Public comments are welcome. The meeting can also be accessed via Webstream. To obtain the access information, to register, to submit written or brief oral comments, or to request special accommodations for persons with disabilities, please register at the SAMHSA Committee's Web site at *https://nac.samhsa.gov/Registration/meetingsRegistration.aspx* or communicate with the Designated Federal Officer for the ACWS, Ms. Nevine Gahed (*see* contact information below). Substantive meeting information and a roster of Committee members may be obtained either by accessing the SAMHSA Committee's Web site at *https://nac.samhsa.gov/WomenServices/index.aspx*, or by contacting Ms. Gahed. The transcript for the meeting will be available on the SAMHSA Committee's Web site within three weeks after the meeting.

Committee Name: SAMHSA's Advisory Committee for Women's Services.

Date/Time/Type: Wednesday, May 26, 2010 from 9 a.m. to 5 p.m. EST: OPEN. Thursday, May 27, 2010 from 9 a.m. to 12 noon EST: OPEN.

Place: 1 Choke Cherry Road, Seneca Conference Room, Rockville, Maryland 20857.

Contact: Nevine Gahed, Designated Federal Officer, SAMHSA Advisory Committee for Women's Services, 1 Choke Cherry Road,

Room 8–1112, Rockville, Maryland 20857, *Telephone:* (240) 276–2331; *Fax:* (240) 276–2220 and *E-mail: nevine.gahed@samhsa.hhs.gov*.

Toian Vaughn,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 2010–10778 Filed 5–6–10; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; 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 Biomedical Imaging and Bioengineering Special Emphasis Panel—NIBIB Training SEP.

Date: July 7–9, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Manana Sukhareva, PhD, Scientific Review Officer, National Institute of Biomedical Imaging & Bioeng, National Institutes of Health, 6707 Democracy Boulevard, Suite 959, Bethesda, MD 20892, 301–451–3397, *sukharem@mail.nih.gov*.

Dated: April 30, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–10892 Filed 5–6–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center on Minority and Health Disparities; 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 materials, 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 Center on Minority Health and Health Disparities Special Emphasis Panel, Faith Based R21.

Date: June 29–July 1, 2010.

Time: 5 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Prabha L. Atreya, PhD, Chief, Office of Scientific Review, National Center on Minority Health and Health Disparities, 6707 Democracy Boulevard, Suite 800, Bethesda, MD 20892, (301) 594–8696, *atreyapr@mail.nih.gov.*

Dated: April 30, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–10889 Filed 5–6–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel, Basis of Myocardial Injury in the Elderly.

Date: May 27, 2010.

Time: 1 p.m. to 4 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: Bita Nakhai, PhD, Scientific Review Officer, Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814. 301–402–7701. *nakhaib@nia.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. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 29, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–10888 Filed 5–6–10; 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: Brain Disorders and Clinical Neuroscience Integrated Review Group, Clinical Neuroplasticity and Neurotransmitters Study Section.

Date: June 3–4, 2010.

Time: 8 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: The Melrose Hotel, 2430 Pennsylvania Avenue, NW., Washington, DC 20037.