

regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 15, 2010. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 10, 2010.

**Jane A. Axelrad,**

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2010-14814 Filed 6-17-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control

Special Emphasis Panel (SEP): Cooperative Agreement Program for the National Academic Centers of Excellence in Youth Violence Prevention (U01), Funding Opportunity Announcement (FOA) CE10-004, Initial Review

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

*Times and Dates:* 8 a.m.–5 p.m., July 22, 2010 (Closed). 8 a.m.–5 p.m., July 23, 2010 (Closed).

*Place:* Embassy Suites Atlanta—Buckhead, 3285 Peachtree Road, NE., Atlanta, Georgia 30305, Telephone: 404-261-7733.

*Status:* The meetings will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92-463.

*Matters to be Discussed:* The meeting will include the initial review, discussion, and evaluation of applications received in response to “Cooperative Agreement Program for the National Academic Centers of Excellence in Youth Violence Prevention (U01), FOA CE10-004.”

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* J. Felix Rogers, Ph.D., M.P.H., NCIPC/ERPO, CDC, 4770 Buford Highway, NE., M/S F63, Atlanta, Georgia 30341-3724, Telephone (770) 488-4334. The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 10, 2010.

**Elaine L. Baker,**

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010-14772 Filed 6-17-10; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0295 ]

#### Web-Based Public Meeting To Discuss Issues Related to the Development of an Enforcement Action Plan; Request for Data, Information, and Views

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

**ACTION:** Notice of Web-based public meeting; request for data, information, and views.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Tobacco Products is announcing that it is hosting a Web-based public meeting to discuss issues regarding the development of an enforcement action plan to enforce restrictions on promotion and advertising of menthol and other cigarettes to youth, including youth in minority communities. FDA is seeking participation in the Web-based public meeting and data, information, and views from all interested parties, including, but not limited to, public health organizations, minority community groups and leaders, other stakeholders with demonstrated expertise and experience in serving minority communities, groups serving youth, patient groups, advertising agencies, the regulated industry, and other interested parties. This Web-based public meeting and the data, information, and views we receive are intended to help FDA in developing an enforcement action plan. FDA is seeking input on a number of specific issues, but is interested in other pertinent information as well.

**DATES:** The Web-based public meeting will be held on June 30, 2010, from 9 a.m. to 5 p.m. EDT. Persons interested in participating in the Web-based public meeting must submit written or electronic registration by close of business on June 23, 2010. Submit written and electronic data, information, and views by August 2, 2010.

**ADDRESSES:** Submit data, information, and views electronically to <http://www.regulations.gov>. Submit written data, information, and views to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic registration to [CTPCompliance@fda.hhs.gov](mailto:CTPCompliance@fda.hhs.gov). Submit written registration to Anthony W. Lee, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

#### FOR FURTHER INFORMATION CONTACT:

Anthony W. Lee, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 877-287-1373, email: [AnthonyW.Lee@fda.hhs.gov](mailto:AnthonyW.Lee@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31; 123 Stat. 1776) was enacted on June 22, 2009, providing FDA with the authority to regulate tobacco products in order to protect the public health generally and to reduce tobacco use by minors. Tobacco products are responsible for more than 440,000 deaths each year in the United States (Ref. 1). In enacting the Tobacco Control Act, Congress found, among other things, that the use of tobacco products by children is a pediatric disease and virtually all new users of tobacco products are under the minimum legal age to purchase such products (sections 2(1) and (4) of the Tobacco Control Act). Advertising, marketing, and promotion of tobacco products have been “especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth” (section 2(15) of the Tobacco Control Act).

Additionally, the rates of tobacco use and tobacco-related mortality are higher among certain racial and ethnic groups, including American Indian and Alaska Natives, and African-American men. As the National Cancer Institute (NCI) noted in Monograph 19, “[t]argeting of various population groups—including \* \* \* specific racial and ethnic

populations \* \* \* has been strategically important to the tobacco industry.” (Ref. 2).

The first Surgeon General’s Report to address the tobacco industry’s history of targeting its marketing to minority communities was published in 1998 (Ref. 3). Additionally, studies from the early 1990s document that outdoor tobacco advertising was disproportionately targeted to young people and to minority communities (Refs. 4 and 5). A longitudinal study conducted from 1990 to 1994 in four types of Los Angeles ethnic neighborhoods found that, “[c]ompared with White neighborhood thoroughfares, African American and Hispanic neighborhoods contained a greater tobacco ad density, and all minority neighborhoods contained greater tobacco ad concentration along the roadsides \* \* \*. These data are consistent with the assertion that tobacco companies target ethnic minorities with higher rates of advertising and ethnically tailored campaigns.” (Ref. 6). A meta-analysis published in 2007 confirmed that “African Americans are exposed to a higher volume of pro-tobacco advertising in terms of both concentration and density.” (Ref. 7). In addition to the volume of advertising, the methods used in targeting advertisements to some specific communities have also been studied. For example, Monograph 19 discusses how advertising for mentholated brands to African-Americans was designed around lifestyle appeals relating to “fantasy and escapism,” “expensive objects,” and “nightlife, entertainment, and music” themes. (Ref. 8). However, as NCI noted, “little attention has been paid to understanding tobacco marketing aimed at American Indians and Alaska Natives, despite their high prevalence of tobacco use.” (Ref. 9). Tobacco marketing to Asian Americans is also under-studied.

Section 102 of the Tobacco Control Act directed the Secretary of Health and Human Services (the Secretary) to publish a final rule which, among other things, prohibits the sale of cigarettes and smokeless tobacco to persons under age 18 and imposes restrictions on the marketing, labeling, and advertising of such products (Youth Access and Advertising Regulation). FDA published the final rule on March 19, 2010 (75 FR 13225) and the rule takes effect on June 22, 2010. Section 105(a) of the Tobacco Control Act (21 U.S.C. 387f-1) requires the Secretary to develop and publish an action plan to enforce restrictions, including those provided in the Youth Access and Advertising Regulation, on

promotion and advertising of menthol and other cigarettes to youth. The provision requires that the Secretary develop this plan in consultation with public health organizations and other stakeholders with demonstrated experience and expertise in serving minority communities. This action plan must also include provisions designed to ensure enforcement of the restrictions, including those provided in the Youth Access and Advertising Regulation, on the promotion and advertising of menthol and other cigarettes to youth in minority communities. FDA is requesting data, information, and views that will assist it in developing an action plan regarding enforcement of restrictions on promotion and advertising of menthol and other cigarettes to youth, including youth in minority communities.

## **II. Scope of the Web-Based Public Meeting and Request for Data, Information, and Views**

We are interested in data, information, and views that will help FDA in developing an enforcement action plan to enforce restrictions on promotion and advertising of menthol and other cigarettes to youth, including youth in minority communities. FDA is seeking any pertinent information from all interested parties, including public health organizations and other stakeholders with demonstrated expertise and experience in serving youth and minority communities as well as others with relevant expertise. In addition to general information, we are specifically interested in information on the following topics as they relate to the restrictions on promotion and advertising of menthol and other cigarettes to youth:

1. A discussion of how FDA can identify companies and others who promote and advertise menthol or other cigarettes to youth in violation of applicable restrictions.

2. A discussion of how FDA can identify companies and others who promote and advertise menthol or other cigarettes to youth in minority communities in violation of applicable restrictions.

3. A discussion of how FDA can better understand the types and placement of promotion and advertising of menthol and other cigarettes to youth.

4. A discussion of how FDA can better understand the types and placement of promotion and advertising of menthol and other cigarettes to youth in minority communities.

5. A discussion of how FDA can understand the themes and techniques

used in promotion and advertising of menthol and other cigarettes to youth.

6. A discussion of how FDA can understand the themes and techniques used in promotion and advertising of menthol and other cigarettes to youth in minority communities.

## **III. How to Submit Data, Information, and Views and Participate in the Web-Based Public Meeting**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either or electronic or written data, information, and views 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. Where relevant, you should annotate and organize your data, information, and views to identify the specific topic addressed by the discussion topic number referenced in section II of this document. Received data, information, and views may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

If you wish to participate in the Web-based public meeting, you must submit written or electronic registration as specified previously in this document (see **ADDRESSES**). Registration is free and will be accepted on a first-come, first-served basis, as participation is limited. We strongly encourage members from public health organizations and other stakeholders with demonstrated expertise and experience in serving youth and minority communities to make an oral presentation at this Web-based public meeting. Other interested parties may also be able to make an oral presentation. If you wish to make an oral presentation during the Web-based public meeting, you must state your intention on your registration submission (see **ADDRESSES**) and submit your name, title, company or organization (if applicable), address, telephone and fax numbers, and email address. FDA has included specific topics for discussion in section II of this document. You should also identify by number each discussion topic(s) you wish to address in your presentation, if relevant, and the approximate desired length of your presentation. FDA will do its best to accommodate requests to speak, and attempt to include equal representation from public health organizations and other stakeholders with demonstrated expertise and experience in serving youth and minority communities. FDA requests that speakers make their presentations

onsite at White Oak Bldg. 1, 10903 New Hampshire Ave., Silver Spring, MD 20993. Presenters unable to appear onsite may submit a slide presentation to be shown during the Web-based public meeting. If possible, individuals and organizations with common interests should consolidate or coordinate their presentations and request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. FDA will contact each presenter prior to the Web-based public meeting with the amount of time available and the approximate time at which his or her presentation is scheduled to begin. Once FDA notifies presenters of their scheduled times, each presenter must submit to FDA an electronic copy of the presentation to be given. In order to be included in the Web-based public meeting, presentations must be received no later than June 25 at 5 P.M. (EDT). Please refer to FDA's Web site (<http://www.fda.gov/Tobacco>) for more information and updates on the Web-based public meeting. Transcripts of the Web-based public meeting will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at <http://www.regulations.gov> approximately 30 days after the Web-based public meeting.

#### IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Centers for Disease Control and Prevention, "Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000–2004," Morbidity and Mortality Weekly Report (serial online); 57(45), pp. 1226–1228, 2008 (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm>).

2. National Cancer Institute, U.S. Department of Health & Human Services, "The Role of the Media in Promoting and Reducing Tobacco Use," Tobacco Control Monograph No. 19; p. 11, 2008 (<http://www.cancercontrol.cancer.gov/tcrb/monographs/19/index.html>).

3. U.S. Department of Health and Human Services, "Tobacco Use Among U.S. Racial/Ethnic Minority Groups—African Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders, and Hispanics," A Report of the Surgeon General;

p. 220, 1998 ([http://profiles.nlm.nih.gov/NN/B/B/F/Q/\\_nnbbfq.pdf](http://profiles.nlm.nih.gov/NN/B/B/F/Q/_nnbbfq.pdf)).

4. Mitchell, O. and M. Greenberg, "Outdoor Advertising of Addictive Products," New Jersey Medicine; 88, p. 331, 1991 (finding that billboards in Black and Hispanic neighborhoods in four New Jersey cities disproportionately contained advertisements for tobacco and alcohol products.)
5. Ammerman, S.D. and M. Nolden, "Neighborhood-Based Tobacco Advertising Targeting Adolescents," *Western Journal of Medicine*; 162, pp. 514–518, 1995 (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1022829/pdf/westjmed00058-0028.pdf>) (finding that adolescent exposure to tobacco billboard advertisements in San Francisco in 1992 and 1993 was greater in Latino neighborhoods due to a greater adolescent population, and finding that qualitative analyses of the tobacco advertisements "suggested that adolescents are the primary targets.")

6. Stoddard, J.L., et al., "Tailoring Outdoor Tobacco Advertising to Minorities in Los Angeles County," *Journal of Health Communication*; 3, p. 137, 1998.

7. Primack, B.A., et al., "Volume of Tobacco Advertising in African American Markets: Systematic Review and Meta-Analysis," *Public Health Reports*; 122, p. 607 2007.

8. National Cancer Institute, U.S. Department of Health and Human Services, "The Role of the Media in Promoting and Reducing Tobacco Use," Tobacco Control Monograph No. 19; p. 57, 2008 (<http://www.cancercontrol.cancer.gov/tcrb/monographs/19/index.html>).

9. Id., p. 15.

Dated: June 15, 2010.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

[FR Doc. 2010-14809 Filed 6-14-10; 4:15 pm]

**BILLING CODE 4160-01-S**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### National Institutes of Health

##### National Institute of Arthritis and Musculoskeletal and Skin Diseases; 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 of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel, Program Project Grant Review.

**Date:** July 2, 2010.

**Time:** 1 p.m. to 3 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, 6701 Democracy Blvd, Suite 800, Bethesda, MD 20892, (Telephone Conference Call).

**Contact Person:** Eric H. Brown, Scientific Review Officer, Scientific Review Branch, NIAMS/NIH, 6701 Democracy Blvd, Suite 824, Bethesda, MD 20892, (301) 594-4955, [brownier@mail.nih.gov](mailto:brownier@mail.nih.gov).

**Name of Committee:** National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel, Clinical Trials Application Review.

**Date:** July 16, 2010.

**Time:** 8 a.m. to 4 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Crowne Plaza—Dulles Airport, 2200 Centerville Road, Herndon, VA 20170.

**Contact Person:** Michael L. Bloom, MBA, PhD, Scientific Review Officer, Scientific Review Branch, NIAMS/NIH, 6701 Democracy Blvd, Suite 820, Bethesda, MD 20892, 301-594-4953, [bloomm2@mail.nih.gov](mailto:bloomm2@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: June 14, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-14771 Filed 6-17-10; 8:45 am]

**BILLING CODE 4140-01-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Centers for Disease Control and Prevention

##### Proposed Office of State, Tribal, Local and Territorial Support (OSTLTS)

In accordance with Presidential Executive Order No. 13175, November 6, 2000, and the Presidential Memorandum of November 5, 2009, and September 23, 2004, Consultation and Coordination with Indian Tribal Governments, the Centers for Disease Control and Prevention (CDC), OSTLTS announces the following Tribal Consultation Advisory Committee (TCAC) Meeting and Tribal Consultation Session:

**Name:** Tribal Consultation Advisory Committee (TCAC) Meeting and 5th Biannual Tribal Consultation Session

**Times and Dates:** TCAC Meeting on July 26–28, 2010, from 8 a.m.–6 p.m. and the 5th