

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by email to

[OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: December 18, 2009.

**Alexandra Hutfinger,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. E9-30606 Filed 12-24-09; 8:45 am]

BILLING CODE 4165-15-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-D-0600]

#### Draft Guidance for Industry on Tobacco Health Document Submission; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Tobacco Health Document Submission." The draft guidance is intended to assist persons making certain document submissions to FDA under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 22, 2010.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Tobacco Health Document Submission" to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD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one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance document may be sent.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** May Nelson, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 240-276-1717, [May.Nelson@fda.hhs.gov](mailto:May.Nelson@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 amended the Federal Food, Drug, and Cosmetic Act (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(a)(4) of the act, as amended by the Tobacco Control Act, requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009, "\* \* \* that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives." Information required under section 904(a)(4) of the act must be submitted to FDA beginning December 22, 2009. FDA recognizes the challenges associated with the collection, review, organization, and production of documents. We also recognize that additional time may be necessary for the production of documents in a digital format, which FDA strongly encourages in order to improve the management and accessibility of submitted documents. Therefore, FDA does not intend to enforce the December 22, 2009, deadline provided you submit by April 30, 2009, all documents described in section 904(a)(4) of the act developed between June 23, 2009, and March 31, 2010.

##### II. Significance of Guidance

FDA is issuing this draft guidance document 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 "Tobacco Health Document Submission." 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 statute and regulations.

##### III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic 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. The draft guidance document and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

##### IV. Paperwork Reduction Act of 1995

This draft guidance contains proposed collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). As required by the PRA, FDA has published an analysis of, among other information collections, the information collection concerning the submission of tobacco health documents (74 FR 45219, September 1, 2009, as corrected by 74 FR 47257, September 15, 2009) and will submit them for OMB approval.

##### V. 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: December 22, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9-30657 Filed 12-22-09; 8:45 am]

BILLING CODE 4160-01-S

## 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, Member Conflicts: Gastrointestinal, Liver and Pancreas Pathophysiology.

*Date:* January 12, 2010.

*Time:* 12 p.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Patricia Greenwel, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301-435-1169, [greenwep@csr.nih.gov](mailto:greenwep@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Conflicts: GI Pathophysiology.

*Date:* January 15, 2010.

*Time:* 12 p.m. to 2:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Patricia Greenwel, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301-435-1169, [greenwep@csr.nih.gov](mailto:greenwep@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: December 17, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-30642 Filed 12-24-09; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Office of Community Services; Award a Single Source Replacement Grant

**AGENCY:** Office of Community Services, ACF, HHS.

**ACTION:** Notice to award a single source replacement grant.

*CFDA No.:* 93.710.

*Amount of Award:* \$50,000.

*Project Period:* September 30, 2009 to September 29, 2010.

*Legislative Authority:* The legislative authority for this grant is provided in Section 674(b)(2) and 678A(a)(1)(A) of the Community Services Block Grant (CSBG) Act, as amended, by the Community Opportunities, Accountability, and Training and Educational Services (Coats Human Services Reauthorization Act of 1998) [Pub. L. 105-285].

**SUMMARY:** The Office of Community Services (OCS) awarded a single source replacement grant of \$50,000 under the Community Services Block Grant (CSBG) Training and Technical Assistance and Capacity Building Program—Earned Income Tax Credit (EITC) and Other Asset Formation Opportunities program to Maryland Volunteer Lawyers Service (MVLS) in Baltimore, Maryland on September 30, 2007. On September 16, 2009, MVLS submitted a letter relinquishing their grant. Job Opportunities Task Force (JOTF) of Baltimore, Maryland, an eligible entity, submitted a letter and grant application on September 16, 2009, requesting approval as a single source replacement grantee for the CSBG EITC project as of September 30, 2009. The Administration for Children and Families (ACF) approved Job Opportunities Task Force as the permanent successor grantee for the award.

JOTF will continue to create strategic opportunities to connect workforce development programs with asset development programs, including statewide training standards for tax preparation and financial counseling training, during the third and final year of the project.

#### FOR FURTHER INFORMATION CONTACT:

Danielle Williams, U.S. Department of Health and Human Services, Office of Community Services, Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC 20047, *Telephone:* (202) 205-4717, *E-mail:* [Danielle.Williams@acf.hhs.gov](mailto:Danielle.Williams@acf.hhs.gov).

Dated: December 11, 2009.

**Yolanda J. Butler,**

*Acting Director, Office of Community Services.*

[FR Doc. E9-30644 Filed 12-24-09; 8:45 am]

**BILLING CODE 4184-27-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 74 FR 52816, dated October 14, 2009) is amended to reflect the reorganization of the Centers for Disease Control and Prevention (CDC). This reorganization is being undertaken to strengthen CDC's response to H1N1 and other public health emergencies, establish systems to better identify and address leading causes of death and disability, and strengthen CDC's ability to support state and local action to improve health.

*I.* Under Part C, Section C-B, Organization and Functions, the following organizational units are deleted in their entirety:

- Coordinating Center for Environmental Health and Injury Prevention (CT)
- National Center for Environmental Health (CTB)
- National Center for Injury Prevention and Control (CTC)
- Coordinating Center for Health Information and Services (CP)
- National Center for Health Marketing (CPB)
- National Center for Health Statistics (CPC)
- National Center for Public Health Informatics (CPE)
- Coordinating Center for Health Promotion (CU)
- National Center on Birth Defects and Developmental Disabilities (CUB)
- National Center for Chronic Disease Prevention and Health Promotion (CUC)
- Coordinating Center for Infectious Diseases (CV)
- National Center for Immunization and Respiratory Diseases (CVG)
- National Center for Zoonotic, Vector-Borne, and Enteric Diseases (CVH)
- National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (CVJ)
- National Center for Preparedness, Detection, and Control of Infectious Diseases (CVK)

*II.* Under Part C, Section C-B, Organization and Functions, make the following changes: