

with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination 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 guidance at either: <http://www.fda.gov/Biologics/BloodVaccines/GuidanceCompliance/RegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/cber/guidelines.htm> or <http://www.regulations.gov>.

Dated: April 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-10046 Filed 4-29-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2005-D-0140] (formerly Docket No. FDA-2005D-0261)

Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry" dated May 2010. The guidance document provides recommendations to blood and plasma establishments, manufacturers, and testing laboratories that are implementing a licensed method for Human Immunodeficiency Virus Type 1 (HIV-1) Nucleic Acid Test (NAT) and Hepatitis C Virus (HCV) NAT, on testing individual samples or pooled samples from donors of human blood and blood components for HIV-1 ribonucleic acid (RNA) and HCV RNA. This guidance also contains recommendations regarding product disposition and donor management based on the results of NAT and serologic testing for markers of HIV-1 and HCV infection on samples,

collected at the time of donation, from donors of human blood and blood components. The guidance announced in this notice finalizes the draft guidance of the same title, dated July 2005. This guidance also supersedes the recommendations for reentry of donors deferred because of anti-HIV-1 test results, HIV-1 p24 antigen test results, and anti-HCV test results that were provided in the FDA memoranda entitled "Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV-1) Transmission by Blood and Blood Products," April 23, 1992; "Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)," August 5, 1993; "Recommendations for Donor Screening with a Licensed Test for HIV-1 Antigen," August 8, 1995.

DATES: Submit electronic or written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic or written comments on the guidance. Submit electronic comments 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: Paul Levine, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry," dated May 2010. The guidance document

provides recommendations to blood and plasma establishments, manufacturers, and testing laboratories that are implementing a licensed method for Human Immunodeficiency Virus Type 1 (HIV-1) Nucleic Acid Test (NAT) and Hepatitis C Virus (HCV) NAT, on testing individual samples or pooled samples from donors of human blood and blood components for HIV-1 ribonucleic acid (RNA) and HCV RNA. This guidance also contains recommendations regarding product disposition and donor management based on the results of NAT and serologic testing for markers of HIV-1 and HCV infection on samples, collected at the time of donation, from donors of human blood and blood components. The guidance announced in this notice finalizes the draft guidance of the same title, dated July 19, 2005. This guidance also supersedes the recommendations for reentry of donors deferred because of anti-HIV-1 test results, HIV-1 p24 antigen test results, and anti-HCV test results that were provided in the FDA memoranda entitled, "Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV-1) Transmission by Blood and Blood Products," April 23, 1992; "Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)," August 5, 1993; "Recommendations for Donor Screening with a Licensed Test for HIV-1 Antigen," August 8, 1995.

In the **Federal Register** of July 27, 2005 (70 FR 43439), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated July 2005.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA'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, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. 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. A copy of the guidance and received comments are available for public examination 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 the guidance at either: <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: April 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-10048 Filed 4-29-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0123]

Impact of Dissolvable Tobacco Use on Public Health; Request for Comments

Correction

In notice document 2010-6216 beginning on page 13556 in the issue of Monday, March 22, 2010, make the following correction:

On page 13556 in the second column, the paragraph that begins with "DATES:" should read: "DATES: Submit written or electronic comments by September 20, 2010."

[FR Doc. C1-2010-6216 Filed 4-29-10; 8:45 am]

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Public Health Research on Craniofacial Malformation, Funding Opportunity Announcement (FOA) DP 10-001, 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:

Time and Date: 3:30 p.m.-5 p.m., May 17, 2010 (Closed).

Place: Teleconference.

Status: The meeting 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 Public Law 92-463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to "Public Health Research on Craniofacial Malformation, FOA DP 10-001."

Contact Person for More Information: Michael Dalmat, Dr.P.H., Scientific Review Officer, National Center for Chronic Disease and Health Promotion, Office of the Director, Extramural Research Program Office, 4770 Buford Highway, NE., Mailstop K-92, Atlanta, GA 30341, Telephone: (770) 488-6423, E-mail: MED1@cdc.gov.

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: April 26, 2010.

Elaine L. Baker,

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

[FR Doc. 2010-10087 Filed 4-29-10; 8:45 am]

BILLING CODE 4163-18-P

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, PhD, 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: April 26, 2010.

Elaine L. Baker,

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

[FR Doc. 2010-10171 Filed 4-29-10; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Developmental Brain Disorders II.

Date: May 5, 2010.

Time: 2 p.m. to 3 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: Jay Joshi, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5196, MSC 7846, Bethesda, MD 20892, (301) 408-9135, joshij@csr.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. 93.306, Comparative Medicine;