

on the draft guidance by November 8, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401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 The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800.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SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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: Benjamin A. Chacko, 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 draft document entitled "Guidance for Industry: Bar Code Label Requirements—Questions and Answers (Question 12 Update)" dated August 2010. FDA regulations require that certain human drug and biological product labels contain a bar code (§ 201.25 (21 CFR 201.25)). This draft guidance provides you, manufacturers of a licensed vaccine, with advice concerning compliance with the bar code label requirements. Previously, FDA issued questions and answers regarding how the bar code label requirements apply to specific products or circumstances in the Bar Code Guidance (October 5, 2006, 71 FR 58739). In this guidance, FDA is proposing to amend our response to question 12 (Q12) in the Bar Code Guidance to provide recommendations to manufacturers of licensed vaccines in connection with the use of alternative coding technologies. We are revising our response because we believe that an alternative regulatory program, comprised of alternative technology such as two dimensional symbology, could render the use of linear bar codes unnecessary for patient safety and could enhance health care providers' ability to comply with the National Childhood

Vaccine Injury Act of 1986 (Public Law 99-660) (42 U.S.C. 300aa-25(a)). We would consider granting a request for exemption to the bar code requirement under § 201.25(d)(ii) in connection with such use.

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. The collection of information in 21 CFR part 201 has been approved under OMB control number 0910-0537.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. 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 draft guidance at either <http://www.fda.gov/Biologics/BloodVaccines/GuidanceCompliance/RegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: August 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-22169 Filed 9-3-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 Mental Health Special Emphasis Panel; ITVC Conflicts.

Date: October 6, 2010.

Time: 11 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call)

Contact Person: Enid Light, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6132, MSC 9608, Bethesda, MD 20852, 301-443-3599, elight@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; K99.

Date: October 18, 2010.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call)

Contact Person: Megan Libbey, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6148, MSC 9609, Rockville, MD 20852-9609, 301-402-6807, libbey@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: August 31, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-22185 Filed 9-3-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 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 Institute on Drug Abuse Special Emphasis Panel, NIDA Clinical Science Conference Grant (R13) Review.

Date: September 29, 2010.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852. (Virtual Meeting)

Contact Person: Gerald L. McLaughlin, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Blvd., Bethesda, MD 20892-8401. 301-402-6626. gm145a@nih.gov.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, NIDA B/Start Small Grant Review.

Date: October 20, 2010.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852. (Virtual Meeting)

Contact Person: Gerald L. McLaughlin, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Blvd., Bethesda, MD 20892-8401. 301-402-6626. gm145a@nih.gov.

Name of Committee: National Institute on Drug Abuse Initial Review Group, Training and Career Development Subcommittee.

Date: November 3-5, 2010.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel, 1150 22nd Street, NW., Rockville, MD 20852, Washington, DC 20037.

Contact Person: Kristen V. Huntley, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892-8401. 301-435-1433. huntleyk@mail.nih.gov.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, NIDA I/Start Small Grant Review.

Date: November 10, 2010.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852. (Virtual Meeting.)

Contact Person: Gerald L. McLaughlin, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC

8401, 6101 Executive Blvd., Bethesda, MD 20892-8401. 301-402-6626. gm145a@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: August 31, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-22183 Filed 9-3-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Negotiated Rulemaking Committee on Designation of Medically Underserved Populations and Health Professional Shortage Areas; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Negotiated Rulemaking Committee on Designation of Medically Underserved Populations and Health Professional Shortage Areas.

Date and time: September 22, 2010, 9:30 a.m. to 5 p.m.

September 23, 2010, 9 a.m. to 4:30 p.m.

September 24, 2010, 9 a.m. to 12 p.m.
Place: The Legacy Hotel, Georgetown Room, 1775 Rockville Pike, Rockville, Maryland 20852, (301) 881-2300.

Status: The meeting will be open to the public.

Purpose: The purpose of the Negotiated Rulemaking Committee on Designation of Medically Underserved Populations and Health Professional Shortage Areas is to establish a comprehensive methodology and criteria for Designation of Medically Underserved Populations and Primary Care Health Professional Shortage Areas, using a Negotiated Rulemaking (NR) process. It is hoped that use of the NR process will yield a consensus among technical experts and stakeholders on a new rule, which will then be published as an Interim Final Rule in accordance with Section 5602 of Public Law 111-148, the Patient Protection and Affordable Care Act of 2010.

Agenda: The meeting will be held on Wednesday, September 22, Thursday, September 23 and Friday, September 24, and will include an orientation to the negotiated rulemaking process, ground rules for Committee operations, and an overview of the key topics on which the

Committee will explore and seek consensus. The Friday morning meeting will include development of the agenda for the next meeting, as well as an opportunity for public comment.

FOR FURTHER INFORMATION CONTACT: For more information, please contact Lauren Krantz, Office of Shortage Designation, Bureau of Health Professions, Health Resources and Services Administration, Room 9A-18, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-9027, E-mail lkrantz@hrsa.gov, or visit <http://bhpr.hrsa.gov/shortage/>.

SUPPLEMENTARY INFORMATION: Requests from the public to make oral comments or to provide written comments to the Committee should be sent to Lauren Krantz at the contact address above at least 10 days prior to the meeting. The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed above at least 10 days prior to the meeting. Members of the public will have the opportunity to provide comments at the Friday morning meeting.

Dated: September 1, 2010.

Sahira Rafiullah,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010-22194 Filed 9-3-10; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0007]

Animal Models—Essential Elements To Address Efficacy Under the Animal Rule; Notice of Public Meeting; and Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; and reopening of comment period.

SUMMARY: The Food and Drug Administration's (FDA or agency) Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) are announcing a public meeting to solicit comments and concerns of industry, other government agencies, and interested parties on the regulatory and scientific challenges as addressed in the draft document entitled "Guidance for