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. to12 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

Industry: Animal Models—Essential Elements to Address Efficacy Under the Animal Rule" dated January 2009 (Draft Guidance), and as related to the development of medical countermeasures under the "Animal Rule" with respect to chemical, biological, radiological, or nuclear (CBRN) threats. Comments on these issues will be considered in connection with the development of a final version of the Draft Guidance.

DATES: The public meeting will be held on November 5, 2010, from 8 a.m. to 5:30 p.m. Attendees who wish to request to make an oral presentation at the public meeting must register and submit their comments electronically by October 1, 2010. All non-presenting attendees must register electronically by October 27, 2010. See section III under **SUPPLEMENTARY INFORMATION** for the electronic submission of registration information, and the electronic submission of a request to make an oral presentation and the comments to be presented. The comment period for the Draft Guidance has been reopened until January 5, 2011.

ADDRESSES: The public meeting will be held at the FDA White Oak Complex, 10903 New Hampshire Ave., Bldg. 31, rm. 1503, Silver Spring, MD, 20993–0002.

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. See section IV under **SUPPLEMENTARY INFORMATION** for information on submission of comments. See section I under **SUPPLEMENTARY INFORMATION** for electronic access to the Draft Guidance.

FOR FURTHER INFORMATION CONTACT:

Eris Mackey, Career Development and Directed Training Branch, Center for Biologics Evaluation and Research (HFM–49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–2000, e-mail: *AnimalModelGuidance@fda.hhs.gov*; or

Susie Dill, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6183, Silver Spring, MD 20993–0002, 301–796–3437, e-mail: *AnimalModelGuidance@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 21, 2009 (74 FR 3610), FDA announced the availability of a draft document entitled "Guidance for Industry, "Animal Models—Essential Elements to Address Efficacy Under the Animal Rule" dated January 2009 (Draft Guidance). The purpose of the Draft Guidance, when finalized, is to assist sponsors in identifying the critical characteristics of an animal model that should be addressed when efficacy of an investigational product will be established under the "Animal Rule" (May 31, 2002, 67 FR 37988). FDA requested comments on the Draft Guidance by March 23, 2009. In 2010, reviews to assess our nation's preparedness against CBRN threats, as well as the major issues and challenges to achieving the desired state of emergency preparedness, were conducted under the auspices of the Public Health Emergency Medical Countermeasure Enterprise. Among the many issues noted was the difficulty of the regulatory path when developing drug or biological products for approval or licensure, respectively, under the "Animal Rule." Therefore, to address this and related issues, FDA is holding a public meeting to solicit comments and concerns on the challenges related to the development of medical countermeasures under the Animal Rule for CBRN threats. FDA will consider the oral comments presented at the public meeting and comments submitted to docket on the Draft Guidance in developing the final version of the Guidance. The Draft Guidance can be found on the Internet at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm078923.pdf*.

II. Purpose and Scope of Meeting

The purpose of this meeting is to receive comments from a broad group of stakeholders on the regulatory and scientific challenges related to the development of medical countermeasures under the Animal Rule (21 CFR 314.600 for drugs; 21 CFR 601.90 for biological products) for CBRN threats as addressed in the Draft Guidance. Each session will have a panel composed of FDA representatives from CBER and CDER to interact with the presenter as necessary to clarify comments and provide limited scientific discussion as appropriate. FDA is particularly interested in obtaining information and public comment on the following areas:

Topic Area A: (1) Natural course of the CBRN agent-induced disease or condition; and (2) Pathophysiologic comparability of the CBRN agent-induced disease or condition between animals and humans.

Topic Area B: (1) Characteristics of the CBRN agent; and (2) Host susceptibility in response to the agent.

Topic Area C: Characterization of medical intervention.

Topic Area D: Design considerations for the animal efficacy studies.

Topic Area E: General comments.

III. Registration and Requests for Oral Presentations

A. Registration

The FDA Conference Center at the White Oak Complex is a Federal facility with security procedures and limited seating. There is no registration fee for the public meeting; however, advance registration is required for all attendees including members of the press and FDA employees. Registrations will be confirmed in the order in which they are received. Attendees who wish to make an oral presentation at the public meeting must register and submit their comments electronically by October 1, 2010 (see section III.B for additional information on requests for oral presentations). All non-presenting attendees must register electronically by October 27, 2010. To register electronically, attendees must e-mail contact information (including name, title, affiliation, address, e-mail, and telephone number), and any requests to make oral presentations to: *AnimalModelGuidance@fda.hhs.gov*.

If you need special accommodations because of a disability, please contact FDA (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

B. Requests for Oral Presentations

Attendees who wish to make an oral presentation at the public meeting must register for the meeting, request to present, and submit their comments electronically to *AnimalModelGuidance@fda.hhs.gov* by October 1, 2010.

In section II under **SUPPLEMENTARY INFORMATION** of this notice, FDA has specified five topic areas for comment. Presenters will also need to identify by letter (A through E) the topic area or areas on which they will comment. Submitted comments to be presented at the public meeting that exceed 10 pages should include a one-page executive summary. Oral presentations are limited to statements; slide presentations will not be permitted.

FDA will do its best to accommodate requests to make oral presentations, and

will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. Prior to the meeting, presenters will be notified of their allotted time and the approximate scheduled time of their remarks. An agenda of the public meeting, including the oral presentation schedule, will be available approximately 3 days before the public meeting at the Division of Dockets Management (Docket No. FDA–2009–D–0007) and on the Internet at *http://www.regulations.gov*.

Pre-registered participants will receive additional information on parking and public transportation with their e-mail registration confirmation.

IV. Comments on the Draft Guidance

Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments regarding the Draft Guidance. Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (see **ADDRESSES**). 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 FDA–2009–D–0007. 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 either electronic or written comments on Draft Guidance by January 5, 2011. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcripts

Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 45 days after the meeting. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: September 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–22198 Filed 9–3–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Cell and Gene Therapy Clinical Trials in Pediatric Populations; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER) is announcing a public workshop entitled "Cell and Gene Therapy Clinical Trials in Pediatric Populations." The purpose of the workshop is to gather information from Institutional Review Boards (IRBs), gene and cellular therapy clinical researchers, and other stakeholders regarding best practices related to cell and gene therapy clinical trials in pediatric populations, as well as challenges and considerations in the review of these clinical trials.

Date and Time: The public workshop will be held on November 2, 2010, from 8 a.m. to 5:30 p.m.

Location: The public workshop will be held at the Bethesda North Marriott Hotel and Conference Center, 5701 Marinelli Rd., North Bethesda, MD 20852.

Contact Person: Bernadette Kawaley, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2000, FAX 301–827–3079; email: *CBERTraining@fda.hhs.gov* (Subject line: Pediatrics Ethics Workshop).

Registration: Email, mail or fax your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by October 1, 2010. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Bernadette Kawaley (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The workshop will include presentations on cell and gene therapy clinical trials in pediatric populations. The workshop will include panel discussions regarding best practices related to cell and gene therapy clinical trials in pediatric populations including those related to: (1) Evaluating these novel therapeutic products prior to initiating pediatric clinical studies; (2) identifying and minimizing risks associated with the administration of cell and gene therapy products in pediatric populations; (3) obtaining informed consent and assent; and (4) conducting continuing review of cell and gene therapy products in pediatric populations. The workshop also will include panel discussions addressing the challenges and considerations in the review of cell and gene therapy clinical trials in pediatric populations and the role of IRBs.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857. A transcript of the public workshop will be available on the Internet at *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm*.

Dated: August 20, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–22168 Filed 9–3–10; 8:45 am]

BILLING CODE 4160–01–S

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 75 FR 45134–45142, dated August 2, 2010) is amended to reflect the reorganization of the Office of Health and Safety, Office of the Chief Operating Officer, Office of the Director, Centers for Disease Control and Prevention.