

management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

#### IV. Electronic Access

Persons with access to the Internet may obtain the guidance document at <http://www.cfsan.fda.gov/guidance.html>.

Dated: December 23, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8-31249 Filed 1-2-09; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0038]

#### Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

**Name of Committees:** Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

**General Function of the Committees:** To provide advice and recommendations to the agency on FDA's regulatory issues.

**Date and Time:** The meeting will be held on January 30, 2009, from 8 a.m. to 4:30 p.m.

**Location:** Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy, Gaithersburg, MD. The hotel phone number is 301-977-8900.

**Contact Person:** Kalyani Bhatt, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, fax: 301-827-6776, e-mail: [Kalyani.Bhatt@fda.hhs.gov](mailto:Kalyani.Bhatt@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), codes 3014512529 or 3014512535. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute

modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Therefore, you should always check the agency's Web site and call the appropriate advisory hotline/phone line to learn about possible modifications before coming to the meeting.

**Agenda:** The committee will discuss the available safety and efficacy data for all propoxyphene-containing products (including hydrochloric acid (HC1), napsylate salts, and combination drugs) and whether any regulatory action is appropriate.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2009 and scroll down to the appropriate advisory committee link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 22, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 9, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 13, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to

a disability, please contact Kalyani Bhatt at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 19, 2008.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E8-31248 Filed 1-2-09; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0651]

#### Training Program for Regulatory Project Managers; Information Available to Industry

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to contact CDER.

**DATES:** Pharmaceutical companies may submit proposed agendas to the agency by March 6, 2009.

**FOR FURTHER INFORMATION CONTACT:** Beth Duvall-Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6466, Silver Spring, MD 20993-0002, 301-796-0700, e-mail: [elizabeth.duvallmiller@fda.hhs.gov](mailto:elizabeth.duvallmiller@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management

staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) First hand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

## II. The Site Tours Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, tracking mechanisms, and regulatory submission operations.

The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

## III. Site Selection

All travel expenses associated with the site tours will be the responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Firms interested in offering a site tour or learning more about this training opportunity should respond by (see **DATES**) by submitting a proposed agenda to Beth Duvall-Miller (see **FOR FURTHER INFORMATION**).

Dated: December 22, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8-31320 Filed 1-2-09; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Part C Early Intervention Services Grant

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice of Non-competitive Program Expansion Supplemental Award.

**SUMMARY:** HRSA will be providing temporary critical HIV medical care and treatment services through the Medical Center of Louisiana at New Orleans to avoid a disruption of HIV clinical care to clients in Orleans Parish in Louisiana.

#### SUPPLEMENTARY INFORMATION:

*Intended recipient of the award:* Medical Center of Louisiana at New Orleans, New Orleans, Louisiana.

*Amount of the award:* \$186,664 to ensure ongoing clinical services to the target population.

**Authority:** Section 2651 of the Public Health Service Act, 42 U.S.C. 300ff-51.

*CFDA Number:* 93.918.

*Project period:* July 1, 2006 to June 30, 2011. The period of supplemental support is from November 1, 2008, to June 30, 2009.

*Justification for the Exception to Competition:* Critical funding for HIV medical care and treatment services to clients in Orleans Parish in Louisiana will be continued through a non-competitive program expansion supplement to an existing grant award to Medical Center of Louisiana at New Orleans, New Orleans, Louisiana. This is a temporary award because the previous grant recipient serving this population notified HRSA that it would not be able to continue participating in the program after the fiscal year (FY) 2008 award was made. Medical Center of Louisiana at New Orleans is the best qualified grantee for this supplement since it serves many of the former grantee's patients and is the closest Part C Program to the former grantee. Further funding beyond June 30, 2009, for this service area will be competitively awarded during the Part C HIV Early Intervention Service (EIS) competing application process for FY 2009.

## FOR FURTHER INFORMATION CONTACT:

Kathleen Treat, through e-mail [ktreat@hrsa.gov](mailto:ktreat@hrsa.gov), or via telephone, 301-443-0493.

Dated: December 19, 2008.

**Elizabeth M. Duke,**

*Administrator.*

[FR Doc. E8-31373 Filed 1-2-09; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Research Resources; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Center for Research Resources Special Emphasis Panel; SBIR Contracts.

*Date:* February 26, 2009.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* Hilton Hotel Gaithersburg, 620 Perry Parkway, Gaithersburg, MD 20877.

*Contact Person:* Guo Zhang, Ph.D., MD, Scientific Review Officer, National Center for Research Resources; or, National Institutes of Health, 6701 Democracy Blvd., 1 Democracy Plaza, Room 1064, MSC 4874, Bethesda, MD 20892-4874, 301-435-0812, [zhanggu@mail.nih.gov](mailto:zhanggu@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: December 24, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8-31388 Filed 1-2-09; 8:45 am]

**BILLING CODE 4140-01-P**