Patriots Plaza Building, Washington, DC 20201, telephone (202) 245–0655, fax (202) 245–0664.

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 the CDC and the Agency for Toxic Substances and Disease Registry.

Dated: November 6, 2009.

Elaine L. Baker,

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

[FR Doc. E9–27623 Filed 11–17–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0143]

Risk Evaluation and Mitigation Strategies for Certain Opioid Drugs; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting with sponsors of certain opioid drug products regarding the development of Risk Evaluation and Mitigation Strategies (REMS) for these products. Other members of the public are invited to attend and observe. The REMS is intended to ensure that the benefits of these drugs continue to outweigh certain risks. FDA has encouraged affected sponsors to work collectively to develop a proposed REMS. The purpose of this meeting is to hear from sponsors about the status of the development of a proposed REMS and their views regarding the specific features of the REMS for these products. To promote transparency of the REMS development process, other members of the public are invited to attend the meeting as observers. Additional opportunities for public input will be provided before FDA finalizes the elements of the REMS.

DATES: The meeting will be held on December 4, 2009, from 9 a.m. to 1 p.m. To ensure consideration at the meeting, submit comments by November 27, 2009. Register to attend the meeting by November 27, 2009. See section III of this document for information on how to register for the meeting.

ADDRESSES: The public meeting will be held at the Holiday Inn Washington-College Park, 10000 Baltimore Ave., College Park, MD 20740.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061. Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. All comments should be identified with the docket number found in brackets in the heading of this document.

A live webcast of this meeting will be viewable at *http://ConnectLive.com/events/fda120409* on the day of the meeting. A video record of the meeting will be available at the same Web address for 1 year.

FOR FURTHER INFORMATION CONTACT: Theresa (Terry) Martin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6196, Silver Spring, MD 20993, 301–796–3448, FAX: 301–847–8753, or

Patrick Frey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6350, Silver Spring, MD 20993, 301–796–3844, FAX: 301–847–8443, e-mail: *OpioidREMS@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On February 6, 2009, the Food and Drug Administration (FDA) sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of the drugs continue to outweigh the risks. A table of opioid products that will be required to have REMS is available on the agency's Web site at *http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163654.htm*. Copies of this document may be requested from Theresa (Terry) Martin (see **FOR FURTHER INFORMATION CONTACT**). The affected opioid drugs include brand name and generic products and are formulated with the active ingredients fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone. The REMS would be intended to ensure that the benefits of these drugs continue to outweigh the risks associated with: (1) Use of high doses of long-acting opioids and extended-release opioid products in non-opioid-tolerant and inappropriately selected individuals; (2) abuse; (3) misuse; and (4) overdose, both accidental and intentional. REMS for these opioids would likely include elements to assure safe use to ensure that prescribers, dispensers, and patients are aware of, and understand, the risks and how these products should be used.

On March 3, 2009, FDA held a meeting with affected sponsors to discuss how the REMS could be designed to manage the risks while also minimizing burdens to the health care system. FDA presented a high-level overview, regulatory background, and the proposed elements of the REMS followed by questions and comments from the sponsors. At this meeting, FDA encouraged sponsors to work collectively to develop a proposed REMS. The FDA presentations and minutes from this meeting are available on the agency's Web site at *http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163660.htm*. In May, FDA held meetings with other affected stakeholders including health care professionals, patient advocates, and pharmacy groups. FDA then held a public meeting on May 27 and 28, 2009, where FDA heard from members of the public on what the REMS should look like for these products, how to minimize the burden on the health care community and patients, and how FDA should evaluate the REMS to determine whether it achieves its objectives. Nearly 100 members of the public spoke at the meeting, and many others have submitted written comments to the docket (Docket No. FDA–2009–N–0143). For additional background information about this issue see 74 FR 17967, April 20, 2009.

II. Purpose of Meeting

The purpose of this meeting is for FDA to hear from sponsors of long-acting opioids and extended-release opioid products on the development of the REMS for these products and their views about the specific features of the REMS. Other members of the public are invited to attend the meeting as observers. Because this is a meeting between FDA staff and the sponsors, only FDA staff will be permitted to question the sponsors at the meeting. However, interested persons who attend the public meeting will be given an opportunity to provide suggestions for questions for FDA staff to ask the sponsors, at FDA's sole discretion. Index cards will be provided for this purpose. There will be additional opportunities for public input before FDA finalizes the elements of the REMS.

III. Attendance and Registration

Registration: Register by e-mail to *OpioidREMS@fda.hhs.gov*. Provide complete contact information for each attendee, including name, title, affiliation, address, e-mail, and phone

number. Registration requests should be received by November 27, 2009. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability on the day of the event starting at 8 a.m.

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

In addition, a live webcast of this meeting will be viewable at *http://ConnectLive.com/events/fda120409* on the day of the meeting. A video record of the meeting will be available at the same Web address for 1 year.

IV. Comments

In addition, any person may submit written or electronic comments to the Division of Dockets Management (see **DATES** and **ADDRESSES**). 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. 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 30 days after the meeting. A transcript will also be made available in either hard copy or on CD–ROM, upon 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: November 12, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–27718 Filed 11–17–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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: National Cancer Institute Initial Review Group; Subcommittee A—Cancer Centers.

Date: December 10–11, 2009.

Time: 8 a.m. to 12:10 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Gail J Bryant, MD, Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8107, MSC 8328, Bethesda, MD 20892–8328, (301) 402–0801, *gb30t@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 12, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–27715 Filed 11–17–09; 8:45 am]

BILLING CODE 4140–01–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; Addictions, Drugs, and Violence.

Date: November 24, 2009.

Time: 3 p.m. to 5 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: Michael Micklin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3136, MSC 7759, Bethesda, MD 20892, (301) 435–1258, *micklinm@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; 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: November 12, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–27704 Filed 11–17–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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