DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Muscular Dystrophy Coordinating Committee (MDCC).

The meeting will be open to the public, 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 inform the Contact Person listed below in advance of the meeting.

Name of Committee: Muscular Dystrophy Coordinating Committee.

Date: November 30, 2009.

Time: 8 a.m. to 3:30 p.m.

Agenda: The 2009 meeting of the MDCC will focus on Federal funding for muscular dystrophy, activities of the Paul Wellstone Cooperative Muscular Dystrophy Research Centers, plans to review the Action Plan for the Muscular Dystrophies, and activities of MDCC member agencies and organizations.

An agenda will be posted prior to the meeting on the MDCC Web site: *http://www.ninds.nih.gov/find_people/groups/mdcc/index.htm.*

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: John D. Porter, PhD, Executive Secretary, Muscular Dystrophy Coordinating Committee, National Institute of Neurological Disorders and Stroke, NIH, 6001 Executive Boulevard, NSC 2172, Bethesda, MD 20892, (301) 496–5739, *porterjo@ninds.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: November 13, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–27706 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 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: Center for Scientific Review Special Emphasis Panel; Member Conflict Applications; CMBK and UKGD.

Date: December 2, 2009.

Time: 2 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: Najma Begum, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2186, MSC 7818, Bethesda, MD 20892, 301–435–1243, *begumn@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–OD–09–007: ARRA AREA Grants Panel 09.

Date: December 7, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Palomar Hotel, 2121 P Street, NW., Washington, DC 20037.

Contact Person: Carole L. Jelsema, PhD, Chief and Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7850, Bethesda, MD 20892, (301) 435–1248, *jelsemac@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Emergency Medical Services for Children.

Date: December 10, 2009.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jacinta Bronte-Tinkew, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3164, MSC 7770, Bethesda, MD 20892, (301) 435–1503, *brontetinkewjm@csr.nih.gov.*

(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. E9–27705 Filed 11–17–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH)

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 following meeting for the aforementioned committee:

Time and Date: 8:30 a.m.–3:45 p.m., December 2, 2009.

Place: Holiday Inn Capitol, 550 C Street, SW., Washington, DC 20024.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people. Teleconference available toll-free; please dial (866) 423–5960, Participant Pass Code 2988491.

Purpose: The Secretary, the Assistant Secretary for Health, and by delegation the Director, Centers for Disease Control and Prevention, are authorized under Sections 301 and 308 of the Public Health Service Act to conduct directly or by grants or contracts, research, experiments, and demonstrations relating to occupational safety and health and to mine health. The Board of Scientific Counselors shall provide guidance to the Director, National Institute for Occupational Safety and Health on research and prevention programs. Specifically, the Board shall provide guidance on the Institute's research activities related to developing and evaluating hypotheses, systematically documenting findings and disseminating results. The Board shall evaluate the degree to which the activities of the National Institute for Occupational Safety and Health: (1) Conform to appropriate scientific standards, (2) address current, relevant needs, and (3) produce intended results.

Matters To Be Discussed: Agenda items include NIOSH Implementation of National Academies Program Recommendations for Traumatic Injuries, Construction Research, and Health Hazard Evaluations; Future Directions for Evaluation of NIOSH Research Programs; Future Meetings and Closing Remarks.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Roger Rosa, Executive Secretary, BSC, NIOSH, CDC, 395 E Street, SW., Suite 9200,

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