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; OBT IRG Member Conflict.

Date: May 17, 2010.
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: Angela Y. Ng, MBA, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6200, MSC 7804 (For courier delivery, use MD 20817), Bethesda, MD 20892, 301–435–1715, nga@csr.nih.gov.


Jennifer Spaeth,
Director, Office of Federal Advisory Committee Policy.

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0204]

Infusion Pumps; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting regarding external infusion pumps. The purpose of the meeting is to inform the public about current problems associated with external infusion pump use, to help the agency identify quality assurance strategies to mitigate these problems, and to solicit comments and input regarding how to bring more effective external infusion pumps to market. Elsewhere in this issue of the Federal Register, FDA is announcing the availability of a draft guidance document entitled “Total Product Life Cycle: Infusion Pump—Premarket Notification (510(k)) Submissions.”

Date and Time: The public meeting will be held on May 25 and 26, 2010, from 8 a.m. to 5 p.m. Persons interested in attending the meeting must register by 5 p.m. on May 18, 2010.

Location: The public meeting will be held at the Hilton Silver Spring hotel, 8727 Colesville Rd., Silver Spring, MD 20910. Seating is limited and available only on a first-come, first-served basis.

Contact Person: Victoria Wagman, Food and Drug Administration, Center for Devices and Radiological Health (CDRH), 10903 New Hampshire Ave., Bldg. 66, rm. 5449, Silver Spring, MD 20993–0002, 301–796–6851, e-mail: victoria.wagman@fda.hhs.gov.

Registration: Register online for webinar or onsite attendance at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm203299.htm (select the appropriate meeting from the list). Please provide complete contact information for each attendee, including name, title, affiliation, address, e-mail, and telephone number. Registration requests should be received by May 18, 2010. For those without Internet access, please call 301–796–6861 to register. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited and therefore FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public meeting will be provided beginning at 7 a.m. Persons needing a sign language interpreter or other special accommodations should notify Victoria Wagman (see Contact Person) at least 7 days in advance.

Additional information is also available at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm181140.htm.

Comments: Regardless of attendance at the public meeting, interested persons may submit written or electronic comments. 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. 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. Please also indicate the specific question(s) addressed. (See section II of this document.)

SUPPLEMENTARY INFORMATION:
I. Background

FDA has seen an increase in the number and severity of external infusion pump incident reports and recalls. During the period from January 1, 2008, to December 31, 2009, FDA received over 56,000 medical device reports associated with the use of external infusion pumps. Of these reports, approximately 1 percent reported deaths, 34 percent reported serious injuries, and 62 percent reported malfunctions. The most frequently reported external infusion pump device problems across all of the adverse reports reviewed included software error messages, human factors (which include but are not limited to use error), broken components, battery failure, alarm failure, over infusion, and under infusion. In some reports, the manufacturer was unable to determine or identify the problem, however, subsequent analyses revealed that many of the problems were preventable. FDA has evaluated a broad spectrum of infusion pumps across manufacturers and has concluded there are numerous, systemic problems with device design, manufacturing, and adverse event reporting. To address these problems, the agency determined that manufacturers may need to conduct additional assessments of new products or make changes to products currently being marketed.

II. Topics for Discussion at the Public Meeting

At the meeting, CDRH will discuss how to improve the safety and efficacy of external infusion pumps and hear input on these issues from a broad range of stakeholders. The agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend the public meeting. To help focus the agency’s strategies, CDRH requests feedback on the following questions, which will serve as the basis for discussion at the public meeting:

- What problems with external infusion pump have you observed in the clinical or home environment? How can FDA, academia, users, patients, and industry work together to improve the safety and efficacy of infusion pumps?
- What factors or criteria should be considered when designing an external infusion pump for the clinical or home environment and the user populations in those environments?
- Why is it important? What is the best way for FDA to receive timely, accurate, and complete adverse events reports?
- When changes to CDRH’s pre- or postmarket regulation of external infusion pumps are warranted, how should the center apply them to devices currently under review?
- How could CDRH better communicate external infusion pump issues or concerns to its stakeholders?

During the meeting, there will be a facilitated discussion between CDRH staff and invited experts from the private and public sectors about the questions presented in this document, as well as periodic open sessions allowing all attendees the opportunity to provide comment and feedback. Information gathered from the public meeting will help the agency in developing topics for further consideration.

III. Transcripts

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public meeting at a cost of 10 cents per page. A link to the transcripts will also be available on the Internet at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm approximately 45 days after the meeting.


Leslie Kux,
Acting Assistant Commissioner for Policy.

[FR Doc. 2010–9208 Filed 4–23–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health
Office of the Director, National Institutes of Health; 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 Scientific Management Review Board. The NIH Reform Act of 2006 (Pub. L. 109–482) provides organizational authorities to HHS and NIH officials to: (1) Establish or abolish national research institutes; (2) reorganize the offices within the Office of the Director, NIH including adding, removing, or transferring the functions of such offices or establishing or terminating such offices; and (3) reorganize, divisions, centers, or other administrative units within an NIH national research institute or national center including adding, removing, or transferring the functions of such units, or establishing or terminating such units. The purpose of the Scientific Management Review Board (also referred to as SMRB or Board) is to advise appropriate HHS and NIH officials on the use of these organizational authorities and identify the reasons underlying the recommendations.

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 notify the Contact Person listed below in advance of the meeting.

Name of Committee: Scientific Management Review Board.
Date: May 18–19, 2010.
Time: May 18, 2010, 8 a.m. to 5 p.m.

Agenda: Presentation and discussion will include updates from two SMRB Working Groups, the Substance Use, Abuse and Addiction group and the Intramural Research Program group. Participants will include both scientific experts and community stakeholders. Additional time will be allotted for presentation and discussion of each Working Group’s draft recommendations to date. Any supporting documentation for this meeting, including the agenda, will be available at http://smrb.od.nih.gov. Sign up for public comment will begin at approximately 7 a.m. on both May 18 and 19 and will be restricted to one sign in per person. In the event that time does not allow for all those interested to present oral comments, anyone may file written comments using the contact person’s address below.

Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Time: May 19, 2010, 8 a.m. to 5 p.m.

Agenda: Continuation of May 18th meeting.

Place: National Institutes of Health, Building 31, 6th Floor, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Lyric Jorgenson, Health Sciences Policy Analyst, Office of Science Policy, Office of the Director, NIH, National Institutes of Health, Building 1, Room 218, MSC 0166, 9000 Rockville Pike, Bethesda, MD 20892, smrb@mail.nih.gov, (301) 496–6837.

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.

The meeting will also be Webcast. The draft meeting agenda and other information about the SMRB, including information about access to the Webcast, will be available at http://smrb.od.nih.gov.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles will be inspected before being allowed on...