

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, 2005, 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 received 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 setting?
- 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.

Dated: April 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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

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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

campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: April 21, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-9618 Filed 4-23-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of 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 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 below in advance of the 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 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 Advisory Neurological Disorders and Stroke Council.
Date: May 27, 2010.

Closed: 10 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, C Wing, Conference Room 10, Bethesda, MD 20892.

Open: 1 p.m. to 5:30 p.m.

Agenda: Report by the Director, NINDS; Report by the Associate Director for Extramural Research; Other Administrative and Program Developments; and an Overview of the NINDS Intramural Program.

Place: National Institutes of Health, Building 31, 31 Center Drive, C Wing, Conference Room 10, Bethesda, MD 20892.

Contact Person: Robert Finkelstein, PhD, Associate Director for Extramural Research, National Institute of Neurological Disorders and Stroke, NIH, 6001 Executive Blvd., Suite 3309, MSC 9531, (301) 496-9248.

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.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <http://www.ninds.nih.gov>, where an agenda and any additional information for the meeting will be posted when available.

(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: April 20, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-9616 Filed 4-23-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; 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: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; P30 Core Research Center Review.

Date: May 21, 2010.

Time: 12 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Susan Sullivan, PhD, Scientific Review Officer, National Institute of Deafness and Other Communication Disorders, 6120 Executive Blvd., Ste. 400C, Rockville, MD 20852, 301-496-8683, sullivas@mail.nih.gov.

Name of Committee: Communication Disorders Review Committee.

Date: June 10-11, 2010.

Time: June 10, 2010, 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Time: June 11, 2010, 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Christopher A. Moore, PhD, Scientific Review Officer, National Institute of Health, NIDCD, 6120 Executive Blvd., MSC 7180, Bethesda, MD 20892, 301-496-8683, moorechristopher@nidcd.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: April 20, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-9615 Filed 4-23-10; 8:45 am]

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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