DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; 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 Board of Scientific Counselors, National Center for Biotechnology Information. 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: Board of Scientific Counselors, National Center for Biotechnology Information.

Date: November 9, 2010.

Open: 8:30 a.m. to 12 p.m.

Agenda: Program Discussion.

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

Closed: 12 p.m. to 2 p.m.

Agenda: To review and evaluate personal qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Date: November 10, 2010.

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

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

Time: November 5, 2010, 8 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Contact Person: Arthur A. Petrosian, PhD, Chief Scientific Review Officer, Division of Extramural Programs, National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892–7968. 301–496–4253. petrosia@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: July 13, 2010.

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

[FR Doc. 2010–17673 Filed 7–19–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, 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 Institute on Drug Abuse Special Emphasis Panel, Research Dissemination (1143).

Date: August 17–18, 2010.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Courtyard by Marriott Rockville, 2500 Research Boulevard, Rockville, MD 20850.

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401. (301) 435–1499, lf33c.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2010–N–0364]

Advancing the Development of Medical Products Used In the Prevention, Diagnosis, and Treatment of Neglected Tropical Diseases; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comment.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to solicit general views and information from interested persons on issues related to advancing the development of medical products (drugs, biological products, and medical devices) used in the prevention, diagnosis, and treatment of neglected tropical diseases. In particular, FDA is seeking these views and information from interested persons on preclinical studies, trial design, regulatory approaches, and optimal solutions as they relate to the prevention, diagnosis, and treatment of neglected tropical diseases. To help solicit such views and information, FDA is seeking comments on specific issues (see section IV of this document).

DATES: Public Hearing: The public hearing will be held on September 22, 2010, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the meeting may extend later or end early.

Registration: Interested parties are encouraged to register early. Registration is free. Seating will be available on a first-come, first-served basis. To register, e-mail your name, title, firm name, address, and telephone numbers to NeglectedDiseasesMtq@dhs.gov or call Ann Staten at 301–796–8504 by September 17, 2010.

Registration on the day of the public hearing will be provided on a space-available basis beginning at 7:30 a.m. To allow sufficient time for parking and clearance through security, we recommend arriving early. See section I of the SUPPLEMENTARY INFORMATION section for information on how to participate in the meeting. If you need special accommodations due to a disability, please contact Ann Staten (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

Notice of Participation and Comments: Submit written or electronic notices of participation and comments by September 1, 2010. The administrative record of the hearing will remain open to receive additional comments until October 20, 2010.

ADDRESSES: Public Hearing: The public hearing will be held at 10903 New Hampshire Ave., Bldg. 31, rm. 1503 (the Great Room), Silver Spring, MD 20993. You must enter through Bldg. 1 and the security check-point to reach Bldg. 31. Additional information on parking may be accessed at http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/default.htm.

Notice of Participation and Comments: Submit notices of participation and comments, identifying the agency and Docket No. FDA–2010–N–0364, by any of the following methods:

Electronic Submissions
Submit electronic notices of participation and comments in the following way:


Written Submissions
Submit written notices of participation and comments in the following ways:

• Fax: 301–827–6870.
• Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.


SUPPLEMENTARY INFORMATION:

I. How to Participate in the Meeting

The procedures governing the hearing are set forth in part 15 (21 CFR part 15) of FDA’s regulations. If you wish to make an oral presentation during the hearing, you must submit a written notice of participation (see ADDRESSES) by September 1, 2010. In the written notice, submit your name, title, business affiliation, address, telephone number, and e-mail address. You should also submit a written statement for each issue in section IV of this document that you intend to address, and other pertinent information related to the topic in your presentation, the names and addresses of all individuals who plan to participate, and the approximate time requested for your presentation. We encourage individuals and organizations with common interests to consolidate or coordinate their presentations to allow adequate time for each request for presentation. Participants should submit to the docket a copy of each presentation.

We will file the hearing schedule indicating the order of presentation and the time allotted to each person to the docket. We will also e-mail or telephone the schedule to each participant before the hearing. In anticipation of the hearing presentations moving ahead of schedule, participants are encouraged to arrive early to ensure their designated order of presentation. Participants who are not present when called risk forfeiting their scheduled time.

II. Background

Approximately one billion people worldwide suffer from neglected tropical diseases, e.g., malaria, tuberculosis, and schistosomiasis. Developing medical products to prevent, diagnose, and treat neglected tropical diseases has not met global public health needs due to an array of challenges. To encourage the development of these much needed medical products, section 740 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriation Act of 2010 (Public Law 111–80) directs FDA to establish a review group to recommend to the Commissioner of Food and Drugs (the Commissioner) appropriate preclinical studies, trial design, regulatory approaches, and optimal solutions to encourage the development of medical products to prevent, diagnose, and treat neglected tropical diseases of the developing world.

III. Purpose and Scope of the Hearing

The purpose of this public hearing is to provide advocates for patients with neglected tropical diseases, academicians, health care providers, the pharmaceutical and medical device industries, and other interested parties an opportunity to address specific topics (see section IV of this document) and present to FDA their views, recommendations, and any other pertinent information related to the scope of this public hearing. This information will assist the FDA review group in making recommendations to the Commissioner regarding appropriate preclinical studies, trial design,