DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Infectious Diseases; 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: Allergy, Immunology, and Transplantation Research Committee.
Date: October 20, 2010.
Time: 10 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Bethesda, MD 20817.
Contact Person: Zhuqing Li, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, DHHS/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892-7616, 301-402-9523, zhuqing.li@nih.gov.
(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities, Office of Science Policy, Office of the Director; 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 the meeting of the National Science Advisory Board for Biosecurity (NSABB).

Name of Committee: National Science Advisory Board for Biosecurity.
Date: October 19, 2010.
Time: 8:30 a.m. to 4 p.m. Eastern Daylight Time (Times are approximate and subject to change).
Agenda: Presentations and discussions regarding: (1) Update of Federal activities relevant to the mission of the NSABB; (2) activities of NSABB Working Groups on Codes of Conduct; Culture of Responsibility; International Engagement; Journal Review Policies; and Outreach and Education; (3) consideration of advances in synthetic biology in relation to NSABB recommendations regarding biosecurity concerns raised by this field; (4) planning for future NSABB meetings and activities; and (5) other business of the Board.
Place: National Institutes of Health, Building 31, Center Drive, C–Wing, 6th Floor, Conference Room 10, Bethesda, Maryland 20892.
Contact Person: Ronna Hill, NSABB Program Assistant, NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 710, Bethesda, Maryland 20892, (301) 496–9836, hillro@od.nih.gov.
Under authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established the NSABB to provide advice, guidance and leadership regarding federal oversight of dual use research, defined as biological research that generates information and technologies that could be misused to pose a biological threat to public health and/or national security.

The meeting will be open to the public, however, pre-registration is strongly recommended due to space limitations. Persons planning to attend should register online at: http://oba.od.nih.gov/biosecurity/biosecurity_meetings.html or by calling Palladian Partners, Inc. (Contact: Joel Yaccarino at 301–650–8660.) Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate these requirements upon registration.

This meeting will also be webcast. To access the webcast, as well as the draft meeting agenda and pre-registration information, connect to: http://oba.od.nih.gov/biosecurity/biosecurity_meetings.html. Please check this site for updates.

Any member of the public interested in presenting oral comments relevant to the mission of the NSABB at the meeting may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of an organization may submit a letter of intent, a brief description of the organization, represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments relevant to the mission of the NSABB. All written comments must be received by October 12, 2010 and should be sent via e-mail to nsabb@od.nih.gov with “NSABB Public Comment” as the subject line or by regular mail to 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892. Attention: Ronna Hill. The statement should include the name, address, telephone number and, when applicable, the business or professional affiliation of the interested person.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye 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 Eye Institute
Date: October 25, 2010.
Time: 8:30 a.m. to 5:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.
Contact Person: Anne E. Schaffner, PhD, Scientific Review Officer, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9390, 301–451–2020, aess@net.nih.gov.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0481]

Center for Veterinary Medicine eSubmitter Workshop; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: “Center for Veterinary Medicine (CVM) eSubmitter Workshop.” The purpose of the public workshop is to provide the regulated animal health industry that submits new animal drug applications to CVM’s Office of New Animal Drug Evaluation (ONADE) access to the beta-release of the electronic submission tool (eSubmitter) developed by CVM as agreed to in the Animal Drug User Fee Amendments (ADUFA II) of 2008 (http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm044941.htm). The ONADE will be soliciting feedback on both the eSubmitter tool and its compatibility with the industry’s current IT systems, as well as the questions asked within the tool.

This workshop will fulfill one of the 10 workshops agreed to in ADUFA II. The workshop will provide insight on the eSubmitter template development and its customization for the animal health industry as well as providing break-out sessions in which specific submissions will be built as part of the demonstration. Lastly, the ONADE will be seeking up to nine participating companies to work with CVM in testing the transmission of eSubmitter developed files through FDA’s electronic submission gateway (ESG) and CVM’s electronic submission system (ESS). Information about the workshop and availability of the eSubmitter tool can be found on FDA’s eSubmitter Web site at http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm.

Dates and Time: The public workshop will be held on October 21, 2010, from 9 a.m. to 4 p.m. (EST/EDST).

Location: The public workshop will be held virtually through both Adobe Connect Pro on-line and with conference call-in numbers. Both the call-in numbers and the Adobe Connect Pro web link will be emailed to all registrants.

Contact Person: Charles Andres, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8229, email: charles.andres@fda.hhs.gov.

Registration: Registration for the workshop can be made at: https://collaboration.fda.gov/cvm_esobuttonter_workshop_oct21/event/registration.html on or before October 15, 2010. There is no registration fee for attendees. If needed, special accommodations due to a disability, please contact Charles Andres (see Contact Person) at least 7 days in advance.

Comments: FDA is holding this public workshop to obtain information about the eSubmitter tool. The deadline for submitting comments regarding this public workshop is December 31, 2010.

Regardless of whether a person attended the public workshop, interested persons may submit either electronic or written comments regarding this document. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HF1–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A recording of the public workshop will be available on the Internet at http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm.

Dated: September 17, 2010.

Leslie Kux,
Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3233–N]

Medicare Program; Town Hall Meeting on the Physician Compare Web Site, October 27, 2010

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: Section 10331 of the Patient Protection and Affordable Care Act of 2010, “Public Reporting of Performance Information” requires CMS to establish a Physician Compare Web site by January 1, 2011. This notice announces a Town Hall meeting to discuss the Physician Compare Web site. The purpose of this Town Hall meeting is to solicit input from stakeholders on the Physician Compare Web site. The opinions and alternatives provided during this meeting will assist us in future expansion of the Physician Compare Web site. The meeting is open to the public, but attendance is limited to space available.

DATES: Meeting Date: Wednesday, October 27, 2010 from 1 to 5 p.m., eastern daylight time (e.d.t.).

Timeframe for Meeting Registration: Monday, September 27, 2010 through Wednesday, October 13, 2010 at 5 p.m., e.d.t.

Deadline for Special Accommodations Requests: Wednesday, October 13, 2010 at 5 p.m., e.d.t.

ADDRESSES: Meeting Location: The Town Hall meeting will be held in the main auditorium of the Centers for Medicare and Medicaid Services single site, 7500 Security Boulevard, Baltimore, MD 21244.

Registration and Special Accommodations: Persons interested in attending the meeting or participating by teleconference must register by completing the online registration via the Web site at http://www.qualitymeasures.gov/qm/. Individuals who require special accommodations should send a request via e-mail or regular mail to the contact specified in the FOR FURTHER INFORMATION CONTACT section of this notice.