DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA’s regulatory issues.

Date and Time: The meeting will be held on November 2, 2012, from 8 a.m. to 5 p.m.

Location: DoubleTree by Hilton Hotel Washington DC-Silver Spring, The Ballroom, 8727 Colesville Rd., Silver Spring, MD. The hotel’s phone number is 301–589–5200.

Contact Person: Philip Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–4627, email: AIDACb@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s Web site at http://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss biologics license application (BLA) 125346, raxibacumab injection, a humanized monoclonal antibody against protective antigen of Bacillus anthracis, by Human Genome Sciences, Inc., for the proposed indication of treatment of inhalational anthrax.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person or before October 19, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 11, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 12, 2012.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Philip Bautista at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).


Yvette Sanchez Fuentes,
Director, Office of Head Start.

FOR FURTHER INFORMATION CONTACT: [Redacted].

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Science Board to the Food and Drug Administration: Request for Nominations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations to serve on the Science Board to FDA (Science Board).

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before October 11, 2012 will be considered for membership on the Science Board. Nominations received after October 11, 2012 will be considered for nomination to the Board should nominees still be needed.

ADDRESSES: All nominations for membership should be sent electronically to CV@FDA.HHS.GOV or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993–0002.

FOR FURTHER INFORMATION CONTACT: [Redacted].
Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA’s Web site by using the following link http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/default.htm.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations to the Science Board. The Science Board will meet approximately three times a year. Meetings of the Science Board will be open to the public. All meetings will be announced in the Federal Register at least 15 days prior to each public meeting.

I. General Function of the Committee

The Science Board shall provide advice primarily to the Commissioner and other appropriate officials on specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board will provide advice that supports the Agency in keeping pace with technical and scientific developments, including in regulatory science and input into the Agency’s research agenda and on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency sponsored intramural and extramural scientific research programs.

II. Desired Expertise

FDA is specifically considering persons knowledgeable in the fields of food science, safety, and nutrition; chemistry; pharmacology; translational and clinical medicine and research; toxicology; biostatistics; medical devices; imaging; robotics; cell and tissue based products; regenerative medicine; public health and epidemiology; international health and regulation; product safety; product manufacturing sciences and quality; and other scientific areas relevant to FDA-regulated products such as systems biology, informatics, nanotechnology, and combination products. Members shall be chosen from academia and industry. The Science Board may also include technically qualified federal members.

III. Nomination Procedures

Any interested person may nominate one or more qualified person(s) for membership on the Science Board. Self-nominations are also accepted. Nominations shall include the name of the committee, complete curriculum vitae of each nominee, and their current business address and/or home address, telephone number, and email address, if available. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask the potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.


Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

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BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of 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 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 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 of Diabetes and Digestive and Kidney Diseases Initial Review Group; Diabetes, Endocrinology and Metabolic Diseases Subcommittee.

Date: October 24–26, 2012.

Open: October 24, 2012, 5 p.m. to 5:30 p.m.

Agenda: To discuss committee activities.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Closed: October 25, 2012, 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: John F. Connaughton, Chief, Chartered Committees Section, Review Branch. DEA, NIDDK, National Institutes of Health, Room 754, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7797, connaughton@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group; Digestive Diseases and Nutrition Subcommittee.

Date: October 24–26, 2012.

Open: October 24, 2012, 6 p.m. to 6:30 p.m.

Agenda: To discuss committee activities.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Closed: October 26, 2012, 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

October 24, 2012, 6:30 p.m. to 10 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Closed: October 24, 2012, 4 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Closed: October 23, 2012, 4:30 p.m. to 8 p.m.