DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET NO. FDA–2012–N–0001]

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, 301–796–9001, FAX: 301–847–8533, email: AIDAC0@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–877–8796 (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 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 on 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.

CV@FDA.HHS.GOV

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET NO. FDA–2012–N–0001]

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 given first consideration 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: Regarding all nomination questions for membership, the primary contact is Martha Monser, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4286, Silver Spring, MD 20993–0002, 301–796–4627, email: martha.monser@fda.hhs.gov.

BILLY J. POTOMAC AVE., NW, BLDG. 5, RM. 3E14, DEPARTMENT OF HEALTH AND HUMAN SERVICES

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