DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2010–N–0001]

Blood Products 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Blood Products 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 by teleconference on April 12, 2010, from 1 p.m. to 5:30 p.m.

Location: National Institutes of Health, 9000 Rockville Pike, Bldg. 29, conference rm. 121, Bethesda, MD, 20892. The public is welcome to attend the meeting at the specified location where a speakerphone will be provided.

Public participation in the meeting is limited to the use of the speakerphone in the conference room. Important information about transportation and directions to the NIH campus, parking, and security procedures is available on the Internet at http://www.nih.gov/about/visitor/index.htm. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.) Visitors must show two forms of identification, one of which must be a Government-issued photo identification such as a Federal employee badge, driver’s license, passport, green card, etc. Detailed information about security procedures is located at http://www.nih.gov/about/visitorsecurity.htm. Due to the limited available parking, visitors are encouraged to use public transportation.

Contact Person: Bryan Emery or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (CBER) (HF–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–877–8823 (301–443–0572 in the Washington, DC area), code 3014519516. Please call the Information Line at least 7 days in advance of the meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On April 12, 2010, the committee will meet in open session to hear updates on the research programs of the Laboratory of Cellular Hematology and the Laboratory of Biochemistry and Vascular Biology, Division of Hematology, Office of Blood Research and Review, CBER, FDA.

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 link.

Procedure: On April 12, 2010, from 1 p.m. to approximately 4:15 p.m., the meeting is open to the public. 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 April 7, 2010. Oral presentations from the public will be scheduled between approximately 3:15 p.m. and 4:15 p.m. Those desiring to make 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 March 30, 2010. 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 March 31, 2010.

Closed Committee Deliberations: On April 12, 2010, from approximately 4:15 p.m. to approximately 5:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the site visit report of the intramural research programs and make recommendations regarding personnel staffing decisions.

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 Bryan Emery or Pearline Muckelvene 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).

Dated: March 11, 2010.

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

BILLING CODE 4160–01–S
Conference Centers, 3501 University Blvd. East, Adelphi, MD. The hotel telephone number is 301–985–7300.

Contact Person: Diem-Kieu Ngo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, email: diem.ngo@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512543. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hotline/phone line to learn about possible modifications before coming to the meeting.

Agency: On May 6, 2010, the committee will discuss supplemental new drug application (sNDA) 22–432, H.P. ACTHAR Gel (repository corticotropin injection), 80 USP units per milliliter, Questcor Pharmaceuticals, proposed for the treatment of infantile spasms.

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 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 April 22, 2010. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Those desiring to make 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 April 14, 2010. 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 April 15, 2010.

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 Diem-Kieu Ngo 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/ucm114462.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).

Dated: March 11, 2010.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Center for Complementary and Alternative Medicine
Announcement of Workshop on Control/Comparison Groups for Trials of Non-Pharmacologic Interventions

ACTION: Notice.

SUMMARY: The National Center for Complementary and Alternative Medicine (NCCAM) invites the public to participate at a Workshop on the choice of control and comparison groups for trials of non-pharmacological interventions (NPI). The purpose of this workshop is to review the strengths and weaknesses of the various control/comparison groups used in studies of NPI and the most appropriate use of these control/comparison groups. This workshop will be divided into six sessions that will feature presentations and discussions focusing on the selection of a particular control/comparison group(s) for a given research question. The first session will provide case studies from the NPI literature, while the remainder will address the choice of control/comparison groups when researching the following questions: What is/are the major active component(s) of the NPI? What is/are the major effective mechanism(s) of the NPI? Does this NPI work at all? Is this NPI as good as (or better than) some other intervention? Does this NPI improve standard-of-care?