DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological 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: Vaccines and Related Biological 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 via teleconference on May 6, 2004, from 1:30 p.m. to 3:30 p.m.

Location: National Institute of Health (NIH) Campus, Food and Drug Administration Bldg. 29B, Conference Room C, 8800 Rockville Pike, Bethesda, MD. This meeting will be held by teleconference. The public is welcome to attend the meeting at the above location. A speakerphone will be provided at the specified location for public participation in this meeting. 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. Visitors must show two forms of identification such as a Federal employee badge, driver's license, passport, green card, etc. If you

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are planning to drive to and park on the NIH campus, you must enter at the South Drive entrance of the campus which is located on Wisconsin Ave. (the medical center metro entrance), and allow extra time for vehicle inspection. 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: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM-71), 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314 or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear an overview on the Laboratory of DNA Viruses, Division of Viral Products, Office of Vaccines Research and Review, Center for Biologics and Research (CBER), and in closed session will discuss the report from the laboratory site visit of March 4, 2004.

Procedure: On May 6, 2004, from 1:30 p.m. to 3 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 by April 29, 2004. Oral presentations from the public will be scheduled between approximately 2 p.m. to 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 30, 2004, 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.

Closed Committee Deliberations: On May 6, 2004, from 3 p.m. to 3:30 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 a review of internal research programs in the Office of Vaccines Research and Review, Division of Viral Products, CBER.

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 Christine Walsh or Denise Royster at least 7 days in advance of the meeting.

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

Dated:

April 9, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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