

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). The meeting will be open 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 on February 18, 2004, from 8:30 a.m. to 4:30 p.m.; and on February 19, 2004, from 8:30 a.m. to 12:30 p.m.

Location: The meeting will be held at the Sheraton Four-Points Hotel, 8400 Wisconsin Ave., Bethesda, MD.

Contact Person: William Freas or Denise H. Royster, Food and Drug Administration, Center for Biologics Evaluation and Research (CBER) (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 review and discuss the selection of strains to be included in the influenza virus vaccine for the 2004–2005 season. The committee and CBER will begin a discussion of the potential suitability for use in vaccine manufacture of influenza isolates that have been passaged through mammalian cells (e.g., Madin-Darby Canine Kidney cells or Vero cells).

Procedure: On February 18 and 19, 2004, 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 February 4, 2004. Oral presentations from the public will be scheduled between approximately 1 p.m. to 1:30 p.m. on February 18, 2004, and between 8:45 a.m. to 9:15 a.m. on February 19, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 13, 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.

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 William Freas or Denise H. 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: January 12, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

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

BILLING CODE 4160-01-S