

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date 2-6-07
Publication Date 2-7-07
Certifier L. CLAYSON
DDM

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 27, 2007, from 8 a.m. to 5:30 p.m. and on February 28, 2007, from 8 a.m. to 4:15 p.m.

Location: Hilton Hotel, Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 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: On February 27, 2007, in the morning session, the committee will hear presentations and make recommendations on the safety and effectiveness of an H5N1 inactivated influenza vaccine manufactured by Sanofi Pasteur. In the afternoon, the committee will hear presentations and have discussions on clinical development of influenza vaccines for pre-pandemic uses. On February 28, 2007, in the morning, the committee will hear presentations and make recommendations on strain selections for the influenza virus vaccine for the 2007–2008 season. In the afternoon, the committee will hear presentations and have discussions on circulating lineages of influenza type B virus.

FDA intends to make background material available to the public no later than 1 business day 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/ohrms/dockets/ac/acmenu.htm>, click on the year 2007 and 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 February 13, 2007. Oral presentations from the public will be scheduled between approximately 10:45 and 11:15 a.m. and 2:45 and 3:15 p.m. on February 27, 2007, and between approximately 10:40 and 11:10 a.m. and 2:50 and 3:20 p.m. on February 28, 2007. 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

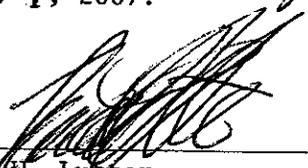
of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 5, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled 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 February 6, 2007.

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: Feb 1, 2007
February 1, 2007.



Randall W. Luster,
Associate Commissioner for Policy and Planning.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**
