

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

PMB

Display Date	2/16/01
Publication Date	7/20/01
Certifier	[Signature]

9370 '01 FEB 15 P4:02
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 on March 7, 2001, from 8 a.m. to 6:30 p.m., March 8, 2001, from 8 a.m. to 6:30 p.m., and March 9, 2001, from 8 a.m. to 12:30 p.m.

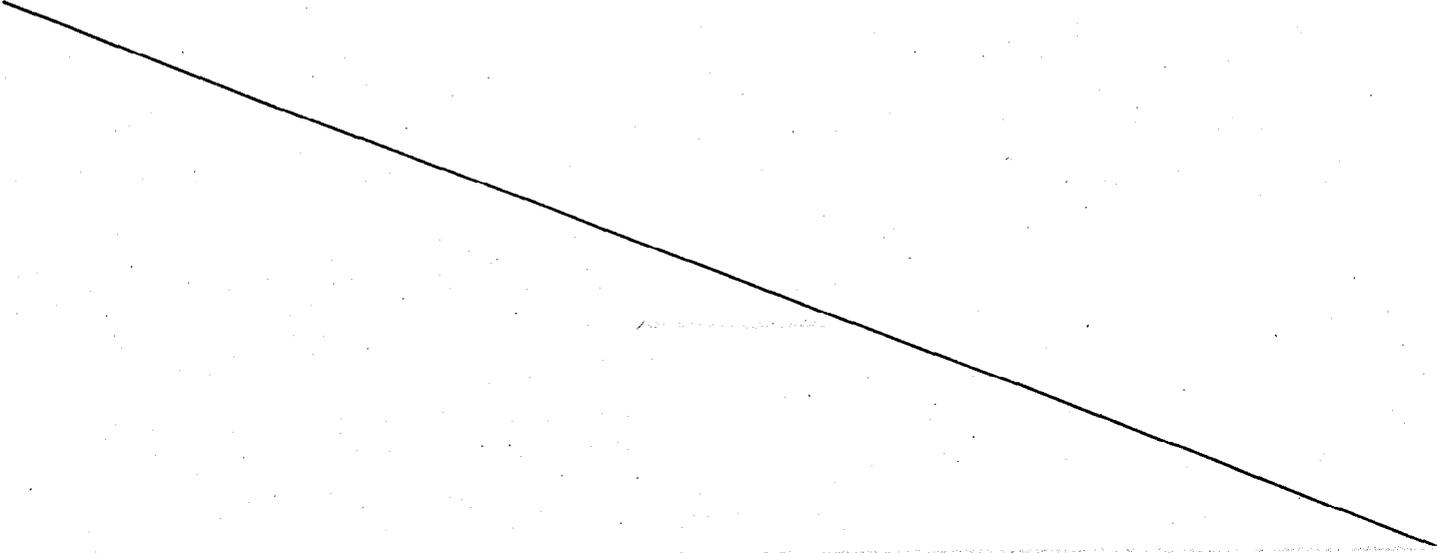
Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 7, 2001, the committee will review safety and immunogenicity data for a combination vaccine, DTaP-Hepatitis B-IPV, manufactured by SmithKline Beecham Biologicals. On March 8, 2001, the committee will discuss approaches to develop new pneumococcal conjugate vaccines for U.S. licensure. On March 9, 2001, the committee will complete recommendations pertaining to the influenza virus vaccine formulations for the 2001 to 2002 season and be briefed on research programs in the Laboratory of Retroviruses and the Laboratory of Immunoregulation.

Procedure: On March 7, 2001, from 9:15 a.m. to 6:30 p.m., the meeting is open to the public. On March 8, 2001, from 10 a.m. to 6:30 p.m., the meeting is open to the public. On March 9, 2001, from 8 a.m. to 11 a.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 February 28, 2001. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2 p.m. on March 7, 2001. On March 8, 2001, oral presentations will be held between approximately 2 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 28, 2001, 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 March 7, 2001, from 8 a.m. to 9 a.m. and on March 8, 2001, from 8 a.m. to 10 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of pending investigational new drug applications or pending product licensing applications. On March 9, 2001, from 11 a.m. to 12:30 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 meeting will be closed to discuss personal information concerning individuals associated with the research programs.



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

2).

Dated: 2/14/01
February 14, 2001.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL



Bonnie H. Malkin

Bonnie H. Malkin,
Special Assistant to the Senior Associate Commissioner.

[FR Doc. 01-???? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-F