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**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.

76100 MM-5 AD-00

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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 January 27, 2000, 8 a.m. to 6:30 p.m., and on January 28, 2000, 8 a.m. to 3 p.m.

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

*Contact Person:* Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-05 72 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On January 27, 2000, the committee will: (1) Review the current understanding of the immune correlates of protection against invasive Haemophilus influenzae type b disease, and (2) discuss the potential clinical significance of reduced antibody responses to PRP (polyribitol phosphate) polysaccharide following administration of combination vaccines containing Haemophilus influenzae type b conjugate vaccines. On January 28, 2000, the committee will: (1) Discuss the influenza virus vaccine formulation for the 2000 to 2001 season, and (2) be briefed

on selected individual research programs in the Laboratory of Pediatric and Respiratory Viral Diseases.

*Procedure:* On January 27, 2000, from 9 a.m. to 6:30 p.m., and on January 28, 2000, from 8 a.m. to 2:25 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 January 19, 2000. Oral presentations from the public will be scheduled between approximately 9:10 a.m. and 9:25 a.m. and between approximately 4 p.m. and 4:15 p.m. on January 27, 2000. Oral presentations from the public will be heard on January 28, 2000, between approximately 8:20 a.m. and 8:30 a.m., between approximately 1:30 p.m. and 1:40 p.m., and between approximately 2:15 p.m. and 2:25 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 19, 2000, 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 January 27, 2000, from 8 a.m. to 9 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 January 28, 2000, from 2:25 p.m. to 3 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: 12/23/99

December 23, 1999

Linda A. Suydam

Linda A. Suydam  
Senior Associate Commissioner

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Michael W. Bell