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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.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). Portions 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 November 4, 1999, 8 a.m. to 6 p.m., and on November 5, 1999, 8 a.m. to 4 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 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 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 4, 1999, the committee will discuss: (1) Ways to demonstrate attenuation of chimeric strains of Cytomegaloviral candidate vaccines to support proceeding into clinical trials, and (2) the safety data following a fifth successive dose of DTaP (Triptedia) manufactured by Connaught Laboratories, Inc. On November 5, 1999, the product license application for Wyeth Lederle Vaccines and Pediatrics' Pneumococcal 7-Valent Conjugate Vaccine (Diphtheria CRM197 protein) will be discussed for use in infants and young children. The

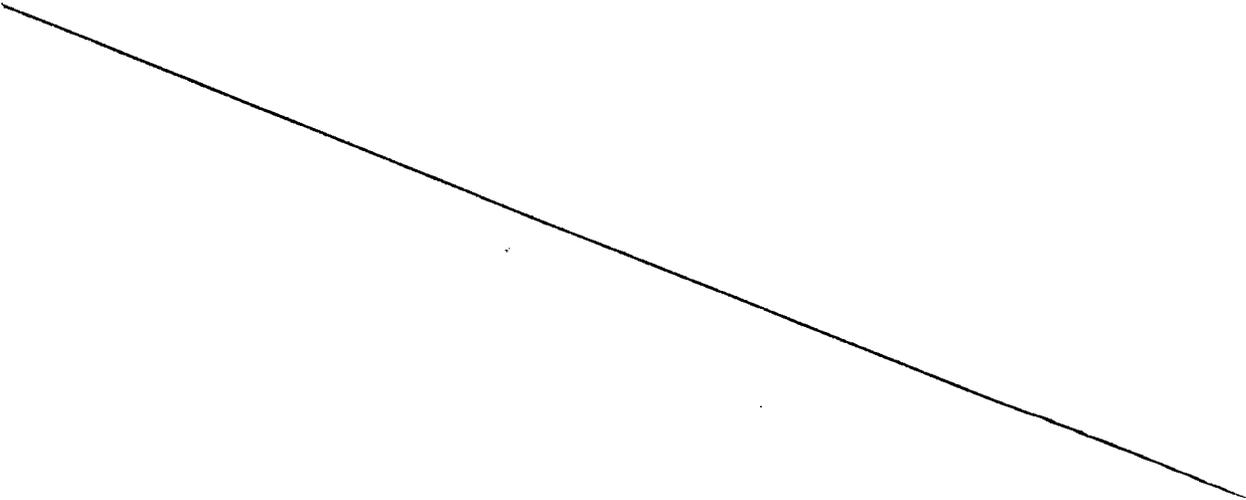
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committee will be asked to consider the safety and efficacy of this vaccine against prevention of invasive disease (bacteremia and meningitis) caused by *Streptococcus pneumoniae* (pneumococcus).

Procedure: On November 4, 1999, from 9 a.m. to 1:30 p.m., and from 2 p.m. to 6 p.m., and on November 5, 1999, from 9 a.m. to 4 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 October 28, 1999. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 11:45 a.m., and between approximately 3:30 p.m. and 3:45 p.m. on November 4, 1999. On November 5, 1999, the oral presentations will be scheduled from approximately 1:30 p.m. to 1:45 p.m., and from approximately 3:15 p.m. to 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 28, 1999, 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 presentations.

Closed Committee Deliberations: On November 4, 1999, from 8 a.m. to 9 a.m., and from approximately 1:30 p.m. to 2 p.m., and on November 5, 1999, 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)). These portions of the meeting will be closed to permit discussion of pending investigational new drug applications or pending product licensing applications.



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

2).

Dated: 10/12/99

October 12, 1999



Linda A. Suydam
Senior Associate Commissioner

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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