

DMB

Employment No.	2/23/00
Publication Date	2/28/00
Certifier	<i>[Signature]</i>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

0672 '00 FEB 23 P3:57
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). 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 9, 2000, 8 a.m. to 6 p.m., and on March 10, 2000, 8 a.m. to 3 p.m.

Location: Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, 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 March 9, 2000, the committee will discuss the safety and efficacy of a combination vaccine from SmithKline Beecham for the prevention of Diphtheria/Tetanus, Pertussis, Polio, and Hepatitis B. On March 10, 2000, the committee will: (1) Complete recommendations pertaining to the influenza virus vaccine formulations for the 2000 to 2001 season, (2) hear a short briefing on the Vaccine Safety Action Plan, and (3) be updated on the status of vaccines for the prevention of rotavirus disease.

oc0032 3600

NM-1

Procedure: On March 9, 2000, from 9:15 a.m. to 6 p.m., and on March 10, 2000, from 8 a.m. to 3 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 March 3, 2000. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 9:45 a.m. and between approximately 4 p.m. and 4:15 p.m. on March 9, 2000. Oral presentations from the public will be heard on March 10, 2000, between approximately 10:20 a.m. and 10:30 a.m., between approximately 12:30 p.m. and 12:45 p.m., and between approximately 2:45 p.m. and 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 1, 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.

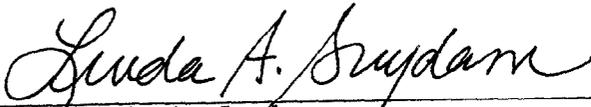
Closed Committee Deliberations: On March 9, 2000, from 8 a.m. to 9:15 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information. (5 U.S.C. 552b(c)(4)). These portions of the meeting will be closed to discuss issues relating to pending or proposed investigational new drug applications.

FDA regrets that it was unable to publish this notice 15 days prior to the March 9 and 10, 2000, Vaccines and Related Biological Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Vaccines and Related Biological Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

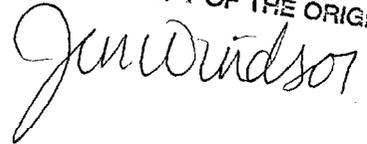
2).

Dated: February 16, 2000



Linda A. Suydam
Senior Associate Commissioner

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F