

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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Certifier	<i>[Signature]</i>

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 November 28, 2001, from 8:30 a.m. to 5:15 p.m.; and on November 29, 2001, from 8:30 a.m. to 2:30 p.m.

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

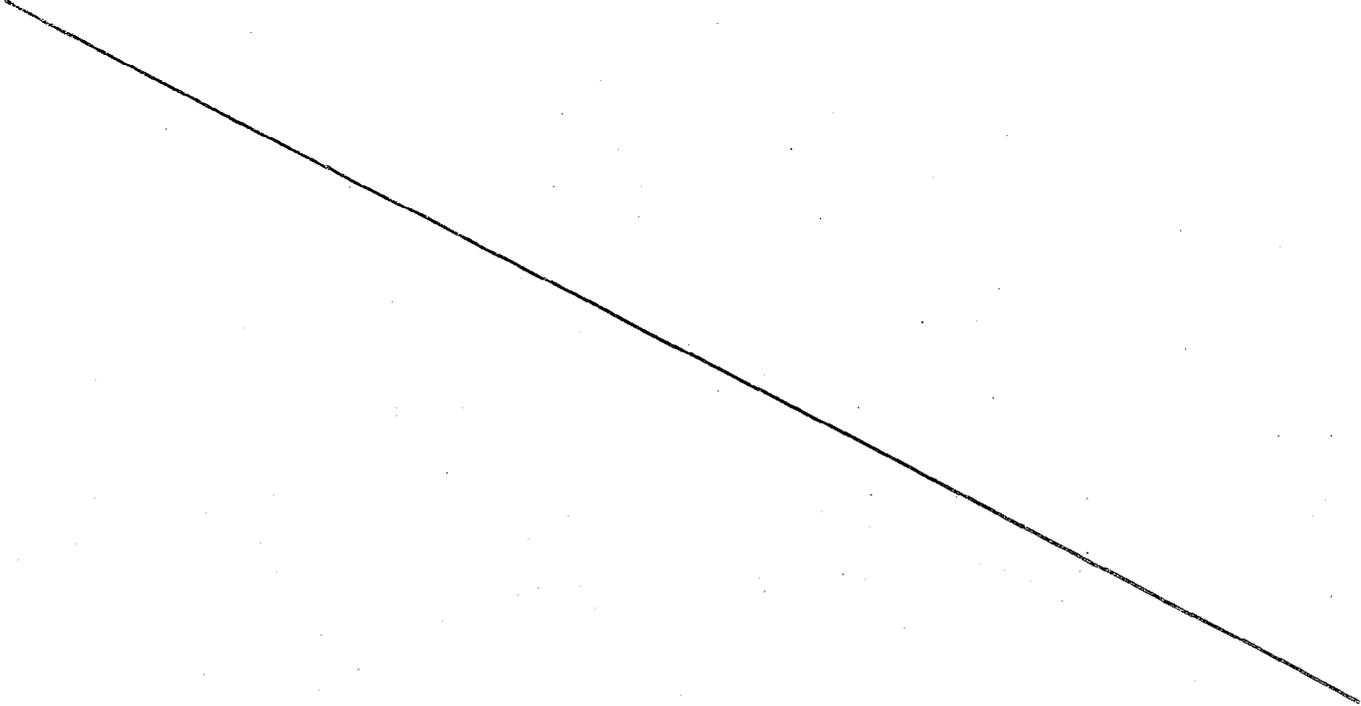
Contact: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 28 and 29, 2001, the committee will review issues surrounding efficacy trial endpoints for vaccines for the prevention of Human Papilloma Virus. On November 29, 2001, the committee will discuss the intramural scientific research of the Laboratory of Bacterial Toxins.

Procedure: On November 28, 2001, from 12:30 p.m. to 5:15 p.m.; and on November 29, 2001, from 8:30 a.m. to 1:40 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

by November 16, 2001. Written submissions may be made to the contact person by November 16, 2001. On November 28, 2001, oral presentations will be held between approximately 3:15 p.m. and 4:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 16, 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.

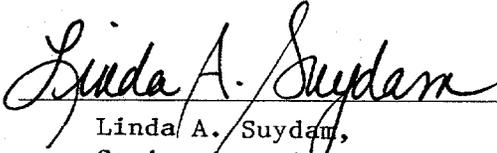
Closed Committee Deliberations: On November 28, 2001, from 8:30 a.m. to 12:30 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). On November 29, 2001, from 1:45 p.m. to 2:30 p.m., the meeting will be closed to permit 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 program.



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

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Dated: 10/16/01
October 16, 2001.

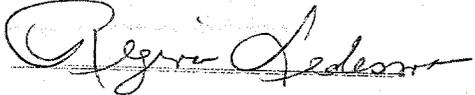


Linda A. Suydam,
Senior Associate Commissioner.

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

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Regina Sedessa