

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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Certifier	<u>[Signature]</u>

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 May 16, 2001, from 8 a.m. to 6:30 p.m., and May 17, 2001, from 8 a.m. to 1:30 p.m.

Location: Holiday Inn, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

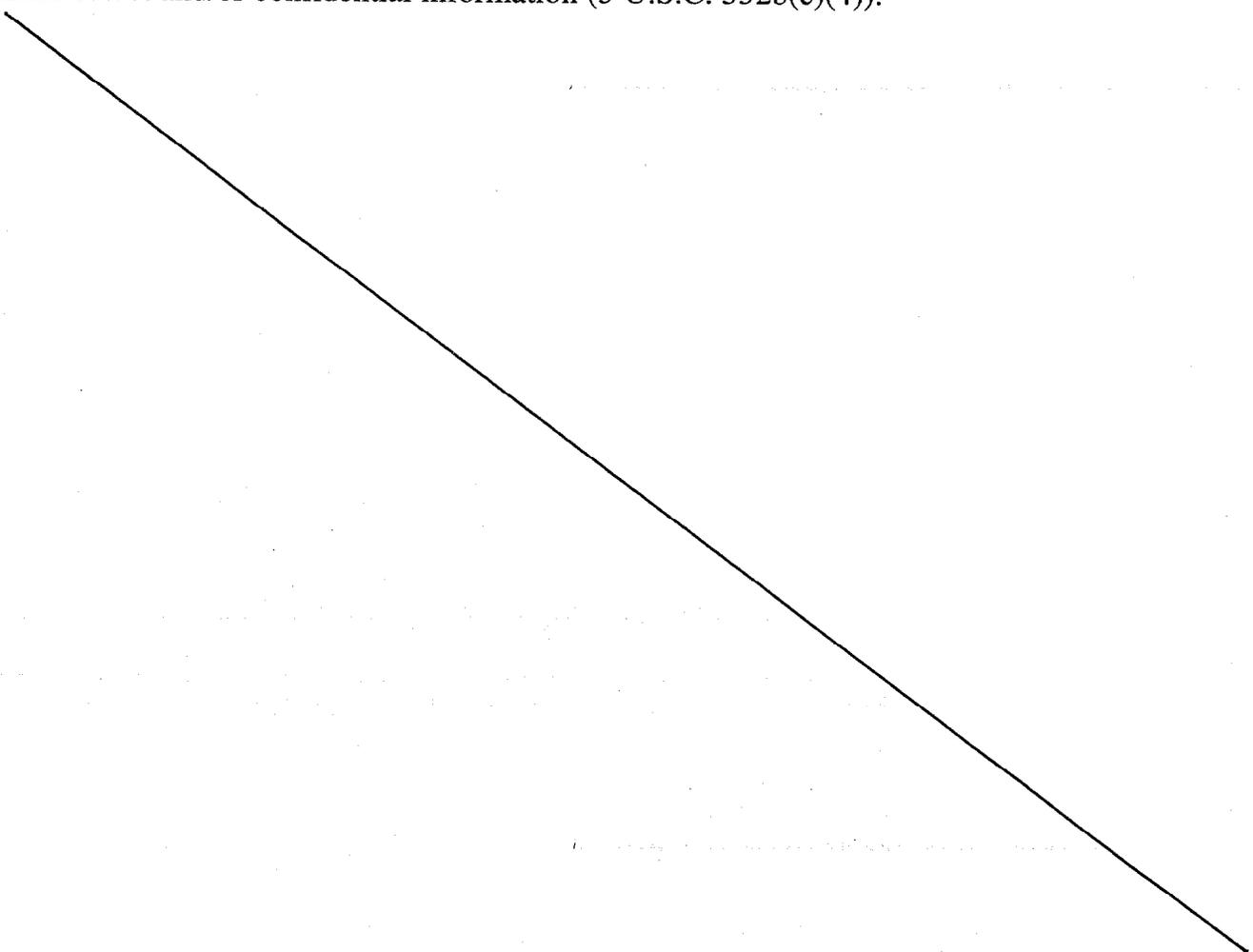
Contact: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluations and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138, (301-443-0572 in the Washington, DC area), code 12391.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

Agenda: On May 16, 2001, the committee will discuss adventitious agent testing, tumorigenicity testing, and issues related to residual cell substrate deoxyribonucleic acid (DNA) of novel and neoplastic cell substrates used to manufacture viral vaccines.

Procedure: On May 16, 2001, from 9 a.m. to 6:30 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 May 8, 2001.

Oral presentations from the public will be held between approximately 2:30 p.m. and 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 May 8, 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 May 16, 2001, from 8 a.m. to 9 a.m. and on May 17, 2001, from 8 a.m. to 1:30 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)).



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

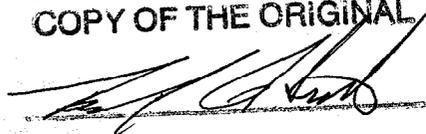
2).

Dated: April 19, 2001.



Linda A. Suydam,
Senior Associate Commissioner.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL



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

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