DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

National Mammography Quality Assurance 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). The meeting will be open to the public.

Name of Committee: National Mammography Quality Assurance 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 31, 2000, 9 a.m. to 6 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Charles A. Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12397. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will: (1) Discuss the establishment of a proposed demonstration project to assess the efficacy of less than annual inspections as described in the Mammography Quality Standards Reauthorization Act of 1998, and (2) continue the discussion of the Mammography Quality Standards Act (the MQSA) compliance guidance. The committee will also receive updates on the status of facility noncompliance under final regulation inspections, accreditation and certification of full field digital mammography, States as certification agencies under the MQSA, and Voluntary Stereotactic Accreditation Programs. The MQSA compliance guidance documents, which are in a question and answer format, are available to the public on the Internet at http://www.fda.gov/cdrh/mammography. The guidance is being updated continually in response to questions that FDA receives from the public. Additional information regarding guidance updates may be obtained by calling the Information Line.

Procedure: 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 10, 2000. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 10, 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.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 28, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

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BILLING CODE 4160–01–F

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). 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 (301–443–0572 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.