

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 September 14, 1999, 1 p.m. to 5 p.m., and on September 15, 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 September 14, 1999, the committee will: (1) Hear reports on recent workshops on Thimerosal in Vaccines and Cell Substrates for Vaccine Development and be updated on recent developments concerning the rotavirus vaccine manufactured by Wyeth Laboratories, Inc., and (2) be briefed on selected individual research programs in the Laboratory of Parasitic Biology and the Laboratory of Biophysics. On September 15, 1999, the committee will discuss the use of

immunologic surrogates for demonstration of protective efficacy of meningococcal conjugate vaccines.

Procedure: On September 14, 1999, from 1 p.m. to 3:10 p.m., and on September 15, 1999, from 8 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 September 7, 1999. Oral presentations from the public will be scheduled between approximately 2:10 p.m. and 2:50 p.m. on September 14, 1999, and between approximately 12:10 p.m. and 12:30 p.m. on September 15, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 7, 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 presentation.

Closed Committee Deliberations: On September 14, 1999, from 3:10 p.m. to 4 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)). This portion of the meeting will be closed to permit discussion of pending investigational new drug applications or pending product licensing applications. Also, on September 14, 1999, from 4 p.m. to 5 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.

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

Dated: August 13, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99-22102 Filed 8-25-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225-99-6002]

Memorandum of Understanding Between the Food and Drug Administration and the State of Iowa

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the State of Iowa. The purpose of the MOU is to establish policies, procedures, and responsibilities for the billing and collection of Mammography Quality Standards Act (MQSA) mammography facility inspection fees for the second year.

DATES: The agreement became effective July 30, 1999.

FOR FURTHER INFORMATION CONTACT: Lireka P. Joseph, Center for Devices and Radiological Health (HFZ-200), Food and Drug Administration, 2094 Gaither Rd., Gaithersburg, MD 20850, 301-443-2845.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this memorandum of understanding.

Dated: August 19, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

BILLING CODE 4160-01-F