

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Subcommittee of the Antiviral Drugs 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:* Subcommittee of the Antiviral Drugs Advisory Committee on Immunosuppressive Drugs.

*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 July 27, 1999, 8:30 a.m. to 5 p.m.

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

*Contact Person:* Rhonda W. Stover, or John Schupp, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The subcommittee will discuss the new drug application (NDA) 21-083, Rapamune® (sirolimus, Wyeth-Ayerst Laboratories) for the prophylaxis of organ rejection in patients receiving renal transplants.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by July 20, 1999. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 20, 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.

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

Dated: June 7, 1999.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Request for Public Comment: 30-Day Proposed Collection: Indian Health Service Medical Staff Credentials and Privileges Files**

**SUMMARY:** In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) provided an opportunity for public comment on the proposed agency information collection project. A notice was previously published in the **Federal Register** on May 1, 1998, (63 FR 24185) and allowed 60 days for public comment. No public comment was received in response to the notice. As required by section 3507(a)(1)(D) of the Act, the proposed information collection has been submitted to the Office of Management and Budget (OMB) for review and approval. The purpose of this notice is to allow an additional 30 days for public comment to be submitted directly to OMB.

**Proposed Collection**

*Title:* 0917-0009, "Indian Health Service Medical Staff Credentials and Privileges Files". *Type of Information Collection Request:* Reinstatement, with minor change, of a previously approved information collection for which approval expired October 31, 1998. *Form Number:* Instruction and information collection formats are contained in an IHS Circular, "Credentials and Privileges Review Process for the Medical Staff." *Need and Use of Information Collection:* The IHS operates health care facilities that provide health care services to American Indians and Alaska Natives. To provide these services, the IHS employs (directly and under contract) several categories of health care providers, including physicians (M.D. and D.O.), dentists, psychologists, optometrists, podiatrists, and audiologists; and in some States, physician assistants, certified registered nurse anesthetists, nurse practitioners, and certified nurse midwives. The IHS policy specifically requires physicians and dentists to be members of the health care facility medical staff where they practice. Health care providers become

medical staff members, depending on the local health care facility's capabilities and medical staff bylaws. There are three types of IHS medical staff applicants: (1) Health care providers applying for direct employment with the IHS, (2) contract health care providers who do not seek to become IHS employees, and (3) employed IHS health care providers who seek to transfer between IHS health care facilities.

National health care standards developed by the Health Care Financing Administration and by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) require health care facilities to review, evaluate, and verify the credentials, training, and experience of medical staff applicants prior to granting medical staff privileges. To meet these standards, IHS health care facilities require each medical staff applicant to provide information concerning their education, training, licensure, and work experience and any adverse disciplinary actions taken against them or medical malpractice payments made on their behalf based on clinical services they performed. This information is then verified with references supplied by the applicant and may include former employers, educational institutions, licensure and certification boards, the American Medical Association, the Federation of State Medical Boards, the National Practitioner Data Bank, and the applicants themselves.

In addition to the initial granting of medical staff membership and clinical privileges, JCAHO standards require that a review of the medical staff be conducted no less than every two years. This review evaluates the current competence of the medical staff and verifies whether they are maintaining their licensure and the certification requirements of their speciality.

The medical staff credentials and privileges records are maintained at the health care facility where the health care provider is a medical staff member. The establishment of these records at IHS health care facilities is not optional; such records must be established and maintained at all health care facilities in the United States that are accredited by JCAHO. This information collection activity is used to evaluate individual health care providers applying for medical staff privileges at IHS health care facilities. *Affected Public:* Individuals, businesses or other for-profit, not-for-profit institutions, and State, local or tribal governments. *Type of Respondents:* Health care providers requesting Medical staff privileges at IHS health facilities.