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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral Drugs Advisory Committee; Notice of Subcommittee 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 meeting of the Antiviral Drugs Advisory Committee on immunosuppressive drugs.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on January 14, 1998, 8:30 a.m. to 5 p.m.

Location: Quality Suites, Potomac Ballroom, Three Research Cts., Rockville, MD.

Contact Person: Rhonda W. Stover or John B. Schupp, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, 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: On January 14, 1998, the subcommittee will discuss new drug application (NDA) 50-722, CellCept® (mycophenolate mofetil), Syntex, USA, Inc., for immunosuppression following cardiac transplantation.

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 7, 1998. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 7, 1998, 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).


Michael A. Friedman,
Deputy Commissioner for Operations.

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