

Its Subcommittee on Privacy and Confidentiality monitors developments in health information privacy and confidentiality on behalf of the full Committee and makes recommendations to the full Committee so that it can advise the Secretary on implementation of the health information privacy provisions of HIPAA.

Purpose: This meeting of the Subcommittee on Privacy and Confidentiality will receive information on the implementation of the regulation "Standards for Privacy of Individually Identifiable Health Information" (45 CFR parts 160 and 164), promulgated under the Health Insurance Portability and Accountability Act of 1996.

The regulation and further information about it can be found on the Web site of the Office for Civil Rights, at <http://www.hhs.gov/ocr/hipaa/>. The regulation has been in effect since April 14, 2001. Most entities covered by the regulation must come into compliance by April 14, 2003, and many are beginning the process of implementing it.

The first day of the meeting will be conducted as a hearing, in which the Subcommittee will gather detailed information about implementation of the regulation's provisions for use and disclosure of health information for marketing and fundraising. The Subcommittee will invite specific representatives of affected groups, in order to obtain information about practical issues in implementation of the regulation with respect to these uses and disclosures of information, and to obtain suggestions about possible solutions for such issues.

The format will include one or more invited panels on these issues and time for questions and discussion. The Subcommittee will ask the invited witnesses for focused, detailed analyses and description, with examples, of the effect the regulation is expected to have, on individuals and on entities subject to the regulation, with respect to these matters, based on early implementation efforts and preliminary assessments of impact.

The second day of the meeting will consist of Subcommittee discussion of the testimony it has heard and deliberations about possible recommendations to the Secretary.

In addition to the panels that will be invited to address these issues, members of the public who would like to make a brief (3 minutes or less) oral comment on one or more of the specified issues during the hearing will be placed on the agenda as time permits. To be included on the agenda, please contact Marietta Squire (301) 458-4524, by E-mail at mrwlinson@cdc.gov, or postal address at NCHS, Presidential Building, Room 1100, 6525 Belcrest Road, Hyattsville, Maryland 20782 by January 17, 2002.

Persons wishing to submit written testimony only (which should not exceed five double-spaced typewritten pages) should endeavor to submit it by that date. Unfilled slots for oral testimony will also be filled on the day of the meeting as time permits. Please consult Ms. Squire for further information about these arrangements.

Additional information about the hearing will be provided on the NCVHS Web site at

<http://www.ncvhs.hhs.gov> shortly before the hearing date.

Contact Person for More Information: Information about the content of the hearing and matters to be considered may be obtained from John P. Fanning, Lead Staff Persons for the NCVHS Subcommittee on Privacy and Confidentiality, Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, 440D Humphrey Building, 200 Independence Avenue SW., Washington DC 20201, telephone (202) 690-5896, E-mail jfanning@osaspe.dhhs.gov, or from Marjorie S. Greenberg, Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 458-4245. Information about the committee, including summaries of past meetings and a roster of committee members, is available on the Committee's Web site at <http://www.ncvhs.hhs.gov>.

Dated: December 20, 2001.

James Scanlon,

Director, Division of Data Policy, Office of the Assistant Secretary for, Planning and Evaluation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Immunosuppressive Drugs 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: Immunosuppressive Drugs Subcommittee of the Antiviral Drugs 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 24, 2002, from 8:30 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Tara P. Turner, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: TurnerT@cder.fda.gov, 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 new drug applications (NDAs) 21-083/SE1-006 and 21-110/SE1-004, RAPAMUNE (sirolimus) oral solution and tablets, Wyeth-Ayerst Research, approved for prophylaxis of organ rejection in patients receiving renal transplants. As stated in the approved labeling, it is recommended that RAPAMUNE be used in a regimen with cyclosporine and corticosteroids. The discussion is for the proposed elimination of cyclosporine from the immunosuppressive regimen 2 to 4 months after transplantation under certain conditions.

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 January 16, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 16, 2002, 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 19, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood 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 Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Blood Products Advisory Committee.