

Evaluation and Research (HFD-350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-6700, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Blood Products Advisory Committee, code 12388.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human diseases.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before March 13, 1995, 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 required to make their comments.

Open committee discussion. On the morning of March 23, 1995, the committee will discuss and provide recommendations for warnings in the labeling for blood products regarding potential transmission of viral agents. Additionally, the committee will discuss and provide recommendations for the format of blood container labeling. In the afternoon, the committee will discuss the practice of alanine aminotransferase (ALT) testing of blood and plasma donors, and they will provide recommendations. On the morning of March 24, 1995, the committee will discuss pool size for the manufacture of plasma products and, in the afternoon, the committee will participate in a workshop entitled, "Human Tissue Intended for Transplantation and Human Reproductive Tissue: Donor Screening and Infectious Disease Testing." The issues to be discussed at the workshop are: (1) Recommendations for donor screening and infectious disease testing needed to clarify the interim rule for human tissue intended for transplantation (21 CFR 1270) that published in the **Federal Register** of December 13, 1993 (58 FR 65514), (2) draft recommendations for screening and testing donors of human reproductive tissue, and (3) the draft registration form. The agency is announcing the availability, before the meeting, of a draft document on the issues to be discussed at the workshop. Requests for single copies of the draft document may be made to the Division

of Congressional, International, and Consumer Affairs, Center for Biologics Evaluation and Research (HFM-11), 1401 Rockville Pike, rm. 200N, Rockville, MD 20857, 301-594-1800.

Joint Meeting of the Nonprescription Drugs and the Dermatologic and Ophthalmic Drugs Advisory Committees, Followed by a Session with Pulmonary-Allergy Drugs Committee Representation, and a Joint Meeting with the Arthritis Advisory Committee

Date, time, and place. March 27 and 28, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing a separate meeting of the Arthritis Advisory Committee to be held on March 27, 1995.

Type of meeting and contact person. Open committee discussion, March 27, 1995, 8 a.m. to 10 a.m.; open public hearing, 10 a.m. to 10:30 a.m., unless public participation does not last that long; open committee discussion, 10:30 a.m. to 3 p.m., open public hearing, 3 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 5:30 p.m.; open committee discussion, March 28, 1995, 8 a.m. to 11:30 a.m.; open public hearing, 11:30 a.m. to 12 m., unless public participation does not last that long; open committee discussion, 12 m. to 4 p.m.; Lee L. Zwanziger or Liz Ortuzar, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Nonprescription Drugs Advisory Committee, code 12541.

General function of the committees. The Nonprescription Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (OTC) (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases. The Dermatologic and Ophthalmic Drugs Advisory Committee reviews and evaluates available data on the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders. The Pulmonary-Allergy Drugs Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of

pulmonary disease and diseases with allergic and/or immunologic mechanisms. The Arthritis Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in arthritic conditions.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before March 22, 1995, 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 required to make their comments.

Open committee discussion. During the morning of March 27, 1995, the Nonprescription Drugs Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee will discuss data relevant to new drug application (NDA) 18-751 to switch econazole nitrate cream 1% (Spectazole®, Johnson & Johnson Consumer Products, Inc.) from prescription to OTC status for the treatment of tinea pedis (athlete's foot). During the afternoon of March 27, 1995, the Nonprescription Drugs Advisory Committee and representatives of the Pulmonary-Allergy Drugs Advisory Committee will discuss data relevant to the efficacy and use of antihistamines for the treatment of the common cold. In the morning on March 28, 1995, the Nonprescription Drugs Advisory Committee and the Arthritis Drugs Advisory Committee will discuss data relevant to NDA 20-512 for ibuprofen suspension (Motrin®, McNeil Consumer Products) for the treatment of fever and of pain in children between 2 and 12 years of age. During the afternoon, the committees will discuss recommendations regarding appropriate OTC indication(s) for muscle relaxants, OTC dose(s) and duration of use, safety profiles, abuse potential, and pharmacokinetic information.

Subcommittee Meeting of the Antiviral Drugs Advisory Committee on Immunosuppressive Drugs

Date, time, and place. March 30 and 31, 1995, 8 a.m., Holiday Inn, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Type of meeting and contact person. Open committee discussion, March 30, 1995, 8 a.m. to 11:30 a.m.; open public hearing, 11:30 a.m. to 12 m., unless public participation does not last that