brocades NV has now withdrawn the petition without prejudice to a future filing (21 CFR 71.6(c)(2)).

Dated: September 22, 1995.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–25971 Filed 10–19–95; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Endocrinologic and Metabolic Drugs Advisory Committee

Date, time, and place. November 16 and 17, 1995, 8 a.m., Holiday Inn—Silver Spring, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Type of meeting and contact person. Open public hearing, November 16, 1995, 8 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 6 p.m.; open public hearing, November 17, 1995, 8 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 4 p.m.; Kathleen R. Reedy, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, FAX 301–443–0699, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area) Endocrinologic and Metabolic Drugs Advisory Committee, code 12536.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in endocrine and metabolic disorders.

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 November 10, 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 November 16, 1995, in the morning, the committee will hear presentations and discuss data submitted regarding the safety and efficacy of dexfenfluramine hydrochloride, new drug application (NDA) 20–344 (Interneuron Pharmaceuticals, Inc.), for an obesity indication, as followup to the meeting of September 28, 1995. In the afternoon, the committee will hear presentations and discuss data submitted regarding the safety and efficacy of sodium fluoride USP, NDA 19–975 (Slow Fluoride, Texas Southwest Medical Center), for an osteoporosis indication. On November 17, 1995, the committee will discuss data regarding the safety and efficacy of probucol, NDA 17–535 (Lorelco®, Hoechst Marion Roussel), for a lipid altering indication and whether the drug should be withdrawn from the market.

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Pulmonary-Allergy Drugs Advisory Committee

Date, time, and place. November 16, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; Lee L. Zwanziger, Liz L. Ortuzar, or Leander B. Madoo, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695, 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 (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases. 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.

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 November 10, 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 requested to make their comments.

Open committee discussion. The committees will first discuss data relevant to investigational new drug (IND) 41,743, sponsored by Sandoz Pharmaceuticals Corp., on the efficacy of clemastine fumarate in the common cold. The committees will then discuss a meta-analysis of data on antihistamines and the common cold to address the inclusion of the common cold indication for the over-the-counter antihistamines, which is currently in the tentative final monograph, in the final monograph.

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee

Date, time, and place. November 17, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 4 p.m.; Lee L. Zwanziger, Liz L. Ortuzar, or Ermona McGoodwin, Center

for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695, 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 (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 concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders.

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 November 10, 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 requested to make their comments.

Open committee discussion. The committees will discuss data relevant to NDA 19–501 to switch Rogaine® (minoxidil 2% topical solution, The Upjohn Co.), for use as a hair regrowth treatment for persons with androgenetic alopecia, from prescription to over-the-counter marketing status.

National Task Force on AIDS Drug Development

Date, time, and place. November 20, 1995, 8:30 a.m.; Hubert H. Humphrey Bldg., rm. 800, 200 C St. NW., Washington, DC.

Type of meeting and contact person. Open task force discussion, 8:30 a.m. to 4:30 p.m.; open public hearing, 4:30 p.m. to 5:30 p.m., unless public participation does not last that long; Heidi C. Marchand or Kimberley M. Thornton, Office of AIDS and Special Health Issues (HF–12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–0104, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), National Task Force on AIDS Drug Development, code 12602.

General function of the task force. The task force shall identify any barriers and provide creative options for the rapid development and evaluation of treatments for the human immunodeficiency virus (HIV) infection and its sequelae. The task force also advises on issues related to such barriers, and it provides options for the elimination of these barriers.

Open task force discussion. The task force will present, hear, and discuss recommendations made at previous meetings and discuss the future of the task force.

Agenda—Open public hearing. Interested persons may present information or views, orally or in writing, on issues pending before the task force. Those desiring to make formal presentations should notify the contact person before November 15, 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.

Immunology Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. November 30 and December 1, 1995, 8 a.m., Holiday Inn—Gaithersburg, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–948–8900 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Ed Rugenstein, Sociometrics, Inc., 301–608–2151. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

Type of meeting and contact person. Open public hearing, November 30, 1995, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 6 p.m.; open public hearing, December 1, 1995, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Immunology Devices Panel, code 12516.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

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 November 15, 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 November 30, 1995, the committee will discuss general issues relating to the review of two premarket approval applications for: (1) An in situ hybridization assay to measure a prognostic marker in breast tumor tissues; and (2) an assay to measure a urinary marker to aid in the detection of recurrence in bladder cancer patients. On December 1, 1995, the committee will discuss a citizen's petition to reclassify from Class III to Class II all serum tumor markers that are intended for monitoring recurrence in previously treated cancer patients.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures

for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: October 16, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95–26053 Filed 10–19–95; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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MEETINGS: The following advisory committee meetings are announced:

Antiviral Drugs Advisory Committee

Date, time, and place. November 6 and 7, 1995, 8:30 a.m., and November 8, 1995, 8 a.m., Quality Hotel, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD.

Type of meeting and contact person. Open committee discussion, November 6, 1995, 8:30 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 5 p.m.; open committee discussion, November 7, 1995, 8:30 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 5 p.m.; open committee discussion, November 8, 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 12:30 p.m.; closed committee deliberations, 12:30 p.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, 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Antiviral Drugs Advisory Committee, code 12531.

General function of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), AIDS-related complex (ARC), and other viral, fungal, and mycobacterial infections.

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 a contact person before October 31, 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 November 6, 1995, the committee will discuss data relevant to new drug applications (NDA's) 20–564 (tablets) and 20–596 (oral solution) for lamivudine (Epivir™, also known as 3TC), sponsored by Glaxo Wellcome. On November 7, 1995, the committee will discuss data relevant to NDA 20–628 for saquinavir (Invirase™), sponsored by Hoffman-La Roche. On November 8, 1995, the committee will discuss confirmatory trials of stavudine (Zerit™, also known as d4T), sponsored by Bristol-Myers Squibb. All products listed above are for the treatment of human immunodeficiency virus infection.

Closed committee deliberations. On November 8, 1995, the committee will discuss trade secret and/or confidential commercial information relevant to pending NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Biological Response Modifiers Advisory Committee

Date, time, and place. November 13, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last