

due to *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, or *T. rubrum*. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for MENTAX (U.S. Patent No. 5,021,458) from Peneder, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 21, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of MENTAX represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for MENTAX is 1,201 days. Of this time, 638 days occurred during the testing phase of the regulatory review period, while 563 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* July 7, 1993. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on July 7, 1993.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* April 5, 1995. The applicant claims April 4, 1995, as the date the new drug application (NDA) for MENTAX (NDA 20-524) was initially submitted. However, FDA records indicate that NDA 20-524 was submitted on April 5, 1995.

3. *The date the application was approved:* October 18, 1996. FDA has verified the applicant's claim that NDA 20-524 was approved on October 18, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 866 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 20, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any

interested person may petition FDA, on or before October 20, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 4, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting 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.

MEETING: The following advisory committee meeting is announced:

Arthritis Advisory Committee

Date, time, and place. May 6 and 7, 1997, 8:30 a.m., Holiday Inn—Gaithersburg, Whetstone Room, Two Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person. Open public hearing, May 6, 1997, 8:30 a.m. to 9 a.m., unless public participation does not last that long; closed presentation of data, 9 a.m. to 11 a.m.; closed committee deliberations, 11 a.m. to 5 p.m.; open public hearing, May 7, 1997, 8:30 a.m. to 9 a.m., unless public participation does not last that long; closed presentation of data, 9 a.m. to 11 a.m.; closed committee deliberations, 11 a.m. to 1 p.m.; Kathleen R. Reedy or LaNise Giles, Center for Drug Evaluation and Research (HFD-21), 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), Arthritis Advisory Committee, code 12532. Please call the hotline for information concerning any possible changes.

General function of committee. The 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 May 1, 1997, 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.

Closed presentation of data. On May 6 and 7, 1997, the committee will hear trade secret and/or confidential commercial information relevant to pending investigational new drug applications (IND's) and new drug applications (NDA's). This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Closed committee deliberations. On May 6 and 7, 1997, the committee will review trade secret or confidential commercial information relevant to

pending IND's and NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above 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. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) 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, 5600 Fishers Lane, rm. 12A-16, 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, 12420 Parklawn Dr., rm. 1-23, 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.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a

clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

FDA regrets that it was unable to publish this notice 15 days prior to the May 6 and 7, 1997, Arthritis Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Arthritis Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

This notice is issued under section 10(a)(1) and (a)(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: April 15, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration [BPD-894-NC]

Medicare and Medicaid Programs; Announcement of Additional Applications From Hospitals Requesting Waivers for Organ Procurement Service Area

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice announces eight additional applications that HCFA has received from hospitals requesting waivers from dealing with their designated organ procurement organizations (OPOs) in accordance