Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Survey of FDA Safety Alert/Public Health Advisory

Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) authorizes FDA to disseminate information concerning imminent danger to public health by any regulated product. The Center for Devices and Radiological Health (CDRH) communicates these risks to user communities through two publications: The ''FDA Safety Alert'' and the ''FDA Public Health Advisory.'' Safety alerts and advisories are sent to organizations such as hospitals, nursing homes, hospices, home health care agencies, manufacturers, retail pharmacies, and other health care providers. Subjects of recent alerts include spontaneous combustion risks in large quantities of patient examination gloves, hazards associated with the use of electric heating pads, and retinal photic injuries from operating microscopes during cataract surgery.

Section 1702(a)(4) of the Public Health Services Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. FDA seeks to evaluate the clarity, timeliness and impact of safety alerts and public health advisories by surveying a sample of recipients. Subjects will receive a questionnaire to be completed and returned to FDA. The information to be collected will address how clearly the problem discussed in the alert or advisory is identified, how easily the problem is understood, how clearly actions for reducing risk are explained, the timeliness of the information, and whether the reader has taken any action to eliminate or reduce risk as a result of information in the alert. Subjects will also be asked whether they wish to receive future alerts electronically, as well as how the safety alert program might be improved.

The information collected will be used to shape FDA's editorial policy for the safety alerts and public health advisories. Understanding how target audiences view these publications will aid in deciding what changes should be considered in their content, format, and method of dissemination.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
308	3	924	.17	157

There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on the history of the safety alert and public health advisory program, it is estimated that an average of three collections will be conducted a year. The total burden of response time was estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey, in addition to discussions with contacts in trade associations.

Dated: April 9, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–10253 Filed 4–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0047]

Determination of Regulatory Review Period for Purposes of Patent Extension; MENTAX

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MENTAX and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product MENTAX (butenafine hydrochloride). MENTAX is indicated for the topical treatment of interdigital tinea pedis (athlete's foot)

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 Penederm, 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.

[FR Doc. 97–10133 Filed 4–18–97; 8:45 am]

BILLING CODE 4160–01–F

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