FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on November 4, 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*: July 31, 1995. FDA has verified the applicant's claim that the new drug application (NDA) for ALLEGRA™ (NDA 20–625) was initially submitted on July 31, 1995.

3. *The date the application was approved*: July 25, 1996. FDA has verified the applicant's claim that NDA 20–625 was approved on July 25, 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 677 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 9, 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 January 7, 1998, 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: June 30, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–18125 Filed 7–10–97; 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.

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: Radiological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on August 18, 1997, 9:30 a.m. to 4:30 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: John C. Monahan, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1212, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12526. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss general issues and make recommendations concerning an original premarket approval application for an ultrasound bone density device.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by August 11, 1997. Oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:45 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 11, 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 requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 7, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–18213 Filed 7–10–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Officer on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Area Health Education Centers (AHEC) and Health Education Training Centers (HETC): Managed Care Inventory Project—New—Section 746(a) of the Public Health Service Act authorizes Federal assistance to schools of medicine (allopathic and osteopathic) which have cooperative arrangements with one or more public or nonprofit private area health education centers (AHECs) for the planning, development and operation of area health education center programs. Section 746(f) of the PHS Act authorizes Federal assistance to schools of allopathic and osteopathic medicine, or parent institutions on behalf of such schools, or a consortium of such schools to plan, develop, establish, maintain or operate HETCs. The support is designed to improve the supply, distribution, quality, and efficiency of (a) personnel providing health services in the State of Florida or along the border between the United States and Mexico and (b) personnel providing, in other urban and rural areas of the U.S., health services to any population group, including Hispanic individuals and recent refugees, that have demonstrated serious health care needs. Program support is also used to encourage health promotion and disease prevention through public education.

A telephone survey is proposed of federally funded AHEC and HETC programs to determine the variety and