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

extent of managed care training activities that are ongoing or planned in the near future. The survey results will be used to formulate recommendations for managed care training, and to help guide the AHEC/HETCs in planning and directing training programs and clinical experience in managed care. The burden estimates are as follows:

Type of center	Number of respondents	Responses per respondent	Hours per response	Total burden hours
AHECs	36	1	2	72
HETCs	10	1	2	20
TOTAL	46	1	2	92

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Virginia Huth, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: July 7, 1997.

Jane Harrison,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. 97–18212 Filed 7–10–97; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health Proposed collection; Comment Request; Gila River Indian Community Demographic Information

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: *Title:* Gila River Indian Community Demographic Information. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This study will identify current residents of the Gila River Indian Community of Arizona, including place of residence, name and date of birth of each individual, familial relationships, degree of Indian blood and tribal heritage. The findings will facilitate current research into the causes of diabetes mellitus in Indians of the southwestern United States, particularly with respect to the genetic determinants of the disease. *Frequency of Response:* One-time collection. *Affected Public:* Individuals or households. *Type of Respondents:* Individuals, Parents, or Guardians. The annual reporting burden is as follows: *Estimated Number of Respondents:* 11,500; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* .25; and *Estimated Total Annual Burden Hours Requested:* 958. The annualized cost to respondents is estimated at: $9,583. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Richard M. Bryan, Administrative Officer, Phoenix Epidemiology & Clinical Research Branch, DIR, NIDDK, NIH, Building 1, 4212 North Sixteenth Street, Phoenix, AZ 85014, or call non-toll-free number (602) 200–5221 or E-mail your request, including your address to: mbryan@phx.niddk.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received by September 9, 1997.

Dated: July 2, 1997.

Clifford Moss, Jr.,

Executive Officer, NIDDK.

[FR Doc. 97–18150 Filed 7–10–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting of the National Heart, Lung, and Blood Advisory Council

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Heart, Lung, and Blood Advisory Council, September 4–5, 1997, National Institutes of Health, 9000 Rockville Pike, Building 31, Conference Room 10, Bethesda, Maryland.

The Council meeting will be open to the public on September 4 from 8:30 a.m. to approximately 12:00 p.m. for discussion of program policies and issues. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., section 10(d) of Public Law 92–463, the meeting will be closed to the public from approximately 1:00 p.m. on September 4 to adjournment on September 5, for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Executive Secretary in advance of the meeting.

Dr. Ronald G. Geller, Executive Secretary, National Heart, Lung, and Blood Advisory Council, Rockledge