SUMMARY: The Food and Drug Administration (FDA) is announcing that Eastman Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 1,4-cyclohexanedimethanol as a polyhydric alcohol for use in polyester resins intended for coatings in contact with food.

DATES: Written comments on the petitioner's environmental assessment by August 11, 1997.

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

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3086.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 7B4547) has been filed by the Eastman Chemical Co., P.O. Box 1994, Kingsport, TN 37662. The petition proposes to amend the food additive regulations in § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) to provide for the safe use of 1,4-cyclohexanedimethanol as a polyhydric alcohol for use in polyester resins intended for coatings in contact with food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before August 11, 1997, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: June 24, 1997.

Laura M. Tarantino,

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

[FR Doc. 97–18127 Filed 7–10–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96E–0386]

Determination of Regulatory Review Period for Purposes of Patent Extension; ALLEGRA™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ALLEGRA™ 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 ALLEGRA™ (fexofenadine hydrochloride). ALLEGRA™ is indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 12 years of age and older. Symptoms treated effectively include sneezing, rhinorrhea, itchy nose/palate/throat, itchy/watery/red eyes. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ALLEGRA™ (U.S. Patent No. 4,254,129) from Hoechst Marion Roussel, 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 March 7, 1997, FDA advised the Patent and Trademark office that this human drug product had undergone a regulatory review period and that the approval of ALLEGRA™ 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 ALLEGRA™ is 996 days. Of this time, 635 days occurred during the testing phase of the regulatory review period, while 361 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*: November 4, 1993.

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