calls, provided automated voice-response information to those callers, and provided 1.5 million pages of automated fax information. Information is provided in several levels of detail and complexity in order to reach a broad audience more effectively including the general public and health care professionals.

During August 1997, the Voice/Fax Information Service (VIS) will be converting to toll-free access for callers to ensure health and prevention information availability to all audiences. Callers will continue to be able to access information via voice-response and fax-on-demand. The new number for information via voice response is 1–888-CDC-FACTS (1–888–232–3228) and 1–888-CDC-FAXX (1–888–232–3299) for information via fax. In the future, CDC will be offering all of the information on health topics via TDD services for the hearing-impaired and several languages. In addition, much of this same information is available through the Internet on CDC's web site at: http://www.cdc.gov.

Dated: August 15, 1997.

Joseph R. Carter

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–22150 Filed 8–20–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Reallotment of Funds for FY 1996; Low Income Home Energy Assistance Program (LIHEAP)

AGENCY: Office of Community Services, ACF, DHHS.

ACTION: Notice of determination concerning funds available for reallotment.

SUMMARY: In accordance with section 2607(b) of the Low Income Home Energy Assistance Act (the Act), Title XXVI of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. 8621 *et seq.*), as amended, a notice was published in the **Federal Register** on May 21, 1997 (62 FR 27768) announcing the Secretary's preliminary determination that $457,022 in Fiscal Year 1996 Low Income Home Energy Assistance Program (LIHEAP) funds may be available for reallotment to other LIHEAP grantees.

We received comments from the Tanana Chiefs Conference, Inc., and the Association of Village Council Presidents (Alaska) requesting that they be permitted to retain the funds that were in excess of the 10 per cent carryover, and thus, subject to reallotment.

Also under section 2607(b) of the Act, grantees are required to obligate funds available by the end of the fiscal year in which they are appropriated and may carry over no more than 10 per cent of funds available for obligation in the following fiscal year. We are not able to allow grantees to retain funds that were not obligated in a timely fashion and that exceed the 10 per cent carryover limit. HHS does not have the authority to waive the requirements of the Act regarding the reallotment of LIHEAP funds.

The Tanana Chiefs Conference, Inc., also informed HHS that it had $98,572 in funds for reallotment instead of $21,184 as originally reported.

In accordance with the requirements of section 2607(2)(C), a revised total of $534,410 will be reallotted to most current LIHEAP grantees based upon the allocation formula contained in section 2604 of the Act and under the terms of applicable State/Tribe agreements, except that HHS will not issue grants under $25 because the cost of issuing the grant for that amount is greater than the amount of the grant. These reallotted funds are being distributed by statutory formula to States, Indian Tribes and Tribal organizations, and insular areas that are currently grantees under the LIHEAP program for FY 1997. No other entities may apply for or receive the funds from HHS.

The reallotted funds must be treated by LIHEAP grantees receiving them as an amount appropriated for FY 1997. As FY 1997 funds, they will be subject to all of the requirements of the Act, including section 2607(b)(2), which requires that a grantee must obligate its total block grant allocation for a fiscal year by the end of the fiscal year for which the funds are appropriated, that is, by September 30, 1997.

FOR FURTHER INFORMATION CONTACT: Janet Fox, Director, Division of Energy Assistance, Office of Community Services, Administration for Children and Families, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447; telephone (202) 401–9351.

Dated: August 15, 1997.

Donald Sykes,

Director, Office of Community Services.

[FR Doc. 97–22177 Filed 8–20–97; 8:45 am]

BILLING CODE 4184–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F–0339]

Eastman Chemical Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 expanded safe use of 2,2-dimethyl-1,3-propanediol as a polyhydric alcohol for use only in forming polyester resins for coatings to include contact with alcoholic foods.

DATES: Written comments on the petitioner's environmental assessment by September 22, 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: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

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 7B4552) has been filed by Eastman Chemical Co., P.O. Box 431, 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 expanded safe use of 2,2-dimethyl-1,3-propanediol as a polyhydric alcohol for use only in forming polyester resins for coatings to include contact with alcoholic foods.

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 September 22, 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: July 31, 1997.

Alan M. Rulis,

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

[FR Doc. 97–22265 Filed 8–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96E–0272]

Determination of Regulatory Review Period for Purposes of Patent Extension; INTEGRA® Artificial Skin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for INTEGRA® Artificial Skin 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 medical device.

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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device INTEGRA® Artificial Skin. INTEGRA® Artificial Skin is indicated for the post-excisional treatment of life-threatening full-thickness or deep partial-thickness thermal injury where sufficient autograft is not available at the time of excision or not desirable due to the physiological condition of the patient. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for INTEGRA® Artificial Skin (U.S. Patent No. 4,947,840) from the Massachusetts Institute of Technology, 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 12, 1997, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of INTEGRA® Artificial Skin represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office represented that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for INTEGRA® Artificial Skin is 4,477 days. Of this time, 3,173 days occurred during the testing phase of the regulatory review period, while 1,304 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: November 30, 1983. FDA has verified the applicant's claim that the date the investigational device exemption (IDE), required under section 520(g)of the Federal Food, Drug, and Cosmetic Act, for human tests to begin became effective on November 30, 1983.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e)*: August 6, 1992. The applicant claims May 4, 1990, as the date the premarket approval application (PMA) for INTEGRA® Artificial Skin (PMA P900033) was initially submitted. However, FDA records indicate that the PMA P900033, which was mailed May 4, 1990, was received by FDA on May 7, 1990. However, FDA notified the applicant that the PMA contained insufficient information for filing on June 22, 1990. After a number of additional documents were submitted to the PMA, the PMA was ultimately filed based on a document received August 6, 1992, which is considered the initially submitted date for the PMA.

3. *The date the application was approved*: March 1, 1996. FDA has verified the applicant's claim that PMA P900033 was approved on March 1, 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 923 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 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 February 17, 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