requirements found in 36 CFR 800.5e (When the effect is adverse). In compliance with these requirements, GSA will: notify the Advisory Council on Historic Preservation (Council); consult with the SHPO and involve interested persons as participating consulting parties; document the finding of Adverse Effect according to 36 CFR 800.8; inform the public of the finding of Adverse Effect; and execute a Memorandum of Agreement (MOA) with the SHPO specifying how the effects will be taken into account. The MOA is expected to provide an agreement on ways in which GSA will minimize or mitigate these adverse impacts.

VII. Environmental Planning Process

The Scoping process including the publication of the Notice of Intent in the **Federal Register** on October 25, 1995 followed by a series of scoping meetings held to identify issues of concern to the community and government agencies. A public scoping meeting was held on November 7, 1995 at the Naval Surface Warfare Center in White Oak, and an agency scoping meeting was held on November 21, 1995.

The National Environmental Policy Act of 1969 (NEPA), as amended, requires that the public and affected agencies be provided the opportunity to review and comment on the Environmental Impact Statement (EIS). A 75-day review period of the draft EIS, commenced on March 15, 1996 and concluded on May 31, 1996 in order to comply with these requirements. During this period, a public hearing was held on April 16, 1996 at the Naval Surface Warfare Center at the site of the Proposed Action to receive comments from the public.

A Final Environmental Impact Statement was prepared to address comments made on the Draft EIS, and was filed with the U.S. EPA on May 2, 1997. The Final EIS was also made available to the public and affected agencies for an additional 30-day review period (May 2, 1997 through June 2, 1997). Comments on the Final EIS were taken into consideration by GSA and FDA in the preparation of this Record of Decision.

GSA believes that there are no other outstanding environmental issues to be resolved with respect to the proposed construction on the White Oak site with approximately 2,111,421 gsf of offices laboratories and support facilities, and 4,500 parking spaces for approximately 5,947 employees and 500 visitors per day. The mitigation program for the development of the White Oak site will be developed during the design phase. Mitigation measures will be developed from those recommended in the Final EIS or other state-of-the-art practices. Questions regarding the EIS prepared for this action should be directed to Mr. Jag Bhargava, P.E., Development Director, General Services Administration National Capital Region, Room 2120, 7th and D Streets, SW, Washington, DC 20407, telephone 202–708–6570.

Dated: June 26, 1997.

Nelson Alcalde,

Regional Administrator, General Services Administration.

[FR Doc. 97–18135 Filed 7–10–97; 8:45 am]

BILLING CODE 6820–23–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F–0283]

Akzo Nobel Chemical Co.; Filing of a Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Akzo Nobel Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of monoester of α-hydro-ω-hydroxy-poly(oxyethylene) poly(oxypropylene) poly(oxyethylene) (15 mole minimum) blocked copolymer derived from low erucic acid rapeseed oil as a component of defoaming agents used in the washing of sugar beets for processing into sugar.

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: Vivian M. Gilliam, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3167.

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 6A4494) has been filed by Akzo Nobel Chemical Co., 5 Livingstone Ave., Dobbs Ferry, NY 10522–3407. The petition proposes to amend the food additive regulations in § 173.340 *Defoaming agents* (21 CFR 173.340) to provide for the safe use of monoester of α-hydro-ω-hydroxy-poly (oxyethylene) poly(oxypropylene) poly(oxyethylene) blocked copolymer derived from low erucic acid rapeseed oil as a component of defoaming agents used in the washing of sugar beets for processing into sugar.

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 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 13, 1997.

Alan M. Rulis,

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

[FR Doc. 97–18126 Filed 7–10–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F–0284]

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 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.