

colorant for all polymers intended for use in contact with food.

**DATES:** Written comments on the petitioner's environmental assessment by September 26, 1996.

**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:** John R. Bryce, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3023.

**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 6B4493) has been filed by Hoechst Celanese Corp., 500 Washington St., Coventry, RI 02816. The petition proposes to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the expanded safe use of 4-chloro-2-[[5-hydroxy-3-methyl-1-(3-sulfophenyl)-1H-pyrazol-4-yl]azo]-5-methylbenzenesulfonic acid, calcium salt (1:1) (C.I. Pigment Yellow 191) as a colorant for all polymers intended for use 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 September 26, 1996, 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: August 19, 1996.

Alan M. Rulis,

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

[FR Doc. 96-21850 Filed 8-26-96; 8:45 am]

BILLING CODE 4160-01-F

**[Docket No. 96F-0176]**

**Indirect Food Additives: Polymers  
Toray Industries (America) Inc.; Filing  
of Food Additive Petition**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Toray Industries (America) Inc., has filed a food additive petition proposing that the food additive regulations be amended to provide for the safe use of Nylon 6/12 copolymers for use as a non-food contact layer of laminated articles intended for use with food.

**DATES:** Written comments on the petitioner's environmental assessment by September 26, 1996.

**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:** Elke Jensen, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3109.

**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 6B4505) has been filed by Toray Industries (America) Inc., c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in Part 177 Indirect Food Additives: Polymers (21 CFR part 177) to provide for the safe use of Nylon 6/12 copolymers for use as a non-food contact layer of laminated articles intended for use 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 September 26, 1996, 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: May 24, 1996.

Alan M. Rulis,

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

[FR Doc. 96-21847 Filed 8-26-96; 8:45 am]

BILLING CODE 4160-01-F

**[Docket No. 96F-0293]**

**Zeneca Inc.; Filing of Food Additive  
Petition**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Zeneca Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 2-methyl-4,5-trimethylene-4-isothiazolin-3-one as a preservative for paper and paperboard coatings used in contact with food.

**DATES:** Written comments on the petitioner's environmental assessment by September 26, 1996.

**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-216), 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 6B4516) has been filed by Zeneca Inc., Foulkstone 1405, 2d, 1800 Concord Pike, Wilmington, DE 19850-5457. The petition proposes to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of 2-methyl-4,5-trimethylene-4-isothiazolin-3-one as a preservative for paper and paperboard coatings used 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 September 26, 1996, 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: August 8, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval,  
Center for Food Safety and Applied Nutrition.  
[FR Doc. 96-21845 Filed 8-26-96; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 96E-0099]

# **Determination of Regulatory Review Period for Purposes of Patent Extension; CEDAX® Oral Suspension**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for CEDAX® Oral Suspension 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 CEDAX® Oral Suspension (ceftibuten dihydrate). CEDAX® Oral Suspension is indicated for the treatment of individuals with mild-to-moderate infections caused by susceptible strains of the designated microorganisms in the specific conditions: Acute Bacterial Exacerbations of Chronic Bronchitis due to *Haemophilus influenzae* (including B-lactamase-producing strains), *Moraxella catarrhalis* (including B-lactamase producing strains) or *Streptococcus pneumoniae* (penicillin-susceptible strains only), Acute Bacterial Otitis Media due to *Haemophilus influenzae* (including B-lactamase producing strains), *Moraxella catarrhalis* (including B-lactamase producing strains) or *Streptococcus pyogenes*, or Pharyngitis and Tonsillitis due to *Streptococcus pyogenes*. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CEDAX® Oral Suspension (U.S. Patent No. 4,634,697) from Schering-Plough Corp. and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 10, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of CEDAX® Oral Suspension 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 CEDAX® Oral Suspension is 2,641 days. Of this time, 1,179 days occurred during the testing phase of the regulatory review period, while 1,462 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:* September 28, 1988. The applicant claims September 29, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 28, 1988, which was 30 days after FDA receipt of the IND.