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 biologic product, Allergen Patch Test (Thin-layer Rapid Use Epicutaneous (T.R.U.E.) Test™) (multiple allergen test). T.R.U.E. Test™ is indicated primarily as an aid in the diagnosis of allergic dermatitis in patients whose histories suggest sensitivity to one or more of substances included on the T.R.U.E. Test™ panels. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for T.R.U.E. Test™ (U.S. Patent No. 4,836,217) from Pharmacia AB, and the Patent and Trademark Office requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated June 21, 1995, FDA advised the Patent and Trademark Office that this human biologic product had undergone a regulatory review period and that the approval of T.R.U.E. Test™ 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 T.R.U.E. Test™ is 2,966 days. Of this time, 1,601 days occurred during the testing phase of the regulatory review period, while 1,365 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 became effective*: October 10, 1986. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was on October 10, 1986.

2. *The date application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act*: February 26, 1991. The applicant claims July 16, 1986, as the date the product license application (PLA) for T.R.U.E. Test™ (PLA 91–0118) was initially submitted. However, FDA records indicate that the two-panel test kit for the product that was ultimately approved was submitted on February 26, 1991. Therefore, the PLA was submitted on February 26, 1991.

3. *The date the application was approved*: November 21, 1994. FDA has verified the applicant's claim that PLA 91–0118 was approved on November 21, 1994.

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, the applicant seeks 898 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 2, 1995, 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 30, 1996, 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: July 26, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95–19060 Filed 8–2–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95F–0187]

Ciba-Geigy Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba-Geigy Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of poly[[6-[(1,1,3,3-tetramethylbutyl)amino]-s-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidyl)imino] hexamethylene [(2,2,6,6-tetramethyl-4-piperidyl)imino]] as a light stabilizer in polymers used as an indirect food additive.

DATES: Written comments on the petitioner's environmental assessment by September 5, 1995.

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

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3091.

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 5B4467) has been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of poly[[6-[(1,1,3,3-tetramethylbutyl)amino]-s-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidyl)imino] hexamethylene [(2,2,6,6-tetramethyl-4-piperidyl)imino]] as a light stabilizer in polymers used as an indirect food additive.

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