

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01E-0029] 9853 '01 SEP 20 AM 11:12

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Determination of Regulatory Review Period for Purposes of Patent Extension; Trileptal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Trileptal 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 that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov.dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT:

Claudia Grillo,
Office of Regulatory Policy (HFD-007),
Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857,
301-594-5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 Trileptal (oxcarbazepine). Trileptal is indicated for use as monotherapy or adjunctive therapy in the treatment of partial seizures in adults with epilepsy, and as adjunctive therapy in the treatment of partial seizures in children ages 4 through 16 with epilepsy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Trileptal (U.S. Patent No. 4,559,174) from Novartis, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 11, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Trileptal 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 Trileptal is 2,523 days. Of this time, 2,046 days occurred during the testing phase of the regulatory review period, while 477 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 (the act) (21 U.S.C. 355(i)) became effective: February 18, 1993. The applicant claims

February 4, 1992, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was February 18, 1993, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the act: September 25, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for Trileptal (NDA 21-014) was initially submitted on September 25, 1998.

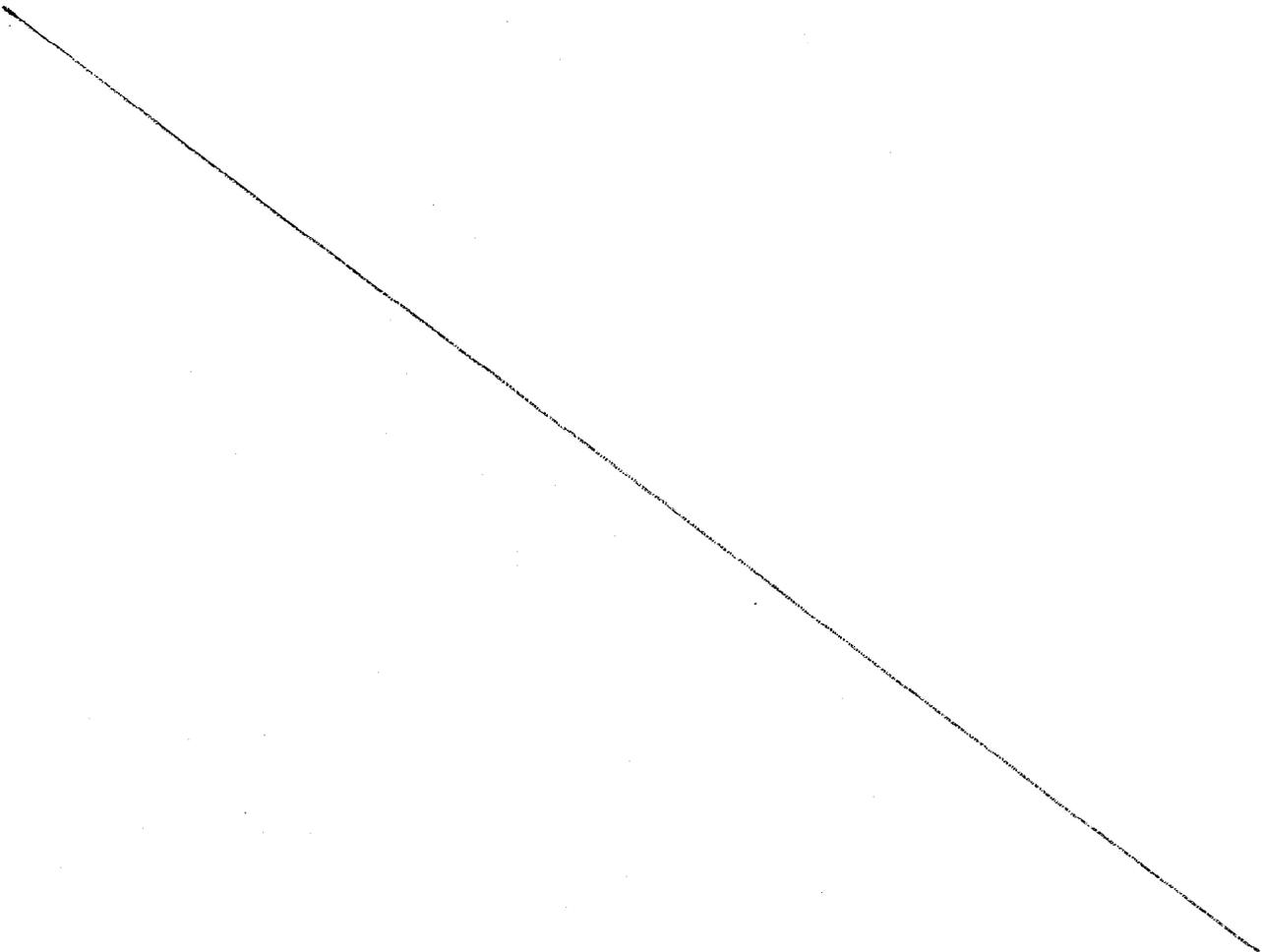
3. The date the application was approved: January 14, 2000. FDA has verified the applicant's claim that NDA 21-014 was approved on January 14, 2000.

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 1,690 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written or electronic comments and ask for a redetermination, by [insert date 60 days after date of publication in the FEDERAL REGISTER]. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence

during the regulatory review period, by [insert date 180 days after date of publication in the FEDERAL REGISTER]. 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. Three copies of any information 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.
Comments and petitions may be seen in the Dockets Management
Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 5, 2001.
September 5, 2001.

Jane A. Axelrad

Jane A. Axelrad,
Associate Director for Policy,
Center for Drug Evaluation and Research.

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

Regina Sedeno