

and Cosmetic Act (21 U.S.C. 355(i)) became effective: July 18, 1990. The applicant claims June 18, 1990, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 18, 1990, which was 30 days after FDA receipt of the IND.

2. *The date the human drug was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* August 27, 1993. FDA has verified the applicant's claim that the new drug application (NDA) for NAVELBINE® Injection (NDA 20-388) was initially submitted on August 27, 1993.

3. *The date the application was approved:* December 23, 1994. FDA has verified the applicant's claim that NDA 20-388 was approved on December 23, 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, this applicant seeks 1,067 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 18, 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 15, 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: June 30, 1995.

Stuart L. Nightingale,
Associate Commissioner for Health Affairs.
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BILLING CODE 4160-01-F

[Docket No. 95E-0075]

Determination of Regulatory Review Period for Purposes of Patent Extension; LAMICTAL®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LAMICTAL® 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, rm. 1-23, 12420 Parklawn Dr., 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 LAMICTAL® (lamotrigine). LAMICTAL® is indicated as adjunctive therapy in the treatment of partial seizures in adults with epilepsy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for LAMICTAL® (U.S. Patent No. 4,602,017) from Burroughs Wellcome Co., 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 12, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of LAMICTAL® 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 LAMICTAL® is 3,703 days. Of this time, 2,693 days occurred during the testing phase of the regulatory review period, while 1,010 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 8, 1984. The applicant claims March 14, 1984, as the date the investigational new drug application (IND) for LAMICTAL® (IND 23,793) was submitted. However, FDA records indicate that IND 23,793 was placed on clinical hold on April 12, 1984, and removed from hold by a letter dated November 8, 1984, which is the IND effective date.

2. *The date the human drug was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* March 23, 1992. The applicant claims March 20, 1992, as the date the new drug application (NDA) for LAMICTAL® (NDA 20-241) was initially submitted. However, FDA records indicate that NDA 20-241 was submitted on March 23, 1992.

3. *The date the application was approved:* December 27, 1994. FDA has verified the applicant's claim that NDA 20-241 was approved on December 27, 1994.

This determination of the regulatory review period establishes the maximum potential length of a patent extension.