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Display Date	12-16-98
Publication Date	12-17-98
Certifier	J. Williams

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E-0849]

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

AGENCY : Food and Drug Administration, HHS.

ACTION : Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Vitreon® 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 medical device .

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Brian J. Malkin,
Office of Health Affairs (HFY-20),
Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857,
301-827-6620.

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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g) (3) (B) .

FDA recently approved for marketing the medical device Vitreon®. Vitreon® is indicated for use as an intraoperative surgical aid during vitreoretinal surgery in patients with primary and recurrent complicated retinal detachments. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Vitreon® (U.S. Patent No. 4,490,351) from Vitrophage, 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 October 29, 1998, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Vitreon® 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 Vitreon® is 2,729 days. Of this time, 603 days occurred during the testing phase of the regulatory review period, while 2,126 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation involving this device was begun: April 13, 1990. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21

U.S. c. 360j (g)) for human tests to begin became effective on November 10, 1989. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on April 13, 1990, which represents the IDE effective date.

2. The date the application was initially Submitted with respect to the device under section 515 of the act (21 U.S.C. 360e): December 6, 1991. FDA has verified the applicant's claim that the premarket approval application (PMA) for Vitreon® (PMA P910068) was initially submitted December 6, 1991.

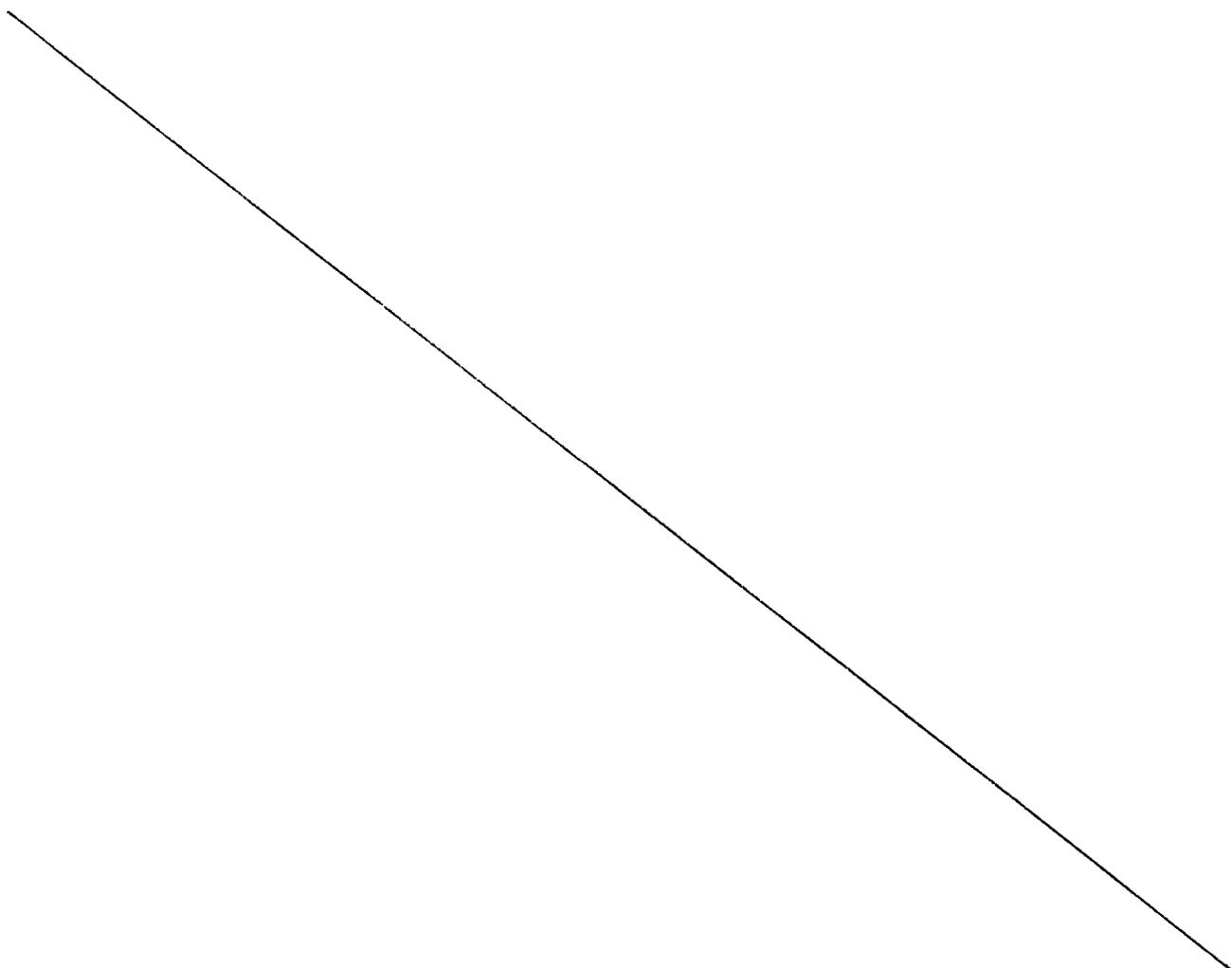
3. The date the application was approved: September 30, 1997. FDA has verified the applicant's claim that PMA P910068 was approved on September 30, 1997.

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 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before (insert date 60 days after date of publication in the FEDERAL REGISTER), 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 (insert date 180 days after date of publication in the FEDERAL REGISTER), 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: December 4, 1998.
December 4, 1998

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Thomas J. McGinnis
Thomas J. McGinnis,
Deputy Associate Commissioner
for Health Affairs

Jen Windsor