

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 February 16, 1999, 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 July 15, 1999, 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.

**Thomas J. McGinnis,**

*Deputy Associate Commissioner for Health Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on January 12, 1999, 8 a.m. to 4:30 p.m.

*Location:* Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

*Contact Person:* Sara M. Thornton, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12396. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for intrastromal corneal ring segments for the correction of myopia from -1.00 to -3.50 diopters in patients having 1.0 diopter or less of astigmatism.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 8, 1999. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9 a.m. on January 12, 1999. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 8, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 8, 1998.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

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