

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02E-0150]

Determination of Regulatory Review Period for Purposes of Patent Extension; GYNECARE INTERGEL

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for GYNECARE INTERGEL 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

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:

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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 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 Director 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 GYNECARE INTERGEL. GYNECARE INTERGEL is indicated for use in patients undergoing open, conservative gynecologic surgery as an adjunct to good surgical technique to reduce postsurgical adhesions. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for GYNECARE INTERGEL (U.S. Patent No. 5,532,221) from Lifecore Medical, 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 31, 2001, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of GYNECARE INTERGEL represented the first permitted commercial marketing or use of the product. 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 GYNECARE INTERGEL is 2,438 days. Of this time, 1,453 days occurred during the testing phase of the regulatory review period, while 985 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: March 17, 1995. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and

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Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective March 17, 1995.

2. The date an application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e): March 8, 1999. The applicant claims March 5, 1999, as the date the premarket approval application (PMA) FOR GYNECARE INTERGEL (PMA P990015) was initially submitted. However, FDA records indicate that PMA P990015 was submitted on March 8, 1999.

3. The date the application was approved: November 16, 2001. FDA has verified the applicant's claim that PMA P990015 was approved on November 16, 2001.

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 867 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see ADDRESSES) 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: \_\_\_\_\_.

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