

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002E-0344] (formerly Docket No. 02E-0344)

Determination of Regulatory Review Period for Purposes of Patent  
Extension; ATS Open Pivot Bileaf Heart Valve

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ATS Open Pivot Bileaf Heart Valve 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 Division of Dockets Management (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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DDM	7-26-0
Display Date	7-26-0
Publication Date	7-27-0
Certifier	N. Hawley

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 approved for marketing the medical device ATS Open Pivot Bileaf Heart Valve. ATS Open Pivot Bileaf Heart Valve is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic or mitral valves. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ATS Open Pivot Bileaf Heart Valve (U.S. Patent No. 5,354,330) from ATS 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 December 30, 2002, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of ATS Open Pivot Bileaf Heart Valve 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 ATS Open Pivot Bileaf Heart Valve is 1,418 days. Of this time, 980 days occurred during the testing phase of the regulatory review period, while 438 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act involving this device became effective: November 27, 1996. 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 Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective November 27, 1996.

2. The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e): August 3, 1999. FDA has verified the applicant's claim that the premarket approval application (PMA) for ATS Open Pivot Bileaf Heart Valve (PMA P990046) was initially submitted August 3, 1999.

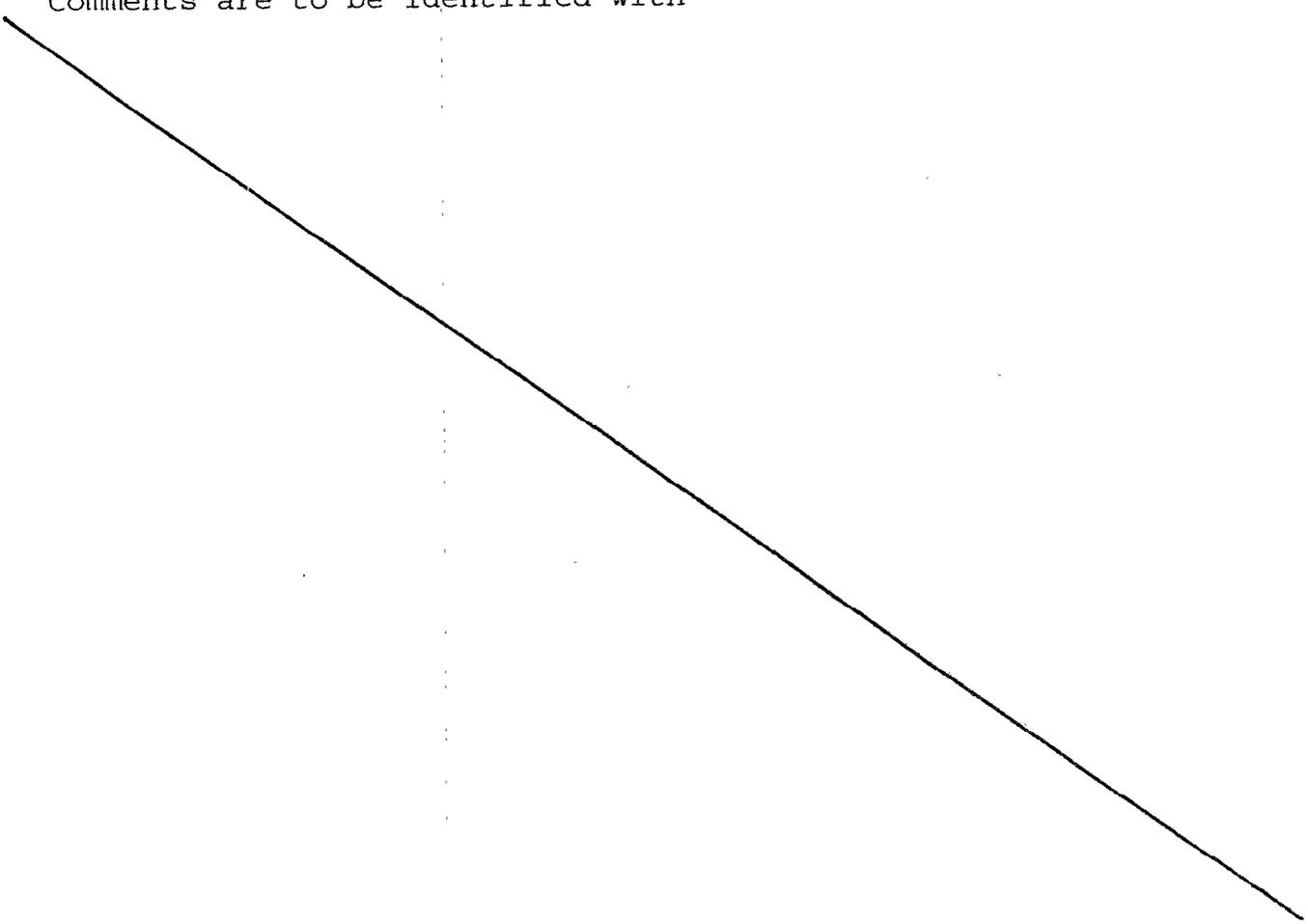
3. The date the application was approved: October 13, 2000. FDA has verified the applicant's claim that PMA P990046 was approved on October 13, 2000.

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 505 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (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 Division of Dockets Management. Three copies of any mailed 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 29, 2005  
June 29, 2005.

Jane A. Axelrad

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[FR Doc. 05-????? Filed ??-??-05; 8:45 am]  
BILLING CODE 4160-01-S

