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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E-0754]

Determination of Regulatory Review Period for Purposes of Patent  
Extension; Omnicef® Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Omnicef® Tablets 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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## FOR FURTHER INFORMATION CONTACT:

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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 Omnicef® Tablets (cefdinir). Omnicef® Tablets is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of specific microorganisms in specified conditions. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Omnicef® Tablets (U.S. Patent No. 4,559,334) from Warner-Lambert 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 December 14, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the

approval of Omnicef® Tablets 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 Omnicef® Tablets is 2,745 days. Of this time, 2,288 days occurred during the testing phase of the regulatory review period, while 457 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective: June 1, 1990. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 1, 1990.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the act: September 4, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Omnicef® Tablets (NDA 50-739) was initially submitted on September 4, 1996.

3. The date the application was approved: December 4, 1997. FDA has verified the applicant's claim that NDA 50-739 was approved on December 4, 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 1,601 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: 5/4/99.  
May 4, 1999

*Thomas J. McGinnis*

Thomas J. McGinnis,  
Deputy Associate Commissioner  
for Health Affairs

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