

Display Date	<u>2-1-00</u>
Publication Date	<u>2-2-00</u>
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99E-0116]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Rotashield® 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 biological product.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Claudia V. Grillo,
Regulatory Policy Staff (HFD-7),
Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857,
301-594-5645.

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 human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biological product Rotashield®. Rotashield® is indicated for immunization of infants at 2, 4, and 6 months of age. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Rotashield® (U.S. Patent No. 4,704,275) from American Home Products Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 16, 1999, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of Rotashield® 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 Rotashield® is 3,804 days. Of this time, 3,226 days occurred during the testing phase of the regulatory review period; while 578 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective: April 3, 1988. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 3, 1988.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: January 31, 1997. FDA has verified the applicant's claim that the product license application (PLA) for Rotashield® (PLA 97-0111) was initially submitted on January 31, 1997.

3. The date the application was approved: August 31, 1998. FDA has verified the applicant's claim that PLA 97-0111 was approved on August 31, 1998.

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 23, 1999
December 23, 1999.

Jane A. Axelrad

Jane A. Axelrad

Associate Director for Policy
Center for Drug Evaluation and Research

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL.

Michael W. Bell