

JUL 24 1998



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
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Washington, D.C. 20231

James A. Poulos, III  
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WASHINGTON DC 20005-2477

Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,863,908

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,863,908, which claims a method of use of the human drug product MONUROL™ (fosfomycin tromethamine), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,527 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,527 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of July 18, 1997 (62 Fed. Reg. 38566). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,428) + 813 \\ &= 1,527 \text{ days} \end{aligned}$$

Since the regulatory review period began November 2, 1990, after the patent issue date (September 5, 1989), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The limitations of 35 U.S.C. § 156(c)(3) and 35 U.S.C. § 156 (g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,863,908
Granted:	September 5, 1989
Original Expiration Date <sup>1</sup> :	February 23, 2005
Applicant:	Dario Chiarino et al.

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<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).

Owner of Record: Zambon, S.p.A.

Title: Mono(2-Ammonium-2-Hydroxymethyl-1,3 Propanediol)(2R-Cis)-3-Methyloxiranyl Phosphonate, Its Preparation and Pharmaceutical Compositions Containing It

Classification: 514/76

Product Trade Name: MONUROL™ (fosfomicin tromethamine)

Term Extended: 1,527 days

Expiration Date of Extension: April 30, 2009

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents  
Box Patent Ext.  
Washington, D.C. 20231

By FAX: (703) 308-6916  
Attn: Special Program Law Office

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

  
Karin Tyson  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

RE: MONUROL™  
FDA Docket No.: 97E-0110