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MAR 20 1997

Randy Walker Duke, Ph.D., Director
Regulatory Affairs/ New Products, New Claims
Rhone Merieux, Inc.
115 Transtech Drive
Athens, GA 30601

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,514,390

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,514,390, which claims the animal drug IMMITICIDE® Sterile Powder (Melarsomine dihydrochloride), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,632 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of March 18, 1996, 61 Fed. Reg. 11054. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2037) + 613 \\ &= 1,632 \text{ days (4.47 years)}\end{aligned}$$

Since the regulatory review period began April 20, 1988, after the patent issue date (April 30, 1985), 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.

Neither the five year limitation of 35 U.S.C. § 156(g)(6)(A) or the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

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 1,632 days.

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

U.S. Patent No.: 4,514,390

Granted:	April 30, 1985
Original Expiration Date:	April 30, 2002
Applicant:	Ernst A. H. Friedheim
Owner of Record:	The Rockefeller University
Title:	Melaminylthioarsenites
Classification:	514/184
Product Trade Name:	IMMITICIDE® Sterile Powder (Melarsomine dihydrochloride)
Term Extended:	1,632 days
Expiration Date of Extension:	October 18, 2006

Any correspondence from applicant 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

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

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



Hiram H. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

(703) 305-9285

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: IMMITICIDE® Sterile Powder
(Melarsomine dihydrochloride)
FDA Docket No.: 95E- 0364