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Washington, D.C. 20231

MAY - 5 1998

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WARNER-LAMBERT COMPANY  
2800 Plymouth Road  
Ann Arbor, MI 48105

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,260,769

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,260,769, which claims the human drug product CEREBYX® (fosphenytoin sodium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be five years.

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 five years.

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 March 20, 1997 (62 Fed. Reg. 13387). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (3,218) + 530 \\ &= 2,139 \text{ days (5.86 years)}\end{aligned}$$

Since the regulatory review period began May 4, 1986, after the patent issue date (April 7, 1981), 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 five year limitation of 35 U.S.C. § 156(g)(6)(B) applies in the present situation because the patent was issued before the date of enactment (September 24, 1984) of 35 U.S.C. § 156, but no action described in 35 U.S.C. § 156(g)(6)(B) was taken before the date of enactment (the date that the request for exemption became effective was May 4, 1986). Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(B), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does 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:

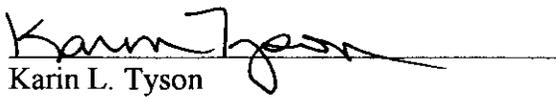
U.S. Patent No.:	4,260,769
Granted:	April 7, 1981
Original Expiration Date:	April 7, 1998
Applicant:	Valenino J. Stella et al.
Owner of Record:	Merck & Co., Inc.
Title:	5,5-Diphenylhydantoins
Classification:	548/112
Product Trade Name:	CEREBYX® (fosphenytoin sodium)
Term Extended:	Five years

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 L. 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: CEREBYX®  
FDA Docket No.: 96E-0442