



Mailed: June 21, 2004

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New Brunswick NJ 08933-7003

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,513,006

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,513,006, which claims the human drug product TOPAMAX® (topiramate), 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 Director will issue a certificate of extension, under seal, for a period of five years.

If the patent term extension were calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of March 19, 2003 (68 Fed. Reg. 13315), the period of extension:

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2984 - 0) + 860 \\ &= 2,352 \text{ days (6.4 years)} \end{aligned}$$

Since the regulatory review period began June 18, 1986, after the patent issued (April 23, 1985), the entire regulatory review period is considered in the above determination of the length of the extension period according to 35 U.S.C. § 156(c). 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)(A) applies in the present situation, however, because the patent was issued after the date of enactment of 35 U.S.C. § 156. 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)(A), 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.: 4,513,006  
Granted: April 23, 1985

Original Expiration Date <sup>1</sup> :	September 26, 2003 <sup>2</sup>
Applicant:	Bruce E. Maryanoff, et al.
Owner of Record:	McNeil Lab, Inc.
Title:	Anticonvulsant Sulfamate Derivatives
Classification:	514/23
Product Trade Name:	TOPAMAX® (topiramate)
Term Extended:	5 years
Expiration Date	September 26, 2008

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

By mail:      Mail Stop Patent Ext.  
                  United States Patent and Trademark Office  
                  P.O. Box 1450  
                  Alexandria, VA 22313-1450

By fax:        By FAX:        (703) 872-9411  
                  Attn: Office of Patent Legal Administration

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

/s/

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Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc:      Office of Regulatory Policy  
          HFD - 13  
          5600 Fishers Lane  
          Rockville, MD 20857

RE: TOPAMAX® (topiramate)  
FDA Docket No.: 98E-1217

Attention: Claudia Grillo

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

<sup>2</sup>This patent has been extended under 35 U.S.C. 156(e)(2) for a period of one year.