



Mailed: August 13, 2003

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Re: Patent Term Extension
Application for
U.S. Patent No. 4,943,639

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,943,639, which claims the human drug product KEPPRA® (levetiracetam), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,157 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 Director will issue a certificate of extension, under seal, for a period of 1,157 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 January 25, 2002 (67 Fed. Reg. 3725). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,707 - 0) + 303 \\ &= 1,157 \text{ days} \end{aligned}$$

Since the regulatory review period began June 1, 1994, after the patent issue date (July 24, 1990), 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 14 year exception of 35 U.S.C. § 156(c)(3) nor the limitations of 35 U.S.C. § 156(g)(6) operate to 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.: 4,943,639

Granted: July 24, 1990

Original Expiration Date¹: June 6, 2006
Applicant: Jean Gobert, et al.
Owner of Record: UCB SOCIETE ANONYME
Title: (S)-Alpha-Ethyl-2-Oxo-1-Pyrrolidineacetamide
Classification: 548/550
Product Trade Name: KEPPRA® (levetiracetam)
Term Extended: 1,157 days
Expiration Date of Extension: August 6, 2009

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

By mail: Commissioner for Patents
Mail Stop Patent Ext.
P.O. Box 1450
Alexandria, VA 22313-1450
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/ _____
Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read RE: KEPPRA® (levetiracetam)
Acting Director Health Assessment Policy Staff, CDER FDA Docket No.: 00E-1346
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

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

