



AUG 18 2003

Rec'd 9/4/03 j/b

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Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,565,447

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,565,447, which claims the human drug product AXERT® (almotriptan malate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 569 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 569 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 16, 2002 (67 Fed. Reg. 46682). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (843 - 0) + 505 \\ &= 927 \text{ days} \end{aligned}$$

Since the regulatory review period began August 30, 1997, after the patent issue date (October 15, 1996), 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.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 927 days, would extend the patent from October 15, 2013 (35 U.S.C. § 154) to April 29, 2016, which is beyond the 14-year limit (the approval date is May 7, 2001, thus the 14 year limit is May 7, 2015). The period of extension is thus limited to May 7, 2015, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, October 15, 2013, to and including May 7, 2015, or 569 days.

The limitations of 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.: 5,565,447  
Granted: October 15, 1996

02E-0019

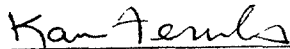
CEP 1

Original Expiration Date<sup>1</sup>: October 15, 2013  
Applicant: Dolors F. Fornier, et al.  
Owner of Record: ALMIRALL PRODEFARMA, S.A.  
Title: Indole Derivatives  
Classification: 514/212  
Product Trade Name: AXERT® (almotriptan malate)  
Term Extended: 569 days  
Expiration Date of Extension: May 7, 2015

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.



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  
Acting Director Health Assessment Policy Staff, CDER  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852  
RE: AXERT (almotriptan malate)  
FDA Docket No.: 02E-0019

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