

Mailed: Nov. 6, 2003

Charles Van Horn  
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1300 I Street NW  
Washington DC 20005-3315

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,798,827

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,798,827, which claims the human drug product SYNERCID® (quinupristin and dalfopristin)(New Drug Application No. 50-748), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,770 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 1,770 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 September 21, 2001 (66 Fed. Reg. 48690)(corrected October 17, 2001 (66 Fed. Reg. 52774)). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,046) + 747 \\ &= 1,770 \text{ days}\end{aligned}$$

Since the regulatory review period began January 30, 1992, after the patent issue date (January 17, 1989), 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 limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) 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.	:	4,798,827
Granted	:	January 17, 1989

Original Expiration Date : May 21, 2007  
Applicant : Jean-Claude Barriere, et al.  
Owner of Record : AVENTIS PHARMA S.A.<sup>1</sup>  
Title : Synergistin Derivatives and Pharmaceutical  
Compositions Which Contain Them  
Classification : 514/183  
Product Trade Name : SYNERCID® (quinupristin and dalfopristin)  
(New Drug Application No. 50-748)  
Term Extended : 1,770 days  
Expiration Date of Extension : March 25, 2012

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

By mail: Commissioner for Patents                      By FAX:        (703) 872-9411  
          Mail Stop Patent Ext.                              Attn: Office of Patent Legal Administration  
          P.O. Box 1450  
          Alexandria, VA 22313-1450

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: SYNERCID®  
          Acting Director Health Assessment Policy Staff, CDER    FDA Docket No.: 00E-1250  
          Food and Drug Administration  
          1451 Rockville Pike, HFD-7

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<sup>1</sup>A change of name was recorded at Reel 11641, Frame 0962

Rockville, MD 20852