

Mailed: Nov. 6, 2003

Charles Van Horn
Finnegan Henderson Farabow Garrett & Dunner, LLP
1300 I Street NW
Washington DC 20005-3315

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,668,669

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,668,669, which claims the human drug product SYNERCID® (quinupristin and dalfopristin)(New Drug Application No. 50-747), and a method of use of SYNERCID®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,333 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 1,333 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of September 21, 2001 (66 Fed. Reg. 48688). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,172) + 747 \\ &= 1,333 \text{ days}\end{aligned}$$

Since the regulatory review period began June 22, 1994, after the patent issue date (May 26, 1987), 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.	:	4,668,669
Granted	:	May 26, 1987

Original Expiration Date : January 10, 2006
Applicant : Jean-Claude Barriere, et al.
Owner of Record : AVENTIS PHARMA S.A. ¹
Title : Pristinamycin II_B Derivatives and
Compositions Containing Them
Classification : 514/183
Product Trade Name : SYNERCID® (quinupristin and
dalfopristin) (New Drug Application No.
50-747)
Term Extended : 1,333 days
Expiration Date of Extension : September 4, 2009

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.: 00N-1251
 Food and Drug Administration
 1451 Rockville Pike, HFD-7
 Rockville, MD 20852

¹A change of name was recorded at Reel 11641, Frame 0962.