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David J. Levy, Ph.D.
Patent Counsel
Glaxo Wellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709

Re: Patent Term Extension
Application for
U.S. Patent No. 5,008,256

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,008,256, which claims the human drug TRITEC® (ranitidine bismuth citrate), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 387 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 Commissioner will issue a certificate of extension, under seal, for a period of 387 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 April 4, 1997 (62 Fed. Reg. 16166). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase) + Approval Phase} \\ &= \frac{1}{2} (485) + 589 \\ &= 832 \text{ days} \end{aligned}$$

Since the regulatory review period began September 1, 1993, after the patent issue date (April 16, 1991), 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, 832 days, would extend the patent from July 17, 2009 (35 U.S.C. § 154) to October 27, 2011, which is beyond the 14-year limit (the approval date is August 8, 1996, thus the 14 year limit is August 8, 2010). The period of extension is thus limited to August 8, 2010, 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, July 17, 2009, to and including August 8, 2010, or 387 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:

