



JUL 24 2000

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Suite 660
La Jolla CA 92037Re: Patent Term Extension
Application for
U.S. Patent No. 5,234,404

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,234,404, which claims the method of use of the human drug product GenESA®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 398 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 398 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 May 11, 1999 (64 Fed. Reg. 25350). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,295 - 1,145) + 1,346 \\ &= 1,421 \text{ days} \end{aligned}$$

Since the regulatory review period began June 22, 1990, before the patent issued (August 10, 1993), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From June 22, 1990 to August 10, 1993 is 1,145 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, however, 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, 1,421 days, would extend the patent from August 10, 2010 (35 U.S.C. § 154) to July 1, 2014, which is beyond the 14-year limit (the approval date is September 12, 1997, thus the 14 year limit is September 12, 2011). The period of extension is thus limited to September 12, 2011, 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, August 10, 2010, to and including September 12, 2011, or 398 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:

J.S. Patent No.	5,234,404
Granted:	August 10, 1993
Original Expiration Date	August 10, 2010
Applicant	Ronald R. Tuttle, et al.
Owner of Record	Gensia Sicor, Inc.
Title:	Diagnosis, Evaluation and Treatment of Coronary Artery Disease by Exercise Simulation Using Closed Loop Drug Delivery of an Exercise Simulating Agent Beta Agonist
Classification	604/20
Product Trade Name:	GenESA® (arbutamine)
Term Extended:	398 days
Expiration Date of Extension:	September 12, 201

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

By mail Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX (703) 308-6916
Attn: Special Program Law Office

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.


Kafin L. Tyson
Senior Legal Advisor, Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
 Acting Director Regulatory Policy Staff, CDER
 Food and Drug Administration
 1451 Rockville Pike, HFD-7
 Rockville, MD 20852

RE: GenESA®
FDA Docket No.: 98E-0319

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