



JUL 27 2000

Michael W. Glynn
Patent and Trademark Dept.
Novartis Corporation
564 Morris Ave.
Summit NJ 07901In Re: Patent Term Extension
Application for
U.S. Patent No. 4,978,672

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,978,672, which claims the human drug product FEMARA™ and the method of use of FEMARA™, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,263 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 1,263 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 May 10, 1999 (64 Fed. Reg. 25046). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (366) + 1,794 \\ &= 1,263 \text{ days} \end{aligned}$$

Since the regulatory review period began August 28, 1991, after the patent issue date (December 18, 1990), 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 five year limitation of 35 U.S.C. § 156(g)(6)(A) 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.	4,978,672
Granted	December 18, 1990
Original Expiration Date	December 18, 2007
Applicant	Robert M. Bowman, et al
Owner of Record	Novartis Pharmaceuticals Corporation
Title	Alpha-Heterocyclic Substituted Tolunitriles
Classification	514/383

Product Trade Name	FEMARA™
Term Extended	1,263 days
Expiration Date of Extension :	June 3, 2011

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) 872-9411
 Attn: Special Program Law Office

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


Karin 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: FEMARA™
FDA Docket No.: 98E-0611