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MAY - 5 1998

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Re: Patent Term Extension
Application for
U.S. Patent No. 4,254,129

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,254,129, which claims the human drug product ALLEGRA® (fexofenadine hydrochloride) and a method of use of the product ALLEGRA®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 679 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 679 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 July 11, 1997 (62 Fed. Reg. 37267). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (635) + 361 \\ &= 679 \text{ days}\end{aligned}$$

Since the regulatory review period began November 4, 1993, after the patent issue date (March 3, 1981), 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.

The limitations of 35 U.S.C. §§ 156(c)(3) and 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:

U.S. Patent No.:	4,254,129
Granted:	March 3, 1981

Original Expiration Date: April 10, 1999
Applicant: Albert A. Carr et al.
Owner of Record: Merrell Pharmaceuticals
Title: Piperidine Derivatives
Classification: 514/317
Product Trade Name: ALLEGRA®
Term Extended: 679 days
Expiration Date of Extension: February 17, 2001

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.



Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: ALLEGRA®
FDA Docket No.: 96E-0386