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JUL 25 1997

John J. Maitner
Schering-Plough Corporation
Patent Department (K-6-1-1990)
2000 Galloping Hill Road
Kenilworth, New Jersey 07033-0530

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,235,892

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,235,892, which claims the animal drug NUFLO[®] (florfenicol), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be three years.

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 November 26, 1996 (61 Fed. Reg. 60,106). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (4,205 - 0) + 4 \\ &= 2,107 \text{ days (5.77 years)}\end{aligned}$$

Since the regulatory review period began November 23, 1984, after the patent issue date (November 25, 1980), 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 three year limitation of 35 U.S.C. § 156(g)(6)(C) applies in the present situation because the patent was issued and an action described in paragraph (4)(B) was taken before the relevant date of enactment (November 16, 1988) of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed three years under 35 U.S.C. § 156(g)(6)(C), the period of extension will be for three years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

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 three years.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,235,892
Granted	:	November 25, 1980
Original Expiration Date	:	February 5, 1999
Inventor	:	Tattanahalli L. Nagabhushan
Owner of Record	:	Schering Corporation
Title	:	1-Aryl-2-Acylamido-3-Fluoro-1-Propanols, Methods for Their Use as Antibacterial Agents and Compositions Useful Therefor
Classification	:	514/522
Product Trade Name	:	NUFLOR® (florfenicol)
Term Extended	:	Three Years
Expiration Date of Extension	:	February 5, 2002

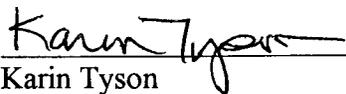
Any correspondence with respect to this matter should be addressed as follows:

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

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

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

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



Karin Tyson
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)
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RE: NUFLOR®
FDA Docket No.: 96E-0315