



UNITED STATES PATENT AND TRADEMARK OFFICE

 COMMISSIONER FOR PATENTS
 UNITED STATES PATENT AND TRADEMARK OFFICE
 P.O. Box 1450
 ALEXANDRIA, VA 22313-1450
 www.uspto.gov

MAILED

JAN 30 2004

FREE EXAM UNIT

Mailed: January 30, 2004

 Teresa Stanek Rea
 Burns, Doane, Swecker, & Mathis, LLP
 PO Box 1404
 Alexandria, VA 22313-1404

 In Re: Patent Term Extension
 Application for
 U.S. Patent No. 4,412,992

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,412,992, which claims the human drug product CALOZAL® (balsalazide disodium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be five years.

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 Director will issue a certificate of extension, under seal, for a period of five years.

The Food and Drug Administration determination's of the length of the regulatory review period was published in the Federal Register of November 14, 2002 (67 Fed. Reg. 69014). If the period of extension was calculated using FDA's determination of the length of the regulatory review period according to 35 U.S.C. § 156(c), the extension would be:

$$\begin{aligned}
 &= \frac{1}{2} \text{ (Testing Phase) + Approval Phase} \\
 &= \frac{1}{2} (1,828) + 1,122 \\
 &= 2,036 \text{ days (5.6 years)}
 \end{aligned}$$

Since the regulatory review period began June 22, 1992, after the patent issued (November 1, 1983), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c).

The five year limitation of 35 U.S.C. § 156(g)(6)(B) applies in the present situation, however, because the patent was issued before the date of enactment of 35 U.S.C. § 156, but no action specified in 35 U.S.C. § 156(g)(6)(B) was taken before the date of enactment. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(B), the period of extension will be for five 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.

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

U.S. Patent No.:	4,412,992
Granted:	November 1, 1983
Original Expiration Date ¹ :	July 8, 2001

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

U.S. Patent No. 4,412,992

Page 2

Applicant: Rosalind P. K. Chan
Owner of Record: Biorex Laboratories Unlimited
Title: 2-HYDROXY-5-PHENYLAZOBENZOIC ACID
DERIVATIVES AND METHOD OF TREATING
ULCERATIVE COLITIS THEREWITH
Classification: 424/226
Product Trade Name: CALOZAL® (balsalzide disodium)
Term Extended: Five Years
Expiration Date: July 8, 2006

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

By mail: Commissioner for Patents
Mail Stop Patent Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (703) 872-9411
Attn: Office of Patent Legal Administration

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


Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

RE: CALOZAL® (balsalzide disodium)
FDA Docket No.: 01E-0094

Attention: Claudia Grillo