

Mailed January 2, 2002

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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,933,456

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,933,456, which claims the human drug product TESLASCAN®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,765 days. U.S. Patent No. 4,933,456 has an original expiration date of June 12, 2007, subject to the provisions of 35 U.S.C. § 41(b). Accordingly, extension of the patent for 1,765 days will result in an extended expiration date of April 11, 2012.

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. Note that the certificate of extension will be issued in the name of the assignee, as reflected in the United States Patent and Trademark Office assignment records, unless applicant submits proof of the change of name of the assignee (i.e., applicant should fax a copy of the document evidencing the change of name from Salutar, Inc. to Nycomed Salutar, Inc. to (703)872-9411). **Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.** In the absence of such request for reconsideration or document evidencing the change of name, the Director will issue a certificate of extension, under seal, for a period of 1,765 days to Salutar, Inc..

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 January 31, 2000. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,325 - 403) + 804 \\ &= 1,765 \text{ days (4.8 years)}\end{aligned}$$

Since the regulatory review period began May 5, 1989, before the patent issue date (June 12, 1990), 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 May 5, 1989 to June 12, 1990 is 403 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.

Neither the limitations of 35 U.S.C. § 156(g)(6) 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.	:	4,933,456
Granted	:	June 12, 1990

Original Expiration Date : June 12, 2007
Applicant : Scott M. Rocklage, et al.
Owner of Record : Salutar, Inc.
Title : Dipyradoxyl Phosphate NMRI Contrast Agents
Classification : 546/5
Product Trade Name : TESLASCAN®
Term Extended : 1,765 days
Expiration Date of Extension : April 11, 2012

Any correspondence with respect to this matter should preferably be faxed to:

FAX: (703) 872-9411

Alternatively, correspondence sent by mail should be directed to:

Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231; **or**

U.S. Patent and Trademark Office, Box Patent Ext.
P.O. Box 2327
Arlington, VA 22202

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

/s/
Karin Tyson
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

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

RE: TESLASCAN®
FDA Docket No.: 98E-0479