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Theresa C. Kavanaugh
Goodwin Proctor
Patent Administrator
53 State Street Exchange Place
Boston, MA 02109-2881

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,599,498

MAR 26 2014

Dear Ms. Kavanaugh:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 6,599,498 for a period of 1,209 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website:

<http://www.fda.gov/opacom/morechoices/fdaforms/default.html>
(<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6284
Silver Spring, MD 20993-0002

RE: FERAHEME®
(ferumoxytol)
Docket No.: FDA-2010-E-0049

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM
UNDER 35 U.S.C. § 156

(68) PATENT NO. : 6,599,498
(45) ISSUED : July 29, 2003
(75) INVENTOR : Ernest B.V. Groman et al.
(73) PATENT OWNER : AMAG Pharmaceuticals, Inc.
(95) PRODUCT : FERAHEME® (ferumoxytol)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 6,599,498 based upon the regulatory review of the product FERAHEME® (ferumoxytol) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 1,209 days

from March 8, 2020, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156.

I have caused the seal of the United States Patent and Trademark Office to be affixed this 19th day of March 2014.

Michelle K. Lee

Michelle K. Lee
Deputy Under Secretary of Commerce for Intellectual Property and
Deputy Director of the United States Patent and Trademark Office





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Goodwin Proctor
Patent Administrator
53 State Street Exchange Place
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In Re: Patent Term Extension
Application for
U.S. Patent No. 6,599,498

OCT - 9 2013

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,599,498, claims of which cover the human drug product FERAHEME® (ferumoxytol), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,209 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 a request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,209 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of May 4, 2012 (77 Fed. Reg. 26557), would be 1,362 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}
\text{Period of Extension} &= \text{RRP} - \text{PGRRP} - \text{DD} - \frac{1}{2} (\text{TP} - \text{PGTP})^1 \\
&= 3,680 - 1,516 - 0 - \frac{1}{2} (3,120 - 1,516) \\
&= 1,362 \text{ (years)}
\end{aligned}$$

Since the regulatory review period began June 5, 1999, before the patent issued (July 29, 2003), 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 June 5, 1999, to and including July 29, 2003, is 1,516 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.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the

¹ Consistent with 35 U.S.C. § 156(c), “RRP” is the total number of days in the regulatory review period, “PGRRP” is the number of days of the RRP which were on and before the date on which the patent issued, “DD” is the number of days of the RRP that the applicant did not act with due diligence, “TP” is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and “PGTP” is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of ½ (TP - PGTP).

extension in the present situation, because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,362, would extend the patent from March 8, 2020, to November 30, 2023, which is beyond the 14-year limit (the approval date is June 30, 2009, thus, the 14 year limit is June 30, 2023). The period of extension is thus limited to June 30, 2023, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, March 8, 2020, to and including June 30, 2023, or 1,209 days.

The limitations of 35 U.S.C. 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:

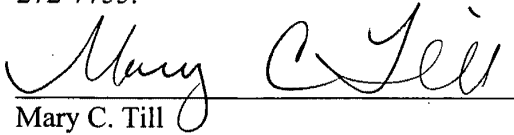
U.S. Patent No.:	6,599,498
Granted:	July 29, 2003
Original Expiration Date ² :	March 8, 2020
Applicant:	Ernest B.V. Groman et al.
Owner of Record:	AMAG Pharmaceuticals, Inc.
Title:	Heat Stable Colloidal Iron Oxides Coated with Reduced Carbohydrates and Carbohydrate Derivatives
Product Trade Name:	FERAHEME® (ferumoxytol)
Term Extended:	1,209 days
Expiration Date of Extension:	June 30, 2023

²Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be submitted via the USPTO's EFS-Web System and should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



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Food and Drug Administration
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Silver Spring, MD 20993-0002

RE: FERAHEME®
(ferumoxytol)
Docket No.: FDA-2010-E-0049

Attention: Beverly Friedman

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