



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

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](mailto: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





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

**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

<sup>1</sup> 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 <sup>2</sup> :	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

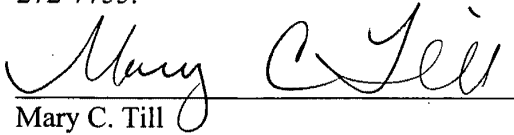
---

<sup>2</sup>Subject 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.



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. 6222  
Silver Spring, MD 20993-0002

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

Attention: Beverly Friedman

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.