



UNITED STATES PATENT AND TRADEMARK OFFICE

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

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 6,465,504 was filed on December 20, 2005, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, EXJADE® (deferasirox), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. We note the following matters concerning the application for patent term extension: The expiration date of the patent is believed to be June 24, 2017 as stated in the application; the benefit claim is clearly stated in the first paragraph of the specification. The request for Certificate of Correction received May 27, 2003 was granted on January 11, 2006. No copy of the receipt for payment of the four-year maintenance fee was included with the application, but PTO records show that the fee was properly paid. No statement as to whether a terminal disclaimer had been filed was included in the application, but PTO records indicate that there were none.

Inquiries regarding this communication should be directed to Kathleen Kahler Fonda at (571) 272-7754 (telephone) or (571) 273-7754 (facsimile).

Kery A. Fries
Senior Legal Advisor
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