



Food and Drug Administration  
Rockville MD 20857

NOV 17 2003

Re: Tracleer  
Docket No. 02E-0064

The Honorable James E. Rogan  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office  
Box Pat. Ext.  
P.O. Box 1450  
Alexandria, VA 22313-1450

NOV 17 2003

Dear Director Rogan:

This is in regard to the patent term extension application for U.S. Patent No. 5,292,740 filed by Hoffman-La Roche, Inc. under 35 U.S.C. § 156. The patent claims Tracleer (bosentan), NDA 21-290.

In the May 7, 2003, issue of the Federal Register (68 Fed. Reg. 24485), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before November 3, 2003, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

cc: George W. Johnston  
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