



UNITED STATES PATENT AND TRADEMARK OFFICE

OCT 30 2006

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Office of Regulatory Policy  
HFD-7  
5600 Fishers Lane (Rockwall II Rm 1101)  
Rockville, MD 20857

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 5,101,013 was filed on June 16, 2000, under 35 U.S.C. § 156. We regret the tardiness in forwarding this application to the Food and Drug Administration.

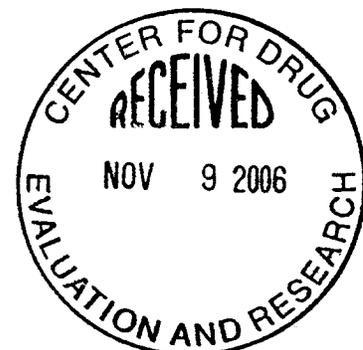
The assistance of your Office is requested in confirming that the product identified in the application, Lantus® (insulin glargine [rDNA origin]), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application 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.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till  
Legal Advisor  
Office of Patent Legal Administration  
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