



DEC 19 2005

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

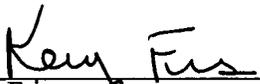
Attention: Claudia Grillo

The attached application for patent term extension of U.S. Patent No. 5,681,814 was filed on October 27, 2005, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, INCRELEX™ (mecasermin [rDNA origin] injection), 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 Kathleen Kahler Fonda at (571) 272-7754 (telephone) or (571)273-7754 (facsimile).



Kery Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Ginger R. Dreger
Heller Ehrmann, LLP
275 Middlefield Road
Menlo Park, CA 94025