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MAY 24 2004

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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. 6,011,068 was filed on May 6, 2004, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, Sensipar™ (cinacalcet hydrochloride), 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. Applications for Patent Term Extension for U.S. Patent Nos. 6,211,244 and 6,313,146 were also filed. Only a single patent may be extended based upon the regulatory review of Sensipar™.

It is noted that the application contains a typographical error in the correspondence address for the application. The correct zip code as shown by the United States Postal Service Internet web site (<http://www.usps.com>) is as shown below.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Richard J. Warburg, Esq.
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2004E-0446

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