DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-688

Amgen Inc.
Attention: Pamela Danagher
Manager, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Dear Ms. Danagher:

Please refer to your new drug application (NDA) dated September 5, 2003, received September 8, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sensipar (cinacalcet HCl) Tablets.

We acknowledge receipt of your submissions dated August 14, October 8, and December 1, 3, 12, and 24, 2003, and January 12, 21, and 22, February 3, 5, 6, 11, 13, 20, and 26, and March 3 and 5, 2004.

This new drug application provides for the use of Sensipar (cinacalcet HCl) Tablets for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis, and the treatment of hypercalcemia in patients with parathyroid carcinoma.

This new drug application also provides for the use of Sensipar (cinacalcet HCl) Tablets for the (b)(4)----------
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(b)(4)- These two indications have been administratively unbundled from the original NDA. The
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We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed-upon labeling text. Accordingly, the application is approved effective on the date of this letter. However,(b)(4)----------are approvable, and the deficiencies will be address----------

Sufficient stability data have been submitted to support a 18-month expiration date for tablets packaged in blister packages, and a 24-month expiration date for tablets packaged in bottles.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted March 5, 2004, carton and container label submitted February 26, 2004). Marketing

the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-688." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

We remind you of your postmarketing study commitments in your submission dated March 3, 2004. These commitments are listed below.

1. To conduct a drug interaction study in healthy volunteers with a preferred CYP2D6 substrate such as desipramine (*J Clin Pharmacol* 2003;43:443) to address cinacalcet's inhibition potential on CYP2D6.

Protocol Submission:	By July 2004
Study Start:	By August 2004
Final Report Submission:	By March 2005

2. To conduct an in vitro drug metabolic enzymes induction study for cinacalcet in human liver cells.

Protocol Submission:	By April 2004
Study Start:	By May 2004
Final Report Submission:	By September 2004

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, the number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments should be prominently labeled "**Postmarketing Study Protocol," "Postmarketing Study Final Report," or "Postmarketing Study Correspondence."**

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Metabolic and Endocrine Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at: www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, call Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 827-6392.

Sincerely,

{See appended electronic signature page}

Robert Meyer, M.D.
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Meyer
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