DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-688/S-011

Amgen Inc.
Attention: Shi-Ru Anderson
Manager, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Dear Ms. Anderson:

Please refer to your supplemental new drug application dated May 28, 2008, received May 29, 2008, 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 July 24, December 12, and 17, 2008.

This supplemental new drug application provides for the following changes to the package insert: (1) the addition of arrhythmia to the WARNINGS and ADVERSE REACTIONS sections, and (2) the addition of metoprolol and carvedilol as examples of drugs that are predominantly metabolized by CYP2D6 to the PRECAUTIONS section.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical in content to the enclosed labeling (text for package insert submitted on DecemerbDecember 17, 2008). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-688/S-011."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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

If you have any questions, call Julie Marchick, Regulatory Project Manager, at (301) 796-1280.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

/s/

Mary Parks

12/19/2008 03:49:21 PM