DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-688/S-006

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

Dear Ms. Anderson:

Please refer to your supplemental new drug application dated June 23, 2006, received June 26, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sensipar (cinacalcet) Tablets.

We acknowledge receipt of your submissions dated January 11, April 3, and October 3, 2007.

Your submission of April 3, 2007, constituted a complete response to our December 26, 2006, action letter.

We also refer to our supplement request letter dated April 24, 2006, in which you were asked to revise the **DRUG INTERATION** subsection of the **CLINICAL PHARMACOLOGY** section and the **DRUG INTERACTIONS** subsection of the **PRECAUTIONS** section of the package insert.

This supplemental new drug application provides for revisions to the following sections of the package insert: the **DRUG INTERATION** subsection of the **CLINICAL PHARMACOLOGY** section, the **DRUG INTERACTIONS** subsection of the **PRECAUTIONS** section, for the addition of a sentence in the ***Secondary Hyperparathyroidism in Patients with Chronic Kidney Disease on Dialysis*** subsection of the **DOSAGE and ADMINISTRATION** section, which states, "PTH levels should be assessed no earlier than 12 hours after dosing with Sensipar," and for removal of "hydrochloride" and "HCl" after "cinacalcet" throughout the package insert.

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.

Within 21 days of the date of this letter, submit 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. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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 this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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

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