DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-223/S-011

Novartis Pharmaceuticals Corporation
Attention: Prem Narang
Vice President, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Mr. Narang:

Please refer to your supplemental new drug application dated April 14, 2005, received April 15, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zometa (zoledronic acid injection).

This "Changes Being Effected" supplemental new drug application provides for a new subsection entitled **Musculoskeletal Pain** in the **PRECAUTIONS** section of the package insert, and updates the **Postmarketing Experience** subsection of the **Adverse Reactions** section to include “uveitis” and “episclerites.”

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 14, 2005.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
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/

David Orloff

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