DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-223/S-008

Novartis Pharmaceuticals Corporation
Attention: Robyn Sterner, Pharm.D.
Associate Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Sterner:

Please refer to your supplemental new drug application dated September 26, 2003, received September 291, 2003, 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 paragraph on the possible association of osteonecrosis of the jaws with i.v. bisphosphonate use to be added to the **Post-Marketing Experience** subsection of the **Adverse Reactions** section of the package insert.

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 September 26, 2003.

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/

Mary Parks
3/24/04 04:18:26 PM
for Dr. Orloff