DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-223/S-014 and S-015

Novartis Pharmaceuticals
Attention: Lynne Fahey McGrath, MPH, PhD
Director Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936

Dear Dr. McGrath:

Please refer to your supplemental new drug applications dated and received May 4, 2007, (NDA 21-223/S-014) and dated and received September 13, 2007, (NDA 21-223/S-015) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zometa (zoledronic acid) Injection Concentrate for Intravenous Infusion 4mg/5mL single dose vial.

We acknowledge receipt of your submissions dated October 16, 2007 (NDA 21-223/S-015), and November 2, 2007 (NDA 21-223/S-014 and S-015).

These supplemental new drug applications provide for:

S-014: Prior Approval - Revised language in the ***Pharmacokinetics/Distribution*** subsection of the ***Clinical Pharmacology*** section of the package insert for Zometa regarding protein binding, including a change in the per cent binding to human plasma proteins from approximately 22% to approximately 43 – 55%.

S-015: "Changes Being Effected" - Physician's Labeling Rule (PLR) format to revise the Zometa Prescribing Information (PI) to be identical in content to the label provided by FDA dated August 27, 2007.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed 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 to the enclosed labeling (text for package insert submitted on November 2, 2007). 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 21-223/S-014 and S-015."

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

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

If you have any questions, call Oluchi Elekwachi, PharmD, MPH, Senior Regulatory Management Officer, at (301) 796-1207.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Approved Package Inserted (PI)

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

/s/

Eric Colman
11/2/2007 03:07:40 PM
Eric Colman for Mary Parks