



NDA 21-223/S-004

Novartis Pharmaceuticals Corporation
Attention: Elizabeth McCartney
Assistant Director, TRD/Global Regulatory CMC
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. McCartney:

Please refer to your supplemental new drug application dated June 20, 2002, received June 21, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zometa (zoledronic acid for injection).

We acknowledge receipt of your submissions dated October 1, 10, and 21, and November 6, 2002, and January 10, and 31, and February 10, and 19, 2003. Your submission of November 6, 2002 constituted a complete response to our October 18, 2002 action letter.

This supplemental new drug application provides for a liquid dosage form of the current lyophilized powder for reconstitution.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels submitted February 10, 2003) and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-223/S-004." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final

print. Submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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, HR-2
FDA
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 Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 827-6392.

Sincerely,

{See appended electronic signature page}

Sheldon Markofsky, Ph.D.
Acting Chemistry Team Leader II, DNDC II for the
Division of Metabolic and Endocrine Drug Products
Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Sheldon Markofsky
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