



Food and Drug
Administration
Rockville MD 20857

NDA 20-036/S-032

Novartis Pharmaceuticals Corporation
Attention: Harinder Dhillon, Pharm.D.
Senior Manager, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Dhillon:

Please refer to your supplemental new drug application dated August 17, 2005, received August 19, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aredia (pamidronate disodium for injection).

This prior approval supplemental new drug application provides for a new subsection entitled **Geriatric Use** in the **PRECAUTIONS** section of the package insert.

We have completed our review of this application. 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) submitted August 17, 2005.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-036/S-032** ". Approval of this submission by FDA is not required before the labeling is used.

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

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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
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/s/

David Orloff
11/16/2005 12:31:04 PM