



NDA 20-036/S-031

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 Aredia (pamidronate disodium for 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.

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

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/s/

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David Orloff  
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