NDA 20-927
NDA 20-036/S-015, S-016

Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover, NJ 07936

Attention: Ellen Cutler
Assistant Director, Drug Regulatory Affairs

Dear Ms. Cutler:

Please refer to your new drug application (NDA) dated September 22, 1997, received September 22, 1997, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aredia® (pamidronate disodium for injection) .

We acknowledge receipt of your submissions dated December 3, 1997; February 4, August 21, and September 17, 1998. The user fee goal date for this application is September 22, 1998.

Please also refer to the approved NDA 20-036/S-011 which provided for the use of Aredia® (pamidronate disodium for injection) in conjunction with standard antineoplastic therapy for the treatment of osteolytic bone metastases of breast cancer. This new drug application provides the results of the one-year extension period of the two Phase 3 studies that were submitted to support the approval of the NDA 20-036/S-011.

Further, please refer to your September 22, 1997 supplemental new drug application NDA 20-036/S-016. This supplement and NDA 20-927 provide for identical changes to the INDICATIONS AND USAGE, CLINICAL PHARMACOLOGY, ADVERSE REACTIONS, and DOSAGE AND ADMINISTRATION sections of the currently approved labeling. We also note that NDA 20-036/S-015, submitted June 4, 1998, is superseded by Supplement-016 and will be retained in your NDA file. All changes submitted under S-015 should be incorporated into the final printed labeling (FPL) for S-016.

We have completed the review of this application, as amended, and the supplemental new drug application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, the application (NDA 20-927) and the supplement application (NDA 20-036/S-016) are approved effective on the date of this letter.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for the approved NDA. All supplements and other submissions should be addressed to the original NDA 20-036 for this drug product, not to this NDA 20-927, except for the 20 copies of final printed labeling and advertising material as noted below.

The FPL must be identical to the enclosed labeling (text for the package insert) except for the addition of changes submitted under NDA 20-036/S-015. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 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 NDA 20-927." 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. Please submit one copy to this Division, one copy to the Division of Endocrine and Metabolic Drug Products, and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

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, contact Debra Catterson, Project Manager, at (301) 827-1544.

Sincerely,

Robert L. Justice, M.D.
Acting Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure