ANDA 75-773 August 24, 2001

American Pharmaceutical Partners, Inc.
Attention: Lincy Michael
2045 North Cornell Avenue
Melrose Park, IL 60160

Dear Madam:

This is in reference to your abbreviated new drug application dated December 29,1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Pamidronate Disodium for Injection, 30 mg/vial and 90 mg/vial.

Reference is also made to your amendments dated March 13, June 18, and July 27, 2001.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product). The determination is subject to change on the basis of new information that may come to our attention.

The listed drug product (RLD) referenced in your application, Aredia Injection of Novartis Pharmaceuticals Corporation, is subject to a period of patent protection which expires on July 29, 2005, [U.S. Patent No. 4,711,880, (the '880 patent)]. Your application contains a Paragraph IV Certification to the '880 patent under Section 505(j)(2)(A)(vii)(IV) of the Act. This certification states that the '880 patent will not be infringed by your manufacture, use, or sale of this drug product. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated new drug application shall be made effectively immediately, unless an action is brought against American Pharmaceutical Partners, Inc. (APP) for infringement of

the patent that is the subject of the certification (the ‘880 patent). You have notified the agency the APP has complied with the requirements of Section 505 (j)(2)(B) of the Act. As a result, litigation is currently underway in the United States District Court for the Northern District of Illinois involving a challenge to the ‘880 patent (Novartis Corporation v. American Pharmaceutical Partners, Inc., Civil Action No. 00C 2313).

Furthermore, please note that ANDA 75-290 submitted by Bedford Laboratories (Bedford) for this drug product and also containing a Paragraph IV Certification was accepted for filing by this office prior to the filing of your application. This application was granted final approval on April 30, 2001. Consequently, Bedford is deemed eligible for 180-days of generic drug market exclusivity as provided for under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) in Section 505(j)(5)(B)(iv) of the Act. Bedford’s exclusivity will begin to run either from the date Bedford begins commercial marketing of the drug product under its ANDA, or in the absence of marketing from the date of a decision of a court finding that Bedford did not infringe the ‘880 patent, whichever event occurs earlier (Section 505(j)(5)(B)(iv)). We refer you to the Agency’s issued guidance document “180 Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments” (June 1998), for additional information.

We believe that your application for this drug product will be eligible for final approval upon your successful resolution of your court case with Novartis or expiration of the 30-month statutory period, and upon the expiration of Bedford’s 180-day generic drug exclusivity.

In order to reactivate your application prior to final approval, please submit a MINOR AMENDMENT – FINAL APPROVAL REQUESTED approximately 90 days prior to the date you believe your application should be considered eligible for final approval. Your amendment should provide:

1. updated information related to final-printed labeling or chemistry, manufacturing and controls data, or any other change in the conditions outlined in this abbreviated application, or

2. a statement that no such changes have been made to the application since the date of tentative approval, and

3. a summary of the legal and/or regulatory events which have occurred and which you believe provide for final approval of this application.

Any changes in the conditions outlined in this abbreviated application and the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures are subject to Agency review before final approval of the application will be made.

In addition to, or instead of, the amendments referred to above, the Agency may, at any time prior to the final date of approval, request that you submit amendments containing the information requested above.

Failure to submit either or both amendments may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug before the effective final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list.

The amendment should be designated as a MINOR AMENDMENT – FINAL APPROVAL REQUESTED in your cover letter. Before you submit the amendment or if you have questions about the status of this application, please contact Sarah Ho, R.Ph., Project Manager, at 301-827-5848, for further instructions.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research