

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-290

APPROVAL LETTER

APR 30 2001

Bedford Laboratories
Attention: Shahid Ahmed
270 Northfield Road
Bedford, Ohio 44146

Dear Sir:

This is in reference to your abbreviated new drug application dated December 23, 1997, 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 December 5, 2000, and January 18, February 20, February 28, April 25, and April 30, 2001.

The listed drug product referenced in your application, Aredia Injection of Novartis Pharmaceuticals Corp., is subject to a period of patent protection which expires July 29, 2005, (U.S. Patent No. 4,711,880). Your application contains a patent certification under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of the Pamidronate Disodium for Injection will not infringe on the patent or that the patent is otherwise invalid. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of the '880 patent within 45-days from the date the notice provided under paragraph (2)(B)(i) is received by the patent and NDA holder. You have notified the agency that Bedford Laboratories complied with the requirements of Section 505(j)(2)(B) of the Act, and as a result on May 8, 1998 Novartis Corporation initiated a patent infringement suit against you in U.S. District Court for the District of New Jersey (Novartis Corporation v. Boehringer Ingelheim Corporation, Civil Action No. 2:00cv00769).

Furthermore, Bedford Laboratories has requested that the agency grant final approval to this abbreviated application in accord with Section 505(j)(5)(B)(iii) of the Act, since the 30-month period during which time FDA was precluded from approving your application, has expired.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Pamidronate Disodium for Injection, 30 mg/vial and 90 mg/vial to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Aredia® Injection, 30 mg/vial, and 90 mg/vial, respectively, of Novartis Pharmaceuticals Corp.).

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Validation of the regulatory methods has not been completed. It is the policy of the Office not to withhold approval until the validation is complete. We acknowledge your commitment to satisfactorily resolve any deficiencies, which may be identified.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Gary Buehler". The signature is fluid and cursive, with the first name "Gary" and last name "Buehler" clearly distinguishable.

Gary Buehler 4/30/01
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research