CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-841

APPROVAL LETTER

ANDA 75-841

JUN 2 7 2002

Faulding Pharmaceutical Company
Attention: Jatin J. Shah, Ph.D.
Mack-Cali Centre II
650 From Road
2nd Floor
Paramus, NJ 07652

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated February 28, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Pamidronate Disodium Injection, 3 mg/mL (packaged in 30 mg/10 mL single-use vials), 6 mg/mL (packaged in 60 mg/10 mL single-use vials, and 9 mg/mL (packaged in 90 mg/10 mL single-use vials).

Reference is also made to your amendments dated March 30, 2001; and March 19 and April 16, 2002. Reference is made to the suitability petition submitted under Section 505(j)(2)(C) of the Act and approved on April 18, 2000, allowing you to submit an ANDA for a drug product that differs in dosage form from the reference listed drug product (RLD). Specifically, your product is intended as a ready-to-use product in contrast to the reference listed drug which is a lyophilized product that requires reconstitution prior to administration.

The listed drug product referenced in your application (RLD), Aredia Injection of Novartis Pharmaceuticals Corp., is subject to a period of patent protection which expires on July 29, 2005, (U.S. patent 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 stating that your manufacture, use or sale of this drug product will not infringe the '880 patent. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated application shall be made effective immediately unless you are sued for patent infringement. This legal action must be brought against you before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received by the owner of the new drug application (NDA) for the reference listed drug product, Aredia® Injection, and the patent holder. You have

notified the agency that Faulding Pharmaceutical Company (Faulding) has complied with the requirements of Section 505(j)(2)(B) of the Act. As a result, Novartis Corporation initiated a patent infringement suit against Faulding in the United States District Court for the District of New Jersey involving a challenge to the '880 patent (Novartis Corporation v. Faulding Inc., Faulding Pharmaceutical Co., and Whitney Pharmaceuticals Inc., Civil Action No. 2:00cv03584). Furthermore, you have notified the agency that Whitney Pharmaceuticals Inc., has received "Notice of Voluntary Dismissal" of the suit dated October 3, 2000, by the United States District Court for the District of New Jersey.

We have completed the review of this ANDA 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. Accordingly, the application is approved. The Division of Bioequivalence has determined your Pamidronate Disodium Injection, 3 mg/mL, 6 mg/mL and 9 mg/mL, can be expected to have the same therapeutic effect as that of the reference listed drug product upon which the agency relied as the basis of safety and effectiveness.

Under Section 505(A) of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this ANDA 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 that 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 associated with the validation process that may be identified.

Sincerely yours,

Gary Buehler 6/27/02
Director
Office of Generic Drugs
Center for Drug Evaluation and Research