DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-113

Bedford Laboratories
Attention: Ms. Molly Rapp
Supervisor, Regulatory Affairs
270 Northfield Road
Bedford, OH 44146

Dear Ms. Rapp:

Please refer to your new drug application (NDA) dated February 26, 1999, received March 2, 1999, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for pamidronate disodium injection.

We acknowledge receipt of your submissions dated September 5 and 12, October 2 and 9, 2001, and January 30, and February 25, 2002. Your submission of September 5, 2001, constituted a complete response to our August 20, 2001, action letter.

This new drug application provides for the use of pamidronate disodium injection for the treatment of moderate or severe hypercalcemia associated with malignancy, with or without bone metastases, for the treatment of patients with moderate to severe Paget's disease of bone, and for the treatment of osteolytic bone metastases of breast cancer and osteolytic lesions of multiple myeloma in conjunction with standard antineoplastic therapy.

We have completed the review of this application, as amended, 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 submitted final printed labeling (package insert submitted on February 25, 2002, immediate container labels, and carton labels submitted on September 5, 2001). Accordingly, the application is approved effective on the date of this letter.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for the indications of this action on this application.

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 and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

David Orloff

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