DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-113/S-004

Bedford Laboratories, Inc.
Attention: Molly Rapp
Manager, Regulatory Affairs
300 Northfield Road
Bedford, OH 44146

Dear Ms Rapp:

Please refer to your supplemental new drug application dated May 13, 2005, received May 16, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pamidronate Disodium Injection.

This "Changes Being Effected" supplemental new drug application provides for adding an '**Osteonecrosis of the Jaw'** and '**Musculoskeletal Pain'** subsections to the '**General'** subsection of the '**PRECAUTIONS'** section of the package insert, removes the 9 mg/mL; 10 mL dosage form and adds 30 mg/vial and 90 mg/vial lyophilized dosage forms to the '**HOW SUPPLIED'** section of the package insert.

We have completed the review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling submitted on May 13, 2005.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 976-1224.

Sincerely,

{See appended electronic signature page}

David 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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