DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-113/S-002

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 April 14, 2004, received April 15, 2004, 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 manufacture of the drug product in a new building using a new· ----------, and revised "Usual Dosage" section of the carton labeling for the 30 mg/10 ml vial so it complies with 21 CFR 201.55 and reads "See package insert for complete prescribing information."

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 (carton) submitted on April 14, 2004.

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) 827-6392.

Sincerely,

{See appended electronic signature page}

Mamta Gautam-Basak, Ph.D.
Chemistry Team Leader II for the
Division of Metabolic and Endocrine Drug Products, HFD-510
DNDC II, Office of New Drug Chemistry
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/

Mamta Gautam-Basak
9/29/04 10:35:29 AM
Approved