DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-113/S-008

Bedford Laboratories
Attention: Molly Rapp
Director, Ben Venue Labs
300 Northfield Road
Bedford, OH 44146

Dear Ms. Rapp:

Please refer to your supplemental new drug application dated January 23, 2009, and received January 27, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for pamidronate disodium injection, solution and pamidronate disodium injection, powder, lyophilized, for solution.

This "Changes Being Effected" supplemental new drug application provides for changes to the (1) **Osteonecrosis of the Jaw** subsection of the **PRECAUTIONS** section and (2) description of osteonecrosis of the jaw in the **Post-Marketing Experience** subsection of the **ADVERSE REACTIONS** section of the Package Insert.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We note that your January 23, 2009, submission included content of labeling in the structured product labeling (SPL) format.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Karl Stiller, Regulatory Project Manager, at (301) 796-1993.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

/s/

SCOTT E MONROE
07/27/2009