DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-858/S-001

Hoffmann-La Roche Inc.
Attention: Margaret Jack
Program Director
340 Kingsland Street
Nutley, NJ 07110

Dear Ms. Jack:

Please refer to your supplemental new drug application dated February 3, 2006 received February 7, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Boniva (ibandronate sodium) Injection.

This "Changes Being Effected" supplemental new drug application provides for a new subsection in the **PRECAUTIONS** section of the package insert entitled **Musculoskeletal Pain** and updates the **What are the possible side effects of BONIVA injection?** section of the patient package insert with information on musculoskeletal pain.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 3, 2006 (package insert and patient package insert).

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) 796-1224.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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

/s/

Eric Colman
8/7/2006 11:14:09 AM
Eric Colman for Mary Parks