DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-455/S-003

Hoffmann-La Roche Inc.
Attention: Barbara Repetto-Wenzl, Ph.D.
Regulatory Sr. Program Manager
340 Kingsland Street
Nutley, NJ 07110

Please refer to your supplemental new drug application dated September 14, 2005 received September 16, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Boniva (ibandronate sodium) Tablets.

This "Changes Being Effected" supplemental new drug application provides for revisions to the patient booklet, and replaces the word “oriental” with “Asian” in the patient package insert.

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 September 14, 2005.

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.
Acting 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/

Mary Parks

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