DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-455/S-007

Hoffman-La Roche, Inc.
Attention: Ruben Diaz
Associate Director, Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Mr. Diaz:

Please refer to your supplemental new drug application dated January 25, 2008, received January 28, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Boniva (ibandronate sodium) tablets.

We acknowledge receipt of your submissions dated March 27, 2008, April 23, 2008, May 22, 2008, August 11, 2008, October 27, 2008, November 21, 2008, and November 24, 2008.

This supplemental new drug application provides for the additional indication for use of Boniva (ibandronate sodium) tablets, 150 mg, for the prevention of osteoporosis in postmenopausal women.

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

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-455/S-007."

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for the prevention of osteoporosis in postmenopausal women because studies are impossible given the lack of pediatric patients with postmenopausal osteoporosis.

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

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

/s/

Scott Monroe

11/28/2008 10:38:27 AM