

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-858

APPROVAL LETTER



NDA 21-858

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

Dear Ms. Jack:

Please refer to your new drug application (NDA) dated December 6, 2004, received December 7, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Boniva (ibandronate sodium) Injection.

We acknowledge receipt of your submissions dated April 6, 13, and 26, June 14, and 17, July 13, and 22, August 15, 19, and 31, September 1, 2(2), 6(2), 7, 8, 9(2), and 14, October 21, and December 5, 13, 15, 16, and 20(2), 2005, and January 5, and 6, 2006.

This new drug application provides for the use of Boniva (ibandronate sodium) Injection every three months for the treatment of postmenopausal osteoporosis.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed-upon labeling text. Accordingly, the application is approved effective on the date of this letter.

Sufficient stability data have been submitted to support a 24-month expiration date.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert and container labels submitted January 5, 2006, and patient package insert submitted December 6, 2004). Marketing this product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug. Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA*. In addition, submit the content of labeling in electronic format as described in 21 CFR 314.50(l)(5) and in the format described at the following website: <http://www.fda.gov/oc/datacouncil/spl.html>. For administrative purposes, designate this submission “**FPL for approved NDA 21-858.**” Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Metabolic and Endocrine Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

We remind you of your postmarketing study commitments in your submission dated January 5, 2006. This commitment is listed below:

1. Commitment to complete a renal safety study in high risk patients receiving intravenous ibandronate, administered as a bolus and infusion, or a weekly oral bisphosphonate.

Submission of protocol	June, 2006
Completion of study	May, 2010
Submission of final study report	December, 2010

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **“Postmarketing Study Commitment Protocol”**, **“Postmarketing Study Commitment Final Report”**, or **“Postmarketing Study Commitment Correspondence.”**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

NDA 21-858

Page 3

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
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/s/

Mary Parks
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