CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-455

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-455

INFORMATION REQUEST LETTER

12/13/02

Hoffmann-La Roche Inc.
Attention: Mark Hope
Regulatory Program Director
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Mr. Hope:

Please refer to your July 15, 2002 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ibandronate Sodium Tablets.

We are reviewing the Human Pharmacokinetics and Bioavailability, and Chemistry, Manufacturing, and Controls sections of your submission and have the following comments and information requests. We request a prompt written response in order to continue our evaluation of your NDA.

1. Develop an in vitro dissolution method, and use it to generate dissolution profiles for the 2.5 mg ibandronate sodium film-coated tablet using 3 different dissolution media in ranges from _____ The test tablets should come from 3 different batches (2 batches from the pivotal clinical study, and one batch from the to-be-marketed formulation) with 12 tablets selected from each batch.

2. Provide individual in vitro dissolution results as raw data from the method used. Also, provide descriptive statistics, and plots.

3. Provide the in vitro dissolution method and acceptance criteria as part of the drug product's release and stability specifications.

If you have any questions, call Randy Hedin, Senior Regulatory Management Officer, at (301) 827-6392.

Sincerely,

{See appended electronic signature page}

Kati Johnson
Chief, Project Management Staff
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-455

8/5/02

Hoffman-La Roche Inc.
Attention: Mark Hope
Regulatory Program Director
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Mr. Hope:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Bonviva (ibandronate sodium) Tablets

Review Priority Classification: Standard (S)

Date of Application: July 15, 2002

Date of Receipt: July 16, 2002

Our Reference Number: NDA 21-455

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on September 14, 2002, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be May 16, 2002.

We note that on April 26, 2002, we granted your January 2, 2002 request for a waiver of the requirement to do pediatric studies under 21 CFR 314.55 for the indications of treatment and prevention of post-menopausal osteoporosis.

Under 21 CFR 314.102(c) of the new drug regulations, you may request an informal conference with this Division (to be held approximately 90 days from the above receipt date) for a brief report on the status of the review but not on the application's ultimate approvability. Alternatively, you may choose to receive such a report by telephone.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. All communications concerning this NDA should be addressed as follows:

U.S. Postal/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Attention: Division Document Room, 14B-19
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, call me at (301) 827-6392.

Sincerely,

{See appended electronic signature page}

Randy Hedin, R.Ph.
Senior Regulatory Management Officer
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

Randy Hedin
8/5/02 04:46:10 PM