CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-933
20-636/SE1-009

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-636/SE1-009
NDA 20-933

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Clare Lavery
900 Ridgebury Rd.
P.O. Box 368
Ridgefield, Connecticut 06877-0368

SEP 11 1998

Dear Ms. Lavery:

Please refer to your supplemental new drug application dated March 13, 1998, received March 16, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIRAMUNE® (Nevirapine) Tablets, 200 mg and to your new drug application dated April 17, 1998, received April 20, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIRAMUNE® (Nevirapine) Oral Suspension, 50 mg/mL .

We acknowledge receipt of your submissions dated:

March 27, 1998	July 16, 1998	August 14, 1998	August 31, 1998
April 22, 1998	July 24, 1998	August 20, 1998	September 9, 1998
May 13, 1998	July 29, 1998	August 26, 1998	September 10, 1998
June 12, 1998	July 30, 1998	August 27, 1998	

The User Fee goal date for NDA 20-636/SE1-009 is September 12, 1998, and the User Fee goal date for NDA 20-933 is October 17, 1998.

The supplemental application provides for the inclusion of pediatric information into the labeling. The new drug application provides for an oral suspension, which is indicated for use in combination therapy with other antiretroviral agents for the treatment of HIV-1 infection.

We have completed the review of these applications, including the submitted draft labeling, according to the regulations for accelerated approval and have concluded that adequate information has been presented to approve VIRAMUNE® (nevirapine) Tablets and VIRAMUNE® Oral Suspension for use as recommended in the draft labeling in the submission dated September 10, 1998. Accordingly, these applications are approved under 21 CFR 314.510. Approval is effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on September 10, 1998. Marketing the products with FPL that is not identical to this draft labeling may render the products misbranded and unapproved new drugs.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED

LABELING" for approved NDAs 20-636/SE1-009, 20-933. In addition, please send an electronic copy of the label in Microsoft Word. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drugs become available, revision of that labeling may be required.

Additionally, we acknowledge your Phase IV commitment specified in your facsimile dated September 8, 1998. In this facsimile, you stated your commitment to provide additional information on the safety and efficacy of nevirapine in pediatric patients by submission of the Executive Summary for ACTG 245. This submission will provide information on the following:

1. The efficacy of the double- and triple-drug regimen of nevirapine as measured by changes of surrogate markers over 48 weeks;

2. The appropriateness of a 2-week lead-in-dosing schedule as assessed by the incidence of rash events;

3. The characteristics of rash occurrence in children including the onset and accompanied symptoms and signs (such as allergic reactions); and

4. The incidence of hepatic adverse events and the significance of the alkaline phosphatase level elevations in the study population.

Protocols, data, and final reports should be submitted to your IND for these products and a copy of the cover letter sent to this NDA. Should an IND not be required to meet your Phase 4 commitments, please submit protocol, data, and final reports to this NDA as correspondences. In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of each commitment. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

We also remind you that, under 21 CFR 314.550, after the initial 120 day period following this approval, you must submit all promotional materials, including promotional labeling as well as advertisements, at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement. Please submit three copies of the introductory promotional material 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 this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and
Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug product when it is available.

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, please contact Christine Kelly, MS, MBA, RN, Consumer Safety Officer, at (301) 827-2335.

Sincerely yours,

/S/

Heidi Jolson, M.D., M.P.H.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL