DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-636/S-35
NDA 20-933/S-26

SUPPLEMENT APPROVAL

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Ann Cherian
Sr. Associate Director, Drug Regulatory Affairs
900 Ridgebury Road, P.O. Box 368
Ridgefield, CT 06877

Dear Ms. Cherian:

Please refer to your Supplemental New Drug Applications (sNDA) dated June 7, 2010, received June 7, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Viramune® (nevirapine) 200 mg Tablets and 50 mg/5 mL Oral Suspension.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated July 15, 2010.

These "Prior Approval" supplemental new drug applications were submitted to update:

- the Boxed Warning, Contraindications and Warnings and Precautions sections of the Package Insert (PI) to contraindicate using Viramune® (nevirapine) for occupational and non-occupational post-exposure prophylaxis due to cases of hepatic failure;

- the Drug Interactions section of the PI to recommend increasing the dose of lopinavir/ritonavir tablets to 500/125 mg twice daily when used in combination with Viramune® (nevirapine): and

- To add the following statement to the Who should not take VIRAMUNE? section of the Medication Guide, "VIRAMUNE is only for people diagnosed with HIV. If you have not been diagnosed as HIV positive, then do not take VIRAMUNE."

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

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Viramune® (nevirapine) was originally approved on June 24, 2008, and a REMS modification was approved on January 13, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS. Your proposed modifications to the

REMS consists of a revised Medication Guide which includes the addition of the following statement to the Who should not take VIRAMUNE? section: "VIRAMUNE is only for people diagnosed with HIV. If you have not been diagnosed as HIV positive, then do not take VIRAMUNE."

Your proposed modified REMS, submitted on June 7, 2010 and appended to this letter, is approved.

The timetable for submission of assessments of the REMS will remain the same as that approved on June 24, 2008.

There are no changes to the REMS assessment plan described in our April 7, 2009 communication.

Assessments of an approved REMS must include, under section 505-1(g)(3)(B) and (C), information on the status of any postapproval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. With respect to any such postapproval study, you must include the status of such study, including whether any difficulties completing the study have been encountered. With respect to any such postapproval clinical trial, you must include the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act. You can satisfy these requirements in your REMS assessments by referring to relevant information included in the most recent annual report required under section 506B and 21 CFR 314.81(b)(2)(vii) and including any material or significant updates to the status information since the annual report was prepared. Failure to comply with the REMS assessments provisions in section 505-1(g) could result in enforcement action.

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of FDCA.

Prominently identify submissions containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 20-636, NDA 20-933
REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 20-636, NDA 20-933
PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 20-636, NDA 20-933
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

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 Linda C. Onaga, MPH Regulatory Project Manager, at (301) 796-0759 or the Division Mainline at (301) 796-1500.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products

Center for Drug Evaluation and Research

ENCLOSURE(S):
REMS
Package Insert
Medication Guide

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20933	SUPPL-26	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	VIRAMUNE (NEVIRAPINE) SUSPENSION
NDA-20636	SUPPL-35	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	VIRAMUNE (NEVIRAPINE) ORAL TABS 200MG

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

/s/

KENDALL A MARCUS
07/20/2010