



NDA 020933/S-022
NDA 020636/S-032

SUPPLEMENT APPROVAL

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Ann Cherian
Senior Associate Director, Drug Regulatory Affairs
900 Ridgebury Rd
P.O. Box 368
Ridgefield, CT 06877-0368

Dear Ms. Cherian:

Please refer to your supplemental new drug applications dated March 23, 2009, received March 24, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Viramune[®] (nevirapine) Oral Suspension, 50 mg/5 mL and Viramune[®] (nevirapine) Tablets, 200 mg.

We acknowledge receipt of your submissions dated July 15, 2009, August 17, 2009, August 28, 2009, September 8, 2009, September 11, 2009, October 2, 2009, October 12, 2009, November 2, 2009, November 6, 2009, November 11, 2009, December 2, 2009, December 8, 2009, and December 14, 2009.

These "Prior Approval" supplemental new drug applications contain proposed changes to the following sections of the U.S. package insert: DRUG INTERACTIONS, CLINICAL PHARMACOLOGY, and PATIENT COUNSELING INFORMATION to include addition of drug-drug interaction information related to the following antiretroviral drugs when co-administered with nevirapine:

- Atazanavir/ritonavir
- Darunavir/ritonavir
- Fosamprenavir and Fosamprenavir/ritonavir
- Maraviroc
- Saquinavir/ritonavir

The supplemental new drug applications also propose modifications to the MEDICATION GUIDE and the approved Risk Evaluation and Mitigation Strategy (REMS), and they contain a REMS assessment.

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text.

Within 14 days from the date of this letter, please 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 structured product labeling (SPL) format that includes the changes approved in this supplemental application.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Viramune (nevirapine) was originally approved on June 24, 2008 and consists of a Medication Guide and a timetable for the submission of the assessments of the REMS. On July 15, 2009, you submitted an assessment of your REMS and on September 11, 2009, you submitted a proposed modified REMS.

After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, your proposed modified REMS is approved and is appended to this letter. The REMS consists of the Medication Guide and a timetable for submission of assessments. The timetable for submission of assessments will remain the same as that approved on June 24, 2008, with the original approval of the REMS.

Please note that:

- this Medication Guide must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling [21 CFR 201.57(c)(18)] or 21 CFR 201.80(f)(2)];
- you are responsible for ensuring that this Medication Guide is available for distribution to every patient who is dispensed a prescription for this product [21 CFR 208.24];
- the final printed Medication Guide distributed to patients must conform to all conditions described in 21 CFR 208.20, including a minimum of 10 point text; and
- you are responsible for ensuring that the label of each container or package includes a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and states how the Medication Guide is provided [21 CFR 208.24(d)].

We remind you that in addition to the assessments submitted according to the timetable 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 §505-1(g)(2)(A) of FDCA.

Prominently identify submissions containing 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:

NDA 20-933/20-636 REMS ASSESSMENT

**NEW SUPPLEMENT FOR NDA 20-933/20-636
PROPOSED REMS MODIFICATION
REMS ASSESSMENT**

NEW SUPPLEMENT (NEW INDICATION FOR USE)

**FOR NDA 20-933/20-636
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, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide). For administrative purposes, please designate this submission, "SPL for approved NDA 020933/S-022 **and** NDA 020636/S-032.

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

LETTERS TO HEALTH CARE PROFESSIONALS

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Amalia Himaya, Regulatory Project Manager, at 301-796-3391 or 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: REMS, Package Insert, and Medication Guide

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20933	SUPPL-22	BOEHRINGER INGELHEIM PHARMACEUTICA LS INC	VIRAMUNE (NEVIRAPINE) SUSPENSION
NDA-20636	SUPPL-32	BOEHRINGER INGELHEIM PHARMACEUTICA LS 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
01/13/2010