DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020933/S-029
NDA 020636/S-038
NDA 201152/S-001

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Maria Gigliotti, M.S.
Associate Director, Regulatory Affairs
900 Ridgebury Rd
P.O. Box 368
Ridgefield, CT 06877-0368

Dear Ms. Gigliotti:

Please refer to your Supplemental New Drug Applications (sNDAs) dated April 5, 2011, received April 5, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Viramune® (nevirapine) Oral Suspension (50 mg/5 mL), Viramune® (nevirapine) Tablets (200 mg), and Viramune® XR™ (nevirapine) Extended-Release Tablets (400 mg).

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated December 17, 2009.

These "Prior Approval" supplemental new drug applications propose to eliminate the requirement for the approved Viramune REMS.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Viramune (nevirapine) was originally approved on June 24, 2008, and the most recent REMS modification was approved on March 25, 2011. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Viramune (nevirapine) Oral Suspension, Tablets, and Extended-Release Tablets.

We have determined that it is no longer necessary to include the Medication Guide as an element of the approved REMS, and that a REMS is no longer necessary to ensure that the benefits of Viramune (nevirapine) Oral Suspension, Tablets, and Extended-Release Tablets outweigh their

risks. Therefore, we agree with your proposal and a REMS for Viramune (nevirapine) Oral Suspension, Tablets, and Extended-Release Tablets is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

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 the Division's main number 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

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
05/06/2011