DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-636/S-022
NDA 20-933/S-012

Boehringer Ingleheim Pharmaceuticals, Inc.
Attention: Mr. Kevin Dransfield
Associate Director, Regulatory Affairs
900 Ridgebury Rd./P.O. Box 368
Ridgefield,CT 06877-0368

Dear Mr. Dransfield:

Please refer to your supplemental new drug applications dated January 29 2004, received January 30 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIRAMUNE® (nevirapine) Tablets and VIRAMUNE® (nevirapine) Suspension.

These "Changes Being Effected" supplemental new drug applications provide for the inclusion of changes in the VIRAMUNE® (nevirapine) labels that add further information about hepatic adverse events and risk factors for these events in patients receiving nevirapine.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on January 29, 2004 (Package insert, Patient Package insert.)

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 call Destry Sillivan, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Jeffrey Murray, M.D.
Deputy Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
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/

Jeffrey Murray
5/24/04 02:02:35 PM