



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 20-636/S-025
NDA 20-933/S-014

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Kevin Dransfield, Senior Associate Director
Drug Regulatory Affairs
900 Ridgebury Road/P.O. Box 368
Ridgefield, CT 06877-0368

Dear Mr. Dransfield:

Please refer to your supplemental new drug applications dated January 12, 2005, received January 13, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Viramune® (nevirapine) tablets and Viramune® (nevirapine) oral suspension.

We acknowledge receipt of your amendments dated January 24, 2005.

These "Changes Being Effected" supplemental new drug applications provide for changes to the Boxed Warning and the Indications and Usage section of the Viramune® package insert to reflect new information about the risk of hepatotoxicity associated with the use of nevirapine. The changes also incorporate the addition of a Medication Guide.

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on January 24, 2005.

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.

NDA 20-636/S-025
NDA 20-933/S-014
Page 2

If you have any questions, call Elizabeth Thompson, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure:
clean copy of labeling

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

/s/

Debra Birnkrant
2/24/05 12:46:23 PM
NDA 20-636, 20-933