DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-636/S-026
NDA 20-933/S-015

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: John P. Barry, Ph.D.
Manager, Drug Regulatory Affairs
900 Ridgebury Rd/P.O. Box 368
Ridgefield, CT 06877-0368

Dear Dr. Barry:

Please refer to your supplemental new drug applications dated July 15, 2005, received July 16, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Viramune® (nevirapine) Tablets and Oral Suspension.

We acknowledge receipt of your submissions dated January 30, 2006, June 1, 2006, October 11, 2006, October 20, 2006, March 30, 2007, April 11, 2007 and April 12, 2007. These submissions constituted a complete response to our January 23, 2006 approvable letter.

These supplemental new drug applications proposed changes to the Microbiology, *Antiviral Activity* section; Clinical Pharmacology, *Gender* section; Adverse Reactions, *Pediatric Patients* section; and the addition of an Immune Reconstitution Syndrome statement in the Precautions section. Updated drug interaction data for methadone, clarithromycin and lopinavir were also proposed. These supplements also included a proposal to change the pregnancy category from C to B.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert). Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* For administrative purposes, designate these submissions "**FPL for approved supplement NDA 20-636/S-026, NDA 20-933/S-015**." Approval of these submissions by FDA is not required before the labeling is used.

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Elizabeth Thompson, M.S., Regulatory Project Manager, at (301) 796-0824.

Sincerely,

{See appended electronic signature page}

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

Enclosure (clean copy of approved PI)

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
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NDA 20-933, 20-636