



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-636/S-029

NDA 20-933/S-019

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 3, 2007, received July 5, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Viramune[®] (nevirapine) Tablets and Viramune[®] (nevirapine) Oral Suspension.

These "Changes Being Effected" supplemental new drug applications provide for changes to the WARNINGS and ADVERSE REACTIONS sections for the addition of wording regarding observation of rhabdomyolysis in patients experiencing skin and/or liver reactions.

We completed our review of these applications, and they 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 submitted labeling (package insert and medication guide submitted July 3, 2007). 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-029, NDA 20-933/S-019.**" 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

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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

**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
8/16/2007 03:21:00 PM
NDA 20-933, 20-636