



NDA 20-636/S-020  
NDA 20-933/S-010

Boehringer Ingelheim 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 May 8, 2003, received May 9, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIRAMUNE<sup>®</sup> (nevirapine) Tablets and VIRAMUNE<sup>®</sup> (nevirapine) Suspension

We acknowledge receipt of your submissions dated May 13, 2003, May 23, 2003, and July 8, 2003.

These supplemental new drug applications provide for the inclusion of multiple changes in the VIRAMUNE<sup>®</sup> (nevirapine) labels regarding hepatic toxicity.

We have completed the review of these applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert) and/or submitted labeling (package insert submitted July 8, 2003, patient package insert submitted July 8, 2003). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-636/S-020, NDA 20-933/S-010." 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, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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, please call Destry Sullivan, 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

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Debra Birnkrant  
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NDA 20-933, 20-636