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.


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/
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Debra Birnkrant
4/13/2007 01:01:12 PM
NDA 20-933, 20-636