DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-412/S-033
NDA 20-413/S-025

Bristol-Myers Squibb Company
Attention: David L. Silberstein
Associate Director, Global Regulatory Science
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Mr. Silberstein:

Please refer to your supplemental new drug applications (NDAs) dated December 3, 2008, received December 3, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zerit® (stavudine) Capsules, 15 mg, 20 mg, 30 mg and 40 mg and Zerit® (stavudine) Powder for Oral Solution, 1mg/mL.

These "Changes Being Effected" supplemental new drug applications provide for the following changes in the Package and Patient Package Inserts regarding the use of stavudine with hydroxyurea:

Package Insert

I. The language "with or without hydroxyurea" was deleted throughout the label.

II. Under WARNINGS, the language "Use with Didanosine and Hydroxyurea Based Regimens" was deleted in the Hepatic Impairment and Toxicity subsection.

III. Under ADVERSE REACTIONS, the paragraph explaining the potential hepatoxicity, pancreatitis, and peripheral neuropathy with didanosine and hydroxyurea was revised and moved from the Adults subsection to Observed During Clinical Practice subsection under a new subheading entitled "Use with Didanosine- and Hydroxyurea-Based Regimens."

Patient Package Insert

I. Deletion and revision of the sentences referring to a ZERIT, didanosine, and hydroxyurea combination in the section "What are the possible side effects of ZERIT?"

II. Deletion of the language "with or without hydroxyurea" in the subsection Pancreatitis under section "What are the possible side effects of ZERIT?"

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 content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on December 3, 2008.

The final printed labeling (FPL) must be identical to the labeling (package and patient package inserts) submitted on December 3, 2008.

In addition, within 21 days of the date of this letter, amend any pending applications for these NDAs with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Amalia Himaya, Regulatory Project Manager, at (301) 796-3391.

Sincerely,

{See appended electronic signature page}

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

Enclosure: labeling

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

/s/

Kendall Marcus

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