DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 209937

NDA 20-412/S-034
NDA 20-413/S-026

Bristol-Myers Squibb Company
Attention: Beatrice Anduze-Faris, M.D.
Group Director, Regulatory Strategy Mature Brands
P.O. Box 4000, Mail Stop D 12-02
Princeton, NJ 08543-4000

Dear Dr. Anduze-Faris:

Please refer to your supplemental new drug applications dated January 23, 2009, received January 23, 2009, 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.

We also acknowledge receipt of your submissions dated June 16, 2009.

These supplemental new drug applications provide for revisions to the Clinical Pharmacology, Metabolism and Elimination subsections, of the U.S. Package Insert to include the results from Study A1445-141.

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.

As soon as possible, but no later than 14 days from the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplements NDAs 20-412/S-034 and 20-413/S-026."

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and patient package insert).

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/

Jeffrey Murray
7/8/2009 01:52:49 PM