DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020412 S-037
NDA 020413/S-029

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Bristol-Myers Squibb Company
Attention: Mary Christian, Pharm.D., MBA
Group Director, Global Regulatory Sciences
Research & Development
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Dr. Christian:

Please refer to your Supplemental New Drug Application (sNDA) dated April 29, 2011, received April 29, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zerit® (stavudine), 15 mg, 20 mg, 30 mg, and 40 mg Capsules and 1 mg/mL Powder for Oral Solution.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated August 23, 2010.

These supplemental new drug applications propose to eliminate the requirement for the approved REMS.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Zerit® (stavudine) Capsules and Powder for Oral Solution was originally approved on December 10, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Zerit® (stavudine) Capsules and Powder for Oral Solution.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS, and a REMS is no longer necessary to ensure that the benefits of Zerit® (stavudine) Capsules and Powder for Oral Solution outweigh

its risks. Therefore, we agree with your proposal and a REMS for Zerit® (stavudine) Capsules and Powder for Oral Solution is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

REPORTING REQUIREMENTS

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 or the Division's main number at (301) 796-1500.

Sincerely,

{See appended electronic signature page}

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

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

/s/

KENDALL A MARCUS
05/11/2011