DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020156/S-047
NDA 021183/S-024

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Bristol-Myers Squibb Company
Attention: Mary Christian, PharmD, MBA
Group Director, Global Affairs Sciences
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Dr. Christian:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received April 20, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Videx (didanosine) Pediatric Powder Oral Solution and Videx EC (didanosine, USP) Capsules.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated April 20, 2011.

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 Videx (didanosine) Pediatric Powder Oral Solution and Videx EC (didanosine, USP) Capsules was originally approved on January 25, 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 Videx (didanosine) Pediatric Powder Oral Solution and Videx EC (didanosine, USP) Capsules.

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 Videx (didanosine) Pediatric Powder Oral Solution and Videx EC (didanosine, USP) Capsules outweigh its risks. Therefore, we agree with your proposal and a

REMS for Videx (didanosine) Pediatric Powder Oral Solution and Videx EC (didanosine, USP) Capsules 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 Linda C. Onaga, Regulatory Project Manager at (301) 796-0759.

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
05/10/2011