DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-156/S044

Bristol-Myers Squibb Company
Attention: Beatrice Anduze-Faris, M.D.
Group Director, Global Mature Brands
Global Regulatory Sciences
Rte 206 & Provinceline Rd
Princeton NJ, 08540

Dear Dr. Anduze-Faris:

Please refer to your supplemental new drug application dated and received December 10, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIDEX (didanosine) pediatric powder for oral solution.

We acknowledge receipt of your submissions dated May 22, 2009 and June 4, 2009.

This supplemental new drug application provides for revisions to the U.S. Package Insert to include results from a drug-drug interaction study evaluating the bioavailability of didanosine when co-administered in subjects who were on a stable dose of methadone, results from a PK study in patients with moderate to severe hepatic impairment, and to change the labeling format in accordance with the Physician's Labeling Rule (PLR) of January 2006.

We completed our review of this application, as amended. This application is 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, please submit the 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 to the enclosed labeling (text for the package insert and text for the patient package insert). 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 NDA 20-156/S-044."

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert). Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

Submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 Stacy Powers Newalu, M.P.H., Regulatory Project Manager, at (301) 796-3978.

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 (clean copy of approved 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
6/11/2009 02:43:25 PM