DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-183 **NDA APPROVAL**

Bristol-Myers Squibb Company
Attn: Katherine Takaki, Ph.D.
Director, Global Regulatory Affairs
5 Research Parkway, Sig 91 Bldg., 3 SIG-511
Wallingford, CT 06492

Dear Dr. Takaki,

Please refer to your supplemental new drug application (NDA) dated March 31, 2008, received April 1, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIDEX EC (didanosine) Delayed Release Capsule.

We acknowledge receipt of your submissions dated September 18, 2008 and we also acknowledge receipt of the September 26, 2008 electronic mail correspondence which contained revised labeling.

This supplemental new drug application provides for the use of Videx EC for the treatment of HIV in pediatric patients who weigh greater than 20 kg. This application also updates the CLINICAL PHARMACOLOGY section of the Package Insert with information related to hepatic impairment. The Patient Package Insert was also updated to include information on pediatric patients.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text and with the minor editorial revision listed below and indicated in the enclosed labeling.

Revision: Table 7 entitled Pharmacokinetic Parameters for Didanosine in HIV-infected Patients footnote (a) was revised as follows:

> [a] The pharmacokinetic parameters (mean ± standard deviation) of didanosine were predicted by a population pharmacokinetic model based on combined clinical studies.

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 21-183\S020."

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for children who weigh less than 20 kg because necessary studies are impossible or highly impracticable. This is because younger children can not reliably swallow intact capsules.

We note that you have fulfilled the pediatric study requirement for patients who weigh greater than or equal to 20 kg for this application.

In addition, 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 the Division of Antiviral Products and two copies of both the promotional materials and the package inserts 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 safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and 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). All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 21-183 for this drug product, not to this NDA. In the future, do not make submissions to this NDA except for the final printed labeling requested above.

If you have any questions, call Stacy Newalu, MPH, 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: Package Insert, Patient Package Insert

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

/s/

Debra Birnkrant
9/29/2008 12:41:57 PM
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