DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-183

Bristol-Myers Squibb Company
Attention: Mari-Laure Papi
Associate, Worldwide Regulatory Affairs
5 Research Parkway
Wallingford, CT 06492

Dear Ms. Papi:

Please refer to your supplemental new drug application dated November 2, 2001, received November 5, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIDEX® EC (didanosine) Delayed Release Capsules.

This "Changes Being Effected" supplemental new drug application provides for the inclusion of new information regarding fat redistribution, to be included in the PRECAUTIONS section of the VIDEX® EC (didanosine) label, as follows:

PRECAUTIONS

Fat Redistribution

Redistribution/accumulation of body fat including central obesity, dorsocervical fat enlargement (buffalo hump), peripheral wasting, facial wasting, breast enlargement, and "cushingoid appearance" have been observed in patients receiving antiretroviral therapy. The mechanism and long-term consequences of these events are currently unknown. A causal relationship has not been established.

PRECAUTIONS / Information for Patients (See Patient Information Leaflet.) section:

Patients should be informed that redistribution or accumulation of body fat may occur in patients receiving antiretroviral therapy and that the cause and long-term health effects of these conditions are not known at this time.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert submitted November 2, 2001, patient package insert submitted November2, 2001). Accordingly, these supplemental applications are approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Destry M. Sillivan, M.S., Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.,
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
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/

Debra Birnkrant
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