

NDA 21-183/S-002

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 March 28, 2001, received March 29, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIDEX® EC (didanosine) Delayed Release Capsules.

We acknowledge receipt of your submissions dated August 30, 2001, September 20, 2001, November 20, 2001, and January 23, 2002.

This supplemental new drug application provides for the inclusion of safety and efficacy data from the final results of study AI454-152 in the VIDEX® EC (didanosine) Delayed Release Capsules package insert.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted January 23, 2002, patient package insert submitted January 23, 2002).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-183/S-002." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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, call Destry M. Sullivan, 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

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/s/

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Debra Birnkrant  
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