

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

**APPLICATION NUMBER: 20-154/S-028
20-155/S-020
20-156/S-021**

APPROVAL LETTER



Food and Drug Administration
Rockville MD 20857

NDA 20-154/S-028
NDA 20-155/S-020
NDA 20-156/S-021

JUL 1 1999

Bristol-Myers Squibb Company
Attention: Cynthia F. Piccirillo
Associate Director, Worldwide Regulatory Affairs
5 Research Parkway
Wallingford, CT 06492

Dear Ms. Piccirillo:

Please refer to your supplemental new drug applications dated June 30, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIDEX (didanosine) Chewable/Dispersible Tablets, Buffered Powder for Oral Solution, and Pediatric Powder for Oral Solution.

We acknowledge receipt of your submissions dated:

November 20, 1998	March 10, 1999	June 29, 1999
January 29, 1999	May 14, 1999	
February 4, 1999	June 17, 1999	

These supplemental new drug applications provide for the use of VIDEX in combination with other antiretroviral agents for the treatment of HIV-1 infection.

We have completed the review of these applications and have concluded that adequate information has been presented to demonstrate that VIDEX is safe and effective for use as recommended in the draft labeling dated July 1, 1999. Accordingly, these applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted July 1, 1999). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 16 paper copies and one diskette that includes a PDF version of the FPL as soon as it is available, in no case 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 "FINAL PRINTED LABELING" for approved NDA 20-154/S-028, NDA 20-155/S-020, and NDA 20-156/S-021. Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). We note that you have not fulfilled the requirements of 21 CFR 314.55 (or 601.27). We are deferring submission of your pediatric studies until December 2, 2000.

If you believe that this drug qualifies for a waiver of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation in accordance with the provisions of 21 CFR 314.55 within 60 days from the date of this letter. We will notify you within 120 days of receipt of your response whether a waiver is granted. If a waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). We acknowledge receipt of your Proposed Pediatric Study Request dated June 7, 1999. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity.

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, contact Melissa M. Truffa, R.Ph., Regulatory Project Manager, at (301) 827-2335.

Sincerely,



Heidi M. Jolson, M.D., M.P.H.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

NDA 20-154
NDA 20-155
NDA 20-156

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Concurrence:

HFD-530/Dir/Jolson
HFD-530/DepDir/Birnkrant 6/29/99
HFD-530/TLMO/Cvetkovich 6/30/99
HFD-530/MO/Fleischer 6/29/99
HFD-530/BioPharmTL/Reynolds 6-28-99
HFD-530/Micro/Mishra 6/30/99
HFD-530/MicroTL/Connors 6/28/99
HFD-530/Stat/Elashoff 6-28-99
HFD-530/StatTL/G. Aras 6/30/99
HFD-530/SCSO/DeCicco 6-28-99
HFD-530/CSO/Truffa 6-28-99

cc:

Archival NDA 20-154, 20-155, 20-156

HFD-530/Div. Files

HFD-530/M. Truffa

HFD-530/Dir/Jolson

HFD-530/DepDir/Birnkrant

HFD-530/TLMO/Cvetkovich

HFD-530/MO/Fleischer

HFD-530/MicroTL/Connors

HF-2/MedWatch (with labeling)

HFD-002/ORM (with labeling)

HFD-104/ADRA (with labeling)

HFD-40/DDMAC (with labeling)

HFD-613/OGD (with labeling).

HFD-95/DDMS (with labeling)

HFD-830/DNDC Division Director

HFD-104/Kweder

HFD-104/Hassall

DISTRICT OFFICE

Drafted by: mmt/June 23, 1999

Initialed by:

final:

filename: v:drive/DAVDP/CSO/truffa/NDA/NDA20154/letters/AP

APPROVAL (AP)