CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-183

PHARMACOLOGY REVIEW(S)

PHARMACOLOGIST'S REVIEW

DRAFT

NDA 21-183

Date Submitted: January 31, 2000
Date Assigned: February 11, 2000
Date Completed: October 25, 2000

SPONSOR: Bristol-Myers Squibb Company
Pharmaceutical Research Institute
5 Research Parkway
Wallingford, CT 06492-7660

DRUG: VIDEX ——— EC (enteric release beadlet capsules)
(BMY-40900, ddI)

STRUCTURE: 2',3'-dideoxyinosine

FORMULATION: Enteric Coated Capsule for Oral Administration in 125, 200, 250 and 400 mg Strengths;

RELATED INDs: Treatment IND ———
NDA 20-154 (Chewable/Dispersible Buffered Tablets for Oral Administration in 25, 50, 100, 150 or 200 mg Strengths)
NDA 20-155 (Buffered Powder for Oral Solution for Oral Administration in 100, 167 or 250 mg Strengths)
NDA 20-156 (Pediatric Powder for Oral Solution for Oral Administration in 2 gm/4 oz or 4 gm/8 oz. Strengths)

INDICATION(S): [redacted]

INTRODUCTION: Didanosine is a synthetic purine nucleoside analog which exhibits activity against HIV-1. It was approved in October, 1991 (NDA 20-154). This submission contains findings in support of a new enteric release beadlet capsule to treat HIV-infected patients and revisions to relevant sections of the VIDEX package insert.

COMMENTS: No new preclinical pharmacology and toxicology studies were submitted to this NDA. Information submitted under NDA 20-154 was referenced. There were no revisions of the preclinical pharmacology and toxicology sections of the package insert for VIDEX in this submission.

CONCLUSION: There are no pharmacology/toxicology issues which would preclude approval of this NDA.

C. Anita H. Bigger, Ph.D.
Pharmacologist

Concurrences:
HFD-530/WDempsey
HFD-530/JFarrelly
HFD-530/ABigger10-25-00

Disk:
HFD-530/JFarrelly

cc:
HFD-530 Original IND
HFD-530 Division File
HFD-340
HFD-530/TCvetkovich
HFD-530/RFleischer
HFD-530/LMishra
HFD-530/KYLo
HFD-530/RKumi
HFD-530/ABigger
HFD-530/DSillivan