CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-183

CHEMISTRY REVIEW(S)

DIVISION OF ANTIVIRAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls Section

NDA #: 21-183
CHEMISTRY REVIEW #: 1 **DATE REVIEWED:** 31-OCT-00

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
Pre-NDA	19-SEP-99	01-OCT-99	01-OCT-99
Original NDA	31-JAN-00		
BC	17-MAR-00	20-MAR-00	
BC	11-SEP-00	12-SEP-00	
BC	16-OCT-00	17-OCT-00	
BC	27-OCT-00	30-OCT-00	
BC	30-OCT-00	31-OCT-00	

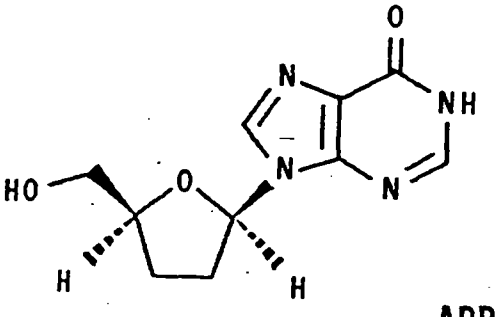
NAME/ADDRESS OF APPLICANT: Bristol-Myers Squibb Company
5 Research Parkway
Wallingford, CT 06492

DRUG PRODUCT NAME
Proprietary: [redacted]
Nonproprietary: Didanosine
Code Name/#:

PHARMACOLOGICAL CATEGORY: Antiviral
INDICATION: Treatment of HIV Infection
DOSAGE FORM/STRENGTH: Delayed-Release Capsules/125, 200, 250 and 400 mg
ROUTE OF ADMINISTRATION: PO Adult Dosing: 400 mg QD
CHEM.TYPE/THER.CLASS: 3P
PHARMACOLOGICAL CATEGORY: Antiviral
INDICATION: Treatment of Symptomatic HIV Disease

Rx/OTC: X Rx _ OTC
SPECIAL PRODUCT: _ Yes X No
CHEMICAL NAME / STRUCTURAL FORMULA:

2',3'-dideoxyinosine
$C_{10}H_{12}N_4O_3$
M.W. 236.23



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SUPPORTING DOCUMENTS:

DMF	TYPE	HOLDER	ITEM REF	CODE	STATUS
	III			4	Adequate
	III			4	Adequate
	III			4	Adequate
	III			4	Adequate
	III			4	Adequate
	III			4	Adequate

1 – DMF Reviewed. Other codes indicate why the DMF was not reviewed, as follows:
2 – Type I DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

RELATED DOCUMENTS:

NDA 20-154 chemistry review for didanosine drug substance
Chemistry facsimile letters dated 9/26/00
Teleconference minutes dated 10/23/00
Teleconference minutes dated 10/30/00

CONSULT REVIEWS:

Trade name review by OPDRA
Product specific inspection of DS and DP manufacturing sites

CONCLUSIONS/RECOMMENDATIONS:

The NDA submission and accompanying amendments provide adequate information on the chemistry, manufacturing and controls for VIDEX EC (didanosine) Delayed-Release Capsules. The manufacturing facilities have acceptable cGMP status. The NDA, as amended, is therefore recommended for approval from the chemistry perspective.

/S/ 11/22/00

Ko-Yu Lo, Ph.D., Review Chemist

Concurrence:
HFD-530/SMiiler /S/ 11/22/00
cc:
Orig. NDA 21-183
HFD-530/Div. File
HFD-530/KLo
HFD-530/SMiller
HFD-530/MO
HFD-530/CSO

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WITHHOLD 15 PAGE (S)

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: **NDA 21183/000**
Priority: **P**
Org Code: **530**
Stamp: **31-JAN-2000** Regulatory Due: **31-OCT-2000**
Action Goal:
District Goal: **01-OCT-2000**
Applicant: **BRISTOL MYERS SQUIBB**
5 RESEARCH PKY
WALLINGFORD, CT 064927660
Brand Name: **VIDEX EC(DIDANOSINE)125/200/250/400MG EC**
Established Name:
Generic Name: **DIDANOSINE**
Dosage Form: **DRC (DELAYED RELEASE CAPSULE)**
Strength: **125, 200, 250, 400 MG**

FDA Contacts:

D. SILLIVAN	**(HFD-530)**		**, Project Manager**
K. LO	**(HFD-530)**	**301-827-2397**	**, Review Chemist**
S. MILLER	**(HFD-530)**	**301-827-2392**	**, Team Leader**

Overall Recommendation:

ACCEPTABLE on 19-OCT-2000 by M. GARCIA (HFD-322) 301-594-0095

Establishment: [redacted]
DMF No:
AADA No:

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **24-AUG-2000**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**
Responsibilities: [redacted]

Establishment: [redacted]
DMF No:
AADA No:

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **19-OCT-2000**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**
Responsibilities: [redacted]

Establishment: **2623241**
BRISTOL MYERS BARCELONETA IN
CARR #2 KM 56.4
BARCELONETA, PR 00617
DMF No:
AADA No: **020154**

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Responsibilities: **DRUG SUBSTANCE MANUFACTURER**

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FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Milestone Date: **14-FEB-2000**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Establishment: **1819504**
BRISTOL MYERS SQUIBB CO
2400 WEST LLOYD EXPY
EVANSVILLE, IN 477210001

DMF No:
AADA No:

Profile: **CTR** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **26-APR-2000**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities: **FINISHED DOSAGE MANUFACTURER**

Establishment: **1825662**
BRISTOL MYERS SQUIBB CO
HWY 62 WEST BLDG 122
MOUNT VERNON, IN 47620

DMF No:
AADA No:

Profile: **CTR** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **26-APR-2000**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities: **FINISHED DOSAGE MANUFACTURER**

Establishment: **2211101**
BRISTOL MYERS SQUIBB CO
1 SQUIBB DR
NEW BRUNSWICK, NJ 08903

DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **22-FEB-2000**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities: **FINISHED DOSAGE STABILITY TESTER**

Establishment: [ ]

DMF No:
AADA No:

Profile: **CTR** OAI Status: **NONE**

Responsibilities: [ ]

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ON ORIGINAL

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Last Milestone: **OC RECOMMENDATION**
Milestone Date: **05-OCT-2000**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Establishment: [redacted]

DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **14-FEB-2000**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities:

APPEARS THIS WAY
ON ORIGINAL