

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: NDA 50-443/S-026

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CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: NDA 50-443/S-026

Trade Name: BLENOXANE 15 & 30 UNIT VIALS

Generic Name:(Sterile Bleomycin Sulfate, USP)

Sponsor: Bristol-Myers Squibb

Approval Date: September 30, 1996

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 50-443/S-026

APPROVAL LETTER

SEP 30 1996

NDA 50-443/S-026

Bristol-Myers Squibb
P.O. Box 4000
Princeton, NJ 08543-4000

Attention: William J. Regan
Director, CMC for Marketed Products

Dear Mr. Regan:

Reference is made to your supplemental new drug application dated March 28, 1996 pursuant to section 507 of the Federal Food, Drug and Cosmetic Act for Blenoxane® (Sterile bleomycin sulfate, USP), 15 unit and 30 unit vials.

The supplemental application provides for
as an alternate site to perform the depressor
substances test on the filled drug product.

We have completed our review of this supplement and it is approved, effective as of 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.

Sincerely yours,

RHW 9-30-96

Rebecca H. Wood, Ph.D.,
Chemistry Team Leader, DNDC I
Division of Oncology Drug Products (HFD-150)
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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cc:

Orig. NDA 20-035
Div File/HFD-150
HFD-150/RHWood
HFD-150/YAHsieh
HFD-150/DSpillman
HFD-358/JCook

APPROVAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 50-443/S-026

CHEMISTRY REVIEW(S)

SEP 30 1996

CHEMIST'S REVIEW		1. ORGANIZATION HFD-150 DODP		2. NDA NUMBER 50-443	
3. NAME AND ADDRESS OF APPLICANT (City and State) Bristol-Myers Squibb P.O. Box 4000 Princeton, NJ 08543-4000 Attention: William Regan Tel: (609)-252-4732				4. AF NUMBER	
				5. SUPPLEMENT (S) NUMBER(S) DATES(S)	
6. NAME OF DRUG Blenoxane®		7. NONPROPRIETARY NAME Sterile Bleomycin Sulfate, USP		SCM-026	28-Mar-96
8. SUPPLEMENT PROVIDES FOR: Change of depressor substances test site				9. AMENDMENTS DATES	
10. PHARMACOLOGICAL CATEGORY antineoplastic		11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC <input type="checkbox"/>		12. RELATED IND/NDA/DMF	
13. DOSAGE FORM(S) sterile powder for injection		14. POTENCY 15 and 30 units/vial			
15. CHEMICAL NAME AND STRUCTURE				16. RECORDS AND REPORTS CURRENT YES <input type="checkbox"/> NO <input type="checkbox"/> REVIEWED YES <input type="checkbox"/> NO <input type="checkbox"/>	
17. COMMENTS CC: HFD-150/Div. File HFD-150/RWood HFD-150/YAHsieh HFD-150/DSpillman R/D Init. by: <i>RHW</i> 9-25-96					
18. CONCLUSIONS AND RECOMMENDATIONS Approval is recommended per attached draft letter.					
19. REVIEWER					
NAME Yung-Ao Hsieh, Ph.D.		SIGNATURE <i>Yung-Ao Hsieh</i>		DATE COMPLETED 10-Sep-96	
DISTRIBUTION ORIGINAL JACKET <input checked="" type="checkbox"/> DIVISION FILE <input checked="" type="checkbox"/> REVIEWER <input checked="" type="checkbox"/> CSO <input checked="" type="checkbox"/> SUP. CHEMIST <input checked="" type="checkbox"/>					