

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**64084**

**CHEMISTRY REVIEW(S)**

Memorandum for the File (Chemistry Review #7)

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DATE: May 22, 1996  
FROM: Susan Rosencrance  
SUBJECT: Minor Amendment submitted 5/21/96 for Pharmacia's  
Sterile Bleomycin Sulfate USP  
TO: AADA 64-084

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The applicant has provided the requested information (batch records, COAs, stability data) for the lots tested and found acceptable by the Denver district (BLF003 & BLS002). The batch records show that both of these lots are subdivisions from 1 lot of bulk solution compounded on 1/7/94 (8.03L; BLT003). The yields for lots BLF003 and BLS002 were 779 vials and 587 vials, respectively. The manufacturing process is the same as that described in the master production record. The stability data show that the product is subject to thermal degradation; however, when stored under refrigeration as indicated in the labeling the batches remained within specification throughout a 2-year period.

Conclusion: Recommend approval for AADA 64-084 - Sterile  
Bleomycin Sulfate, USP - Pharmacia.

cc: AADA 64-084  
Division File  
Field Copy

Endorsements:

HFD-643/SRosencrance/5/22/96  
HFD-643/JHarrison/5/22/96  
X:\NEW\FIRMSNZ\PHARMACI\LTRS&REV\64084AP2.D  
F/T by:RLWest:5/22/96

*IS/* *5/22/96* *12/96*

APPROVAL

**Memorandum for the File (Chemistry Review #6)**

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DATE: April 19, 1996  
FROM: Susan Rosencrance, Chemist  
THROUGH: John Harrison, Chemistry Team Leader  
SUBJECT: Minor Amendment submitted 4/10/96 for Pharmacia's  
Sterile Bleomycin Sulfate USP  
TO: AADA 64-084

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The CMC information in this submission was found acceptable by N. Sager in Chemistry Review #4. Issues remaining prior to approval were acceptable lab results and approval of the bulk application (AADA 64-044). The acceptable lab results were recently received from the Denver district. In addition, the bulk application (AADA 64-044) is now acceptable and currently in the approval matrix. Tables listing the specifications for the drug substance/finished product, stability requirements and components/composition were provided in Chemistry Review #4.

cc: AADA 64-084  
Division File  
Field Copy

Endorsements:

HFD-643/SRosencrance/4/19/96 ✓  
HFD-643/JHarrison/ *J. Harrison* 4/23/96  
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F/T by /  
APPROVAL

*151*  
*5/6/96*

1. CHEMIST'S REVIEW NO. 4
2. AADA # 64-084
3. NAME AND ADDRESS OF APPLICANT

Pharmacia Inc.  
P.O. Box 16529  
Columbus OH 43216-6529

Frederick L. Grab. Ph.D  
(614)764-8128  
(614)764-8102 (FAX)

4. LEGAL BASIS FOR SUBMISSION

21 CFR §450.210

5. SUPPLEMENT(S)

None.

6. PROPRIETARY NAME

n/a

7. NONPROPRIETARY NAME

Sterile Bleomycin Sulfate, USP

8. SUPPLEMENT(S) PROVIDE(S) FOR

None.

9. AMENDMENTS AND OTHER DATES

Submission:	03/24/1993
Receipt:	03/29/1993
Confirmation of receipt:	07/21/1993
Request/Labeling review:	n/a
Labeling review #1:	07/27/1993
Labeling review #2:	05/10/1994
Labeling review #3:	09/07/1994
Labeling review #4:	02/21/1995
Labeling Review #5:	03/27/1995
Samples submitted:	
ADB report:	
Request/Bioeq. Waiver:	
Bioeq. waiver report:	11/02/1993 (acceptable)
Request/Est. Evaluation:	08/27/1994
Est. Evaluation report:	07/05/1994 (acceptable)
Labeling amendment:	07/21/1993
N/A Chemistry:	08/16/1993

N/A Micro: 11/05/1994  
Response Chemistry: 02/02/1994  
Response Micro: 02/07/1994  
N/A Chemistry: 06/07/1994  
Response: 08/02/1994  
Micro review #2: 09/06/1994 (acceptable)  
N/A letter: 09/26/1994  
Response: 10/07/1994

10. PHARMACOLOGICAL CATEGORY

Antineoplastic

11. R or OTC

R

12. RELATED IND/NDA/DMF(s)

AADA 64-044  
DMFs - See checklist

13. DOSAGE FORM

SVP

14. POTENCY

15 Units

15. CHEMICAL NAME AND STRUCTURE

N/A. A mixture of glycopeptide antibiotics isolated for a strain of *Streptomyces verticillus* and converted into sulfates.

16. RECORDS AND REPORTS

As cited throughout the review.

17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS

Issue minor letter with labeling deficiency.

19. REVIEWER: NANCY B. SAGER

DATE COMPLETED: 02/22/95