APPLICATION NUMBER:
64084

CHEMISTRY REVIEW(S)
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

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\LERS&REV\64084AP2.D
F/T by: RLWest: 5/22/96

APPROVAL
Memorandum for the File (Chemistry Review #6)

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

=================================================================

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/4/23/96
X:\NEW\FIRMSNZ\PHARMAC\LTRS&REV\64084AP.D
F/T by /    
APPROVAL
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)
   Est. Evaluation report: 07/05/1994 (acceptable)
   Labeling amendment: 07/21/1993
   N/A Chemistry: 08/16/1993
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10. **PHARMACOLOGICAL CATEGORY**
    Antineoplastic

11. **R or OTC**
    R

12. **RELATED IND/NDA/DMF(s)**
    AADA 64-044
    DMFs - See checklist

13. **DOSSAGE 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