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RESEARCH**

APPLICATION NUMBER:

75-811

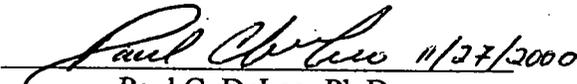
MICROBIOLOGY REVIEW

Office of Generic Drugs, HFD-620

Microbiology Review #1

November 20, 2000

- A. 1. ANDA: 75-811
- APPLICANT: American Pharmaceutical Partners, Inc.
2045 North Cornell Avenue
Melrose Park, Illinois 60160
2. PRODUCT NAME: Mesna Injection
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 100 mg/mL as a 10-mL fill in a 10-mL multiple-use vials; Intravenous injection
4. METHOD OF STERILIZATION:
5. PHARMACOLOGICAL CATEGORY: Antidote for ifosfamide induced cystitis
- B. 1. DATE OF INITIAL SUBMISSION: February 25, 2000 (Received Feb. 28, 2000)
2. DATE OF AMENDMENT: no amendments related to sterility assurance
3. RELATED DOCUMENTS:
4. ASSIGNED FOR REVIEW: November 16, 2000
- C. REMARKS: The subject drug product is 1 on 1
- D. CONCLUSIONS: The submission is recommended for approval on the basis of sterility assurance. Specific comments regarding the aseptic filling process are provided in "E. REVIEW NOTES".


Paul C. DeLeo, Ph.D.

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Micro Rev. 1.

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