

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 50-778

Microbiology Review(s)

REVIEW FOR HFD-150
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA

May 28, 1999

- A. 1. NDA 50-778 (was 21-010)
- SPONSOR Pharmacia & Upjohn, Inc.
2. PRODUCT NAMES: Epirubicin Hydrochloride Injection Preservative Free Solution (PFS)
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: The product is an aqueous solution at 2 mg/mL, in 25, 100 mL volumes in polypropylene vials, and closed with rubber stoppers. The solution is administered by infusion with sodium chloride injection or 5% glucose over a period of 3 to 5 minutes. Labeling states the product should be used within 24 hours of the first penetration of its rubber stopper. Unused portions should be discarded.
4. METHOD(S) OF STERILIZATION: solution and components
5. PHARMACOLOGICAL CATEGORY: Anti-neoplastic
6. DRUG PRIORITY CLASSIFICATION: 1P
- B. 1. DATE OF INITIAL SUBMISSION: December 15, 1998
2. DATE OF AMENDMENT: none
3. RELATED DOCUMENTS: none
4. ASSIGNED FOR REVIEW: February 12, 1999
- C. REMARKS: A copy of volume 5 of the CMC section (Item 4) was provided. The volume follows the format of the December 1993 FR notice's "Guideline for Submitting Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products." Introductory sections were not provided, included labeling which was provided separately.
- This NDA was originally filed as 21-010. Later, it was renumbered as 50-778.

- D. CONCLUSIONS: The submission is recommended for approval. Comments are provided at the end of sub sections 8 and 9 of "E. Review Notes," in this review.

/S/

David Hussong, Ph.D.

cc:

HFD 160/Consult File
HFD 150/Div. File
HFD 150/CSO/P. Guinn
HFD 150/Chemist/S. Kim
HFD 150/Chem TL/R. Wood
HFD 805/D. Hussong

Drafted by: D. Hussong, 05/28/99
R/D initialed by: P. Cooney

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