CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75392

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS, HFD-640

Microbiology Review #1

December 16, 1999

A. 1. **ANDA:** **75-392**

APPLICANT: Gensia Sicor Pharmaceuticals, Inc.
17 Hughes
Irvine, CA 92618

2. PRODUCT NAME: Propofol Injectable Emulsion 10 mg/mL (with 0.025% sodium metabisulfate)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 200 mg in 20-mL single-use glass syringe; intravenous

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Hypnotic Agent (Sedative)

B. 1. DATE OF INITIAL SUBMISSION: May 29, 1998
Subject of this Review (Received June 1, 1998)

2. DATE OF AMENDMENTS:
November 12, 1999 (Response to Labeling deficiencies)
August 30, 1999 (Response to Labeling deficiencies)
September 22, 1998 (Response to Labeling deficiencies)
June 24, 1998 (response to FDA request of a revised maximum batch size)
July 8, 1998 (notice to Zeneca regarding patent)
July 30, 1998 (receipt of notice to Zeneca)
December 1, 1998 (patent amendment)
No sterility assurance amendments were receive by the time of this review.

3. RELATED DOCUMENTS: ANDA 75-102,

4. ASSIGNED FOR REVIEW: September 3, 1999

C. REMARKS: The applicant stated that the subject drug is filled into 20 mL syringes and sterilized at the Gensia Sicor pharmaceutical facility in Irvine, CA.

D. CONCLUSIONS: The submission is **recommended** for approval on the basis of sterility assurance. Specific comments regarding the sterilization process are provided in "E. Review Notes".

/S/ 12/17/99
Paul C. DeLeo, Ph. D.

12/17/99

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Micro #1