CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-881

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS, HFD-620
Microbiology Review #2
February 21, 2001

A. 1. **ANDA 75-881**

APPLICANT : Gensia Sicor Pharmaceuticals, Inc.

2. PRODUCT NAME: Levocarnitine Injection USP

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 200 mg/mL; 2.5 mL (500 mg) in 3.5 mL vials, 5 mL (1 g) in 6 mL vials and 12.5 mL (2.5 g) in 20 mL vials; Intravenous

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Treatment of carnitore deficiency.

B. 1. DATE OF INITIAL SUBMISSION: May 19, 2000

2. DATE OF AMENDMENTS: January 19, 2001
Subject of this Review (Recd. January 22,2001)

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: February 21, 2001

C. REMARKS: The subject amendment provides for the response to microbiology deficiencies in the correspondence dated January 19, 2001.

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

Nrakendra Nath 2/21/01
Nrapendra Nath, Ph. D.

OSE 2/22/01

cc:

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Contain Trade Secret, Commercial/Confidential Information and are not releasable.

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Micro Rev 1

1/12/01

Microbiology Comments to be Provided to the Applicant

ANDA: 75-881 APPLICANT: Gensia Sicor Pharmaceuticals, Inc.

DRUG PRODUCT: Levocarnitine Injection USP, 200mg/mL

A. Microbiology Deficiencies:

1. For Media Fills you state your Action Limit is for a minimum of vials filled and with no upper limit on the number units that may be filled in a run. The use of rate in an open ended cumulative fashion could potentially allow a large number of contaminated units when large batches are filled. Please consider placing a ceiling on the maximum number of contaminated units allowed in a Media Fill irrespective of the total number of units filled. The goal of the aseptic filling is to achieve a 'zero' contamination rate. Your own data show that the goal is achievable since you show 'zero' contaminated units in over --- units filled in Media Fills on two different filling lines over two years. Please discuss.

2. Please provide the total duration of each Media Fill run and describe how it relates to the duration of the filling operation in the production of the subject drug product.

Please clearly identify your amendment to this facsimile as RESPONSE TO MICROBIOLOGY DEFICIENCIES. The RESPONSE TO MICROBIOLOGY DEFICIENCIES should also be noted in your cover page/letter.

Sincerely yours,

Mary Fanning, M.D., Ph.D.
Associate Director of Medical Affairs
Office of Generic Drugs
Center for Drug Evaluation and Research