CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-567

MICROBIOLOGY REVIEW

Office of Generic Drugs, HFD-620

Microbiology Review #2

October 18, 2000

A. 1. ANDA: 75-567

APPLICANT: Bedford Laboratories™
270 Northfield Road
Bedford, OH 44146

2. PRODUCT NAME: Levocarnitine Injection USP

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 200 mg/mL as a 2.5-mL fill in a 3-mL single-use vial or a 5-mL fill in a 5-mL single-use vial; Intravenous injection.

4. METHOD OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: For secondary carnitine deficiency

B. 1. DATE OF INITIAL SUBMISSION: January 12, 1999 (Received Jan. 14, 1999)

2. DATE OF AMENDMENT: October 6, 2000 (Received October 10, 2000)

Subject of this Review

3. RELATED DOCUMENTS:

NDA 20-182 – Sigma Tau (innovator)

4. ASSIGNED FOR REVIEW: October 18, 2000

C. REMARKS: The subject drug is manufactured, filled (Aseptic Suite 11, 13, 111 or 112) and terminally steam sterilized at the Bedford Laboratories facility in Bedford, Ohio.

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

Paul C. DeLeo 10/26/2000

Paul C. DeLeo, Ph.D.

c:

CSO 10/26/00

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Micro Review. 2

10/18/00

Office of Generic Drugs, HFD-620

Microbiology Review #1

May 31, 2000

A. 1. ANDA: 75-567

APPLICANT: Bedford Laboratories™
270 Northfield Road
Bedford, OH 44146

2. PRODUCT NAME: Levocarnitine Injection USP

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 200 mg/mL as a 2.5-mL fill in a 3-mL single-use vial or a 5-mL fill in a 5-mL single-use vial; Intravenous injection.

4. METHOD OF STERILIZATION: [redacted]

5. PHARMACOLOGICAL CATEGORY: Treatment of secondary carnitine deficiency

B. 1. DATE OF INITIAL SUBMISSION: January 12, 1999 (Received Jan. 14, 1999)

Subject of this Review

2. DATE OF AMENDMENT: no amendments related to sterility assurance

3. RELATED DOCUMENTS:

NDA 20-182 – Sigma Tau (innovator)

4. ASSIGNED FOR REVIEW: May 30, 2000

C. REMARKS: The subject drug is manufactured, filled and terminally steam sterilized at the Bedford Laboratories facility in Bedford, Ohio.

The subject application has been designated as the First Generic application for the subject drug product.

The Orange Book indicates exclusivity for use of carnitor injection for the prevention and treatment of carnitine deficiency in patients with end stage renal disease who are undergoing dialysis through December 15, 2002 and Orphan Drug Exclusivity through December 15, 2006.

D. CONCLUSIONS: The submission is **not recommended** for approval on the basis of sterility assurance. Specific comments regarding the process are provided in "E. REVIEW NOTES" and "MICROBIOLOGY COMMENTS TO BE PROVIDED TO THE APPLICANT" found at the end of this review. The deficiencies noted represent **Major Deficiencies**.

Paul C. DeLeo 6/9/2000
Paul C. DeLeo, Ph.D.

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6/9/00

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Micro Rev. 1

5/31/00