

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20997

MICROBIOLOGY REVIEW(S)

AUG 12 1998

REVIEW FOR HFD-170
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 of NDA 20-997
4 August 1998

A. 1. NDA 20-997

APPLICANT: Darwin Discovery Limited
Cambridge Science Park
Milton Road
Cambridge CB4 4WE
England

2. PRODUCT NAMES: CHIROCAINE® (levobupivacaine inj.)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:

The product is provided in 2.5, 5.0, and 7.5 mg/mL strengths at fill volumes of 10 mL in a 10 mL vial and 30 mL in a 30 mL vial, all are single use configurations. The product is intended for infiltrative, epidural, or intrathecal administration.

4. METHODS OF STERILIZATION:

The product is

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:

The product is an anesthetic.

B. 1. DATE OF INITIAL SUBMISSION: 27 April 1998

2. DATE OF AMENDMENT: (none)

3. RELATED DOCUMENTS: (none)

4. ASSIGNED FOR REVIEW: 27 July 1998

C. REMARKS: The drug product is
sterilized, visually inspected, labeled, packaged
and quality control tested at Ben Venue Laboratories,
Inc., 300 Northfield Road, Bedford, OH.

D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.

PS
Paul Stinavage, Ph.D. 4 August 1998
JHC 8/12/98