CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20997

MICROBIOLOGY REVIEW(S)
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 sterilized, visually inspected, labeled, packaged and quality control tested at Ben Venue Laboratories,
   Inc., 300 Northfield Road, Bedford, OH.

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

   2. DATE OF AMENDMENT: (none)

   3. RELATED DOCUMENTS: (none)


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.

\[\text{Paul Stinavage, Ph.D.} \quad \text{4 Aug 1998} \]

\[\text{The 9/12/98} \]