

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-942

MICROBIOLOGY REVIEW(S)

REVIEW FOR HFD-170
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA 20-942
28 May 1998

A. 1. NDA 20-942

APPLICANT: Hoffman-La Roche Inc.
340 Kingsland Street
Nutley, NJ 07110-1199

2. PRODUCT NAMES: VERSED® (midazolam hydrochloride) Syrup

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is an oral dosage form.

4. METHODS OF STERILIZATION:
The product is not a sterile product, but conforms to microbial and preservative effectiveness specifications.

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is used as preoperative sedative.

B. 1. DATE OF INITIAL SUBMISSION: 30 April 1998

2. DATE OF AMENDMENT: (none)

3. RELATED DOCUMENTS: NDA 18-654, IND

4. ASSIGNED FOR REVIEW: 17 May 1998

REMARKS: The application provides for the manufacture of an oral dosage form for this drug product. Since this is not a sterile preparation, the application is reviewed for preservative effectiveness and microbial attributes.

20575
01

20575
01

D. CONCLUSIONS: The application is recommended for approval on the basis of microbiological quality.

/S/

Paul Stinavage, Ph.D. 29 May 1998
Pitc 5/29/98

cc: Original NDA 20-942
HFD-170/Div. Files/Morgan/Ross
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 28 May 1998
R/D initialed by P. Cooney