# CENTER FOR DRUG EVALUATION AND RESEARCH

## APPLICATION: NDA 20-942

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| Final Printed Labeling | | X | | |
| Medical Review(s) | X | | | |
| Chemistry Review(s) | X | | | |
| EA/FONSI | | | X | |
| Pharmacology Review(s) | X | | | |
| Statistical Review(s) | X | | | |
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| Clinical Pharmacology Biopharmaceutics Review(s) | X | | | |
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# CENTER FOR DRUG EVALUATION AND RESEARCH

**Approval Package for:**

**Application Number: NDA 20-942**

**Trade Name: VERSED ORAL SYRUP 2mg/mL**

**Generic Name:(midazolam Hcl)**

**Sponsor: Hoffmann-La Roche**

**Approval Date: October 15, 1998**

**Indication: Is indicated for use in pediatric patients for sedation, anxiolysis and amnesia prior to diagnostic, therapeutic or endoscopic procedures or before induction oa anesthesia**

# CENTER FOR DRUG EVALUATION AND RESEARCH

**Application Number:NDA 20-942**

# APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 15 1998

NDA 20-942

Hoffmann-La Roche
340 Kingsland Street
Nutley, New Jersey 07110-1199

Attention: Margaret J. Jack
Program Director

Dear Ms. Jack:

Please refer to your New Drug Application (NDA) dated February 4, 1998, received February 9, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Versed (midazolam HCl) Oral Syrup 2mg/mL.

We acknowledge receipt of your submission dated August 13, 1998. Your submission of August 13, 1998 constituted a full response to our August 6, 1998 action letter. The user fee goal date for this application is February 15, 1999.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-942." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact David Morgan, Project Manager, at (301) 443-3741.

Sincerely,

/S/

Cynthia G. McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products HFD-170
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

# CENTER FOR DRUG EVALUATION AND RESEARCH

## APPLICATION NUMBER: NDA 20-942

## APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

MORGAN

Food and Drug Administration
Rockville MD 20857

NDA 20-942

AUG 6 1998

Hoffmann-La Roche
340 Kingsland Street
Nutley, New Jersey 07110-1199

Attention: Margaret Jack
Program Director

Dear Ms. Jack:

Please refer to your New Drug Application (NDA) dated February 4, 1998, received February 9, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VERSED (midazolam hydrochloride) Syrup 2mg/mL Oral.

We acknowledge receipt of your submissions dated February 19, April 02, 30; June 08, 12, and July 01, 16, and 17, 1998. The user fee goal date for this application is August 8, 1998.

We have completed the review of this application, as amended, and it is approvable. Before this application may be approved, however, it will be necessary for you to provide an updated Risk Management Plan which finalizes the elements described in your application in draft form and provides for adequate surveillance and reporting of diversion to the periodic safety report submitted to your NDA.

In addition, it will be necessary for you to submit draft labeling.

The attachment to this letter provides a draft of the labeling that the Agency asks you to adopt for Versed (midazolam hydrochloride) Syrup upon its approval. Although sections of this proposal are taken verbatim from the labeling proposed by you in the NDA, other sections have been extensively revised and/or expanded.

If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.120. In the absence of any such action FDA may proceed to withdraw the application. Any amendment should respond to all

the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, contact David Morgan, Project Manager, at (301) 443-3741.

Sincerely,

/S/

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products, HFD-170
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:
Archival NDA 20-942
HFD-170/Div. Files
HFD-170/D.Morgan
HFD-002/ORM
HFD-103/ADRA
HFD-95/DDMS
HFD-40/DDMAC (with labeling)
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: DM/July 27, 1998
Initialed by:
final:
filename: n:\cso\morgan\20942.AE

APPROVABLE (AE)