CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number : 018654/S018 and S029 and S030

Trade Name : VERSED

Generic Name: Midazolam Hydrochloride

Sponsor : Hoffman-La Roche Inc.

Approval Date: S018 and S029-December 31, 1996
S030-March 18, 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Morgan

Food and Drug Administration
Rockville MD 20857

NDA 18-654/S-018 & S-029

DEC 3 1 1996

Hoffmann-La Roche Inc.
340 Kingsland St.
Nutley, New Jersey 07110-1199

Attention: Margaret J. Jack
Program Director
Drug Regulatory Affairs

Dear Ms. Jack:

Please refer to your supplemental new drug applications (NDA) dated April 16, 1989 and September 13, 1995, respectively, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Versed (midazolam HCl) 5mg/ml and 1 mg/ml vials.

We acknowledge receipt of your amendments for supplemental application S-018 dated September 16, 1994; August 26 and October 22, 1996. We also acknowledge receipt of your amendments for supplemental application S-029 dated June 6 and 27; August 26; September 13; and October 22, 1996.

Supplemental application S-018 provides for label revisions of the Pharmacokinetic Data found under the CLINICAL PHARMACOLOGY SECTION.

Supplemental application S-029 provides for continuous infusion for sedation of intubated mechanically ventilated patients.

We have completed the review of these supplemental applications, including the submitted draft labeling, 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 revised draft labeling, submitted on October 22, 1996. Accordingly, the applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed revised draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit sixteen 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 "FINAL

PRINTED LABELING" for approved NDA 18-654. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety or effectiveness of this drug becomes available, revision of that labeling may be required.

Please submit one market package of the drug when it is available.

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

Should you have any questions, please contact:

David Morgan
Consumer Safety Officer
Telephone: (301) 443-3741

Sincerely yours,

Curtis Wright, M.D.,M.P.H.
Acting Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products, HFD-170
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:
Original NDA 18-654
HF-2/MedWatch (with draft labeling)
HFD-2/MLumpkin
HFD-92 (with draft labeling)
HFD-103/PBotstein (with draft labeling)
HFD-170/Div. File
HFD-170/CSO/DMorgan / D. Conner
HFD-170/Landow/Cerny/Lockwood/Ross/Moody
HFD-101/LCarter
HFD-40/DDMAC (with draft labeling)
HFD-613 (with draft labeling)
HFD-735 (with draft labeling
DISTRICT OFFICE
HFD-820/New Drug Chemistry Director
drafted: DM/December 24/18654.29a
r/d initials: CMoody/12-30-96
Final: SLiu/12-30-96

APPROVAL (AP)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NDA 18-654/S-030

Food and Drug Administration
Rockville MD 20857

MAR 18 1997

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

Attention: Margaret J. Jack
Program Director

Dear Ms. Jack:

Please refer to your supplemental new drug application dated September 28, 1995, received October 2, 1995, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Versed (midazolam HCl) 5mg/ml and 1mg/ml vials.

We acknowledge receipt of your submissions dated November 18; December 23, 1996; and February 13, 1997.

The supplemental application provides for intramuscular, intravenous, or continuous intravenous infusion for sedation in pediatric patients.

We have completed the review of this supplemental application including the submitted draft labeling 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 marked-up draft. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed marked-up draft labeling. Marketing the product with FPL that is not identical to this draft labeling 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 "FINAL PRINTED LABELING" for approved supplemental NDA 18-654/S-030. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

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