

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 13-263/S-082

APPROVAL LETTER



NDA 13-263/SCM-082

Hoffmann-La Roche Inc.
Attention: Ms. Christine Hoogmoed
Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Hoegmood:

Please refer to your supplemental new drug application dated November 20, 2000, received November 21, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Valium, Oral tablets 2 mg, 5 mg, and 10 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a change in the process to add a (b)(4)-----
(b)(4)-----

We have completed the review of this supplemental application, and it is approved.

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, call Anna Marie Homonnay, R.Ph., Regulatory Project Manager, at (301) 594-5535.

Sincerely,

{See appended electronic signature page}

Robert H. SeEVERS, Ph.D.
Chemistry Team Leader, Psychiatric Drugs for the
Division of Neuropharmacological Drug Products,
(HFD-120)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Robert H. Seevers
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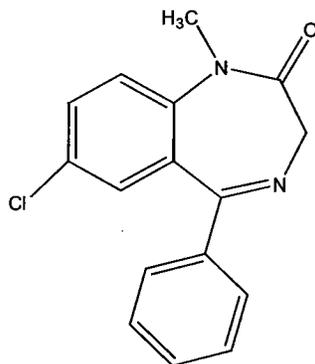
APPLICATION NUMBER: 13-263/S-082

CHEMISTRY REVIEW

CHEMIST REVIEW
OF SUPPLEMENT

1. ORGANIZATION: HFD-120
2. NDA: 13-263
3. SUPPLEMENT NUMBERS/DATES: SCM-082
Letter date: November 20, 2000
Stamp date: November 21, 2000
4. AMENDMENTS/REPORTS/DATES: N/A
5. RECEIVED BY CHEMIST: December 1, 2000
Hoffman-La Roche Inc., 340 Kingsland Street, Nutley,
NJ 07110-1199
Valium

6. APPLICANT NAME & ADDRESS
7. NAME OF DRUG:



8. NONPROPRIETARY NAME: Diazepam
9. CHEMICAL NAME/STRUCTURE: 7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H1,4-benzodiazepin-2-one
10. DOSAGE FORM(S): Tablet
11. POTENCY: 2 mg, 5 mg, 10 mg
12. PHARMACOLOGICAL CATEGORY: Anti-anxiety
13. HOW DISPENSED: X (Rx) (OTC)
14. RECORDS & REPORTS CURRENT: Yes No
15. RELATED IND/NDA/DMF: N/A

SUPPLEMENT PROVIDES FOR: This CBE-30 provides for a change in the process to add a _____

Comments: The change was sought as several validation lots were observed to have _____

Conclusion: This supplement may be approved.

Reviewer's Signature

Team Leader

Christy S. John, Ph.D.

Robert H. Seevers, Ph.D.

DRAFT PORTION OF LETTER ATTACHED: YES _____ NO X .

IND 60,019

HFD-120/CJohn

HFD-120/Division File

HFD-120/RSeevers

HFD-120/SHardeman

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/s/

Christy John
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CHEMIST

Robert H. Seevers
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CHEMIST