DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 13-263/S-086

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

Dear Ms. Hoogmoed:

Please refer to your supplemental new drug application dated October 11, 2001, received October 12, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Valium (diazepam) Tablets, 2 mg, 5 mg, and 10 mg.

This supplemental new drug application provides for revised specifications and directions for testing for the drug substance, diazepam.

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}

Hasmukh Patel, Ph.D.
Acting Chemistry Team Leader, Psychiatric Drugs for the
Division of Neuropharmacological Drug Products,
(HFD-120)
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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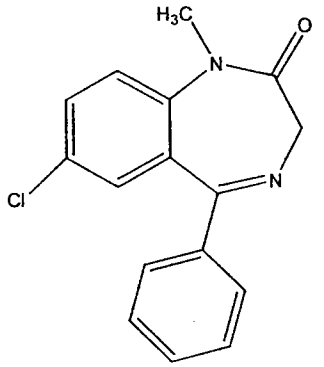
/s/

Hasmukh Patel
2/12/02 10:25:33 AM

CHEMIST REVIEW
OF SUPPLEMENT

1. ORGANIZATION: HFD-120
2. NDA: 13-263
3. SUPPLEMENT NUMBERS/DATES: SCS-086
   Letter date: October 11, 2001
   Stamp date: October 12, 2001
4. AMENDMENTS/REPORTS/DATES: N/A
5. RECEIVED BY CHEMIST: October 16, 2001
6. APPLICANT NAME & ADDRESS: Hoffman-La Roche Inc., 340 Kingsland Street, Nutley, NJ 07110-1199
7. NAME OF DRUG: Valium



8. NONPROPRIETARY NAME: Diazepam
9. CHEMICAL NAME/STRUCTURE: 7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-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 (R_x) _____ (OTC)
14. RECORDS & REPORTS CURRENT: _____ Yes _____ No
15. RELATED IND/NDA/DMF: N/A

SUPPLEMENT PROVIDES FOR: This prior approval supplement provides for revised specifications and directions for testing for the drug substance, diazepam.

Comments: Diazepam is the active pharmaceutical ingredient used in the manufacture of both Valium Tablets under NDA 13-263 and Valium Injection under NDA 16-087. The sponsor has made business decision to only manufacture Valium Tablets and has discontinued manufacture of Valium Injection. The revised specifications reflect that diazepam is designated "for use in oral dosage forms only."

Conclusion: While the proposed changes relax the acceptance criterion, the changes in specifications are not considered to have a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of Valium Tablets as they may relate to the safety or effectiveness of the product. This supplement may be approved.

Reviewer's Signature	Acting Team Leader
Christy S. John, Ph.D.	Hasmukh Patel, Ph.D.

DRAFT PORTION OF LETTER ATTACHED: YES___ NO__X__.
NDA 13-263
HFD-120/CJohn
HFD-120/Division File
HFD-120/HPatel
HFD-120/AHomonnay

ATTACHMENT A.

4 page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable

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/s/

Christy John
2/11/02 12:59:12 PM
CHEMIST

Hasmukh Patel
2/11/02 01:05:12 PM
CHEMIST

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 13-263/S-086

PRIOR APPROVAL SUPPLEMENT

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

Dear Ms. Hoogmoed:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Valium® (diazepam) Tablets

NDA Number: 13-263

Supplement number: 086

Date of supplement: October 11, 2001

Date of receipt: October 12, 2001

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on December 10, 2001 in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of Neuropharmacological Drug Products, HFD-120
Attention: Division Document Room, 4008
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Neuropharmacological Drug Products, HFD-120
Attention: Division Document Room, 4008
1451 Rockville Pike
Rockville, Maryland 20852-1420

If you have any questions, call Anna Marie Homonnay, Regulatory Project Manager, at (301) 594-5535.

Sincerely yours,

Robert H. Seevers, Ph.D.
Chemistry Team Leader
Psychiatric Drugs for the
Division of Neuropharmacological Drug Products
HFD-120
DNDC 1, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Robert H. Seevers
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