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
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