DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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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