

NDA 13-263/S-072/075

NDA 16-087/S-079/081

Roche Products Inc.
Attention: Lynn DeVenezia-Tobias
Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. DeVenezia-Tobias:

Please refer to your new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Valium (diazepam) Tablets (NDA 13-263) and Valium (diazepam) Injection (NDA 16-087).

We additionally refer to the following supplemental applications:

NDA	Supplement	Dated
13-263	S-072	March 2, 1988
13-263	S-075	January 18, 1994
16-087	S-079	October 2, 1987 and amended on March 2, 1988
16-087	S-081	January 18, 1994

These "Changes Being Effected" supplemental new drug applications provide for the following revisions to product labeling:

13-263/S-072 & 16-087/S-079

1. The replacement of the subsection entitled **Physical and Psychological Dependence** with a **Drug Abuse and Dependence** subsection under the **WARNINGS** section.
2. The addition of a section under the **WARNINGS** section referring the prescriber to the **Drug Abuse and Dependence** section.
3. The addition of a subsection entitled **Information for Patients** under the **PRECAUTIONS** section.
4. The addition of the dye contents to the Valium tablet prescriber labeling under the **DESCRIPTION** section in accordance with a Federal Register Notice dated June 8, 1987.
5. The deletion of the Valium injection 10 ml vials packaged in configurations of 10 vials to the Valium injection prescriber labeling under the **HOW SUPPLIED** section.

We note that these revisions were requested by the Agency in letters dated July 6, 1987 and January 5, 1988.

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Revisions to the **MANAGEMENT of OVERDOSAGE** section regarding the use of flumazenil for the complete or partial reversal of the sedative effects due to suspected benzodiazepine overdose as requested in an Agency letter dated January 28, 1993.

We have completed the review of these supplemental applications, as amended, 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 submitted final printed labeling (package insert submitted January 18, 1994/Label Codes 13-06-78950-0693 [NDA 13-263] and 13-06-78965-0282 [NDA 16-087]). Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Russell Katz
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