DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 13-263/S-080/S-083

Roche Products Inc.
Attention: Margaret J. Jack
Program Director, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Jack:

Please refer to your supplemental new drug applications dated August 25, 1998 (S-080), and February 12, 2001 (S-083), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Valium (diazepam) Tablets.

We acknowledge receipt of your submission dated January 17, 2008.

Your submission dated January 17, 2008, constituted a complete response to our March 22, 2007 action letter.

These "Prior Approval" supplemental new drug applications propose the following revisions to product labeling:

S-080
This supplement provides for a new subsection under the PRECAUTIONS section entitled Geriatric Use to comply with a Federal Register Notice dated August 27, 1997.

S-083
This supplement provides for numerous revisions to the following sections of product labeling: DESCRIPTION, CLINICAL PHARMACOLOGY, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, DRUG ABUSE AND DEPENDENCE, OVERDOSAGE, and DOSAGE AND ADMINISTRATION. These proposed revisions are based upon the review of your safety database so that the labeling is consistent with the worldwide safety information available for this product.

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed final printed labeling (FPL) submitted on January 17, 2008.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 LCDR Janet Cliatt, Regulatory Project Manager, at (301) 796-0240.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Thomas Laughren

5/12/2008 09:20:53 AM