NDA 17-533/S-031

Hoffmann-La Roche Inc.
Attention: Duane Voss
Program Director, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110

11 APR 2001

Dear Mr. Voss:

Please refer to your supplemental new drug application dated August 26, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Klonopin (clonazepam) 0.5 mg, 1 mg, and 2 mg Tablets.

This supplemental application provides for the creation of a new subsection under the **PRECAUTIONS** section entitled **Geriatric Use** to comply with an August 27, 1997 Federal Register Notice requiring that sponsors add geriatric use data to product labeling.

We have completed the review of this supplemental application 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 agreed upon labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted August 26, 1998).

Please submit the copies of final printed labeling (FPL) electronically to the application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-533/S-031." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" 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,

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