NDA 17-105/S-059/062

Abbott Laboratories
Attention: Steven Townsend
Associate Director, PPD Regulatory Affairs
200 Abbott Park Rd., D-491, AP30-1E
Abbott Park, IL 60064-6157

Dear Mr. Townsend:

Please refer to your supplemental new drug applications dated April 16, 1987 (S-059) and September 10-1987 (S-062), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tranxene (clorazepate dipotassium) dosages.

We acknowledge receipt of your amendments dated December 23, 1987, and June 7, 1994, submitted to supplemental application 062.

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

S-059
The placement of a revision date, a substance symbol, and the use of the "T-Tab" symbol in labeling.

S-062
Revisions in labeling to incorporate additional information on withdrawal problems associated with benzodiazepines, additional pharmacokinetic information, and editorial revisions. We note that this supplement responded to an Agency letter dated July 8, 1987, and February 17, 1988, requesting revisions to product labeling. We additionally note that you incorporated our requested revisions verbatim.

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 June 7, 1994/Label Code 03-4490-R13). 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 this page is the manifestation of the electronic signature.

/s/

Russell Katz
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