NDA 10-392/S-041
NDA 10-485/S-018
NDA 11-111/S-033
NDA 11-459/S-036
NDA 11-795/S-018

Pfizer Pharmaceuticals
Attention: Jeannette Barrett, Ph.D.
Director, Regulatory Affairs
235 East 42nd Street
New York, NY 10017-5755

21 MAR 2001

Dear Dr. Barrett:

Please refer to your supplemental new drug applications dated August 23, 1999, received August 24, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ATARAX (hydroxyzine HCl) Tablets, ATARAX (hydroxyzine HCl) Syrup, VISTARIL (hydroxyzine HCl) Intramuscular Injection, VISTARIL (hydroxyzine pamoate) Capsules, and VISTARIL (hydroxyzine pamoate) Oral Suspension.

These supplemental new drug applications provide for a geriatric use labeling statement in the 'Precautions' section of the package inserts.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted draft labeling texts dated August 23, 1999. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package inserts submitted August 23, 1999).

Please submit the copies of final printed labeling (FPL) electronically to each 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 they are available but no more than 30 days after they are printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 10-392/S-041, 10-485/S-018, 11-111/S-033, 11-459/S-036, 11-795/S-018." Approval of these submissions by FDA is not required before the labeling is used.

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 should have any questions, please call Ms. Anna Marie Homonnay, R.Ph., Regulatory Health Project Manager, at (301) 594-5535.

Sincerely,

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