DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 16-584/S-055/S-047
NDA 16-758/S-016/S-011

Pfizer, Inc.
Attention: Denise F. Andrews
Director, Worldwide Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Ms. Andrews:

Please refer to your supplemental new drug applications dated June 7, 2001, received June 8, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Navane (thiothixene HCl) Capsules and Oral Concentrate.

These "Changes Being Effected" supplemental new drug applications provide for labeling changes as requested in our letter of September 25, 2000, specifically modification of labeling text to more clearly state that these agents are indicated for the treatment of schizophrenia.

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 final printed labeling (package insert submitted June 7, 2001). Accordingly, these supplemental applications are approved effective on the date of this letter.

A search of our database also revealed that final printed labeling was submitted to the above applications on March 17, 1987, in response to our action letter of January 8, 1987. We note that these changes have either been incorporated or superceded by the approval of your supplement of June 7, 2001. Therefore, supplement 047 to NDA 16-584 and supplement 011 to NDA 16-758 will be retained in our files with no further action.

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 Steven D. Hardeman, R.Ph., Senior Regulatory Project Manager, at (301) 594-5525.

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
7/31/01 09:54:04 AM