



NDA 16-584 / S-059
NDA 16-758 / S-020
NDA 16-904 / S-034

Pfizer, Inc.
Attention: Carol Haley
Worldwide Regulatory Affairs & Quality Assurance
235 East 42nd Street
New York, NY 10017

Dear Ms. Haley:

Please refer to your supplemental new drug applications dated and received on May 5, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NAVANE (thiothixene) Capsules 1 mg, 2 mg, 5 mg, 10 mg, and 20 mg [NDA 16-584], NAVANE (thiothixene) Oral Concentrate 5mg base / mL [NDA 16-758], and NAVANE (thiothixene) Injectable 2 mg base/mL and 10 mg base/mL [NDA 16-904].

We acknowledge receipt of your submissions dated June 17, 2009, to each of the supplements referenced above.

Reference is made to our letter dated April 5, 2009, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for the entire class of antipsychotic drugs. This information pertains to the risk of leukopenia, neutropenia, and agranulocytosis.

We also refer you to the letter we sent on June 2, 2009, informing you that we determined that a 30-day extension of the discussion period was warranted to allow us to complete our review and reach agreement on the content of the labeling. We also refer to modified labeling language that we sent to you via email on June 9, 2009.

The supplemental new drug application, as amended, provides for the addition of the subsection PRECAUTIONS/ Leukopenia, Neutropenia and Agranulocytosis to the labeling for NAVANER (thiothixene).

We have completed our review of these supplemental applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text (text for the package insert).

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the

package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, **“SPL for approved supplements NDA 16-584 / S-059, NDA 16-758 / S-020, and NDA 16-904 / S-034.”**

In addition, within 21 days of the date of this letter, amend any pending applications for these NDAs with content of labeling in structured product labeling (SPL) format to include the changes approved in these applications.

Failure to make these changes within the specified period of time could make your product misbranded under 21 USC 321(n) and 352(a).

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

LETTERS TO HEALTH CARE PROFESSIONALS

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 these NDAs and a copy to the following address:

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

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please contact Doris J. Bates, Ph.D., Safety Regulatory Project Manager, at (301)796-2260.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Package Insert labeling

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

/s/

Mitchell Mathis
7/19/2009 07:50:38 AM
For Dr. Laughren