DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-825 / S-027
NDA 20-919 / S-019

Pfizer Inc.
Attention: Eileen De Micco
Associate Director, US Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Ms. De Micco:

Please refer to your supplemental new drug applications dated February 7, 2008, February 8, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Geodon (ziprasidone) Capsules and Injection.

We acknowledge receipt of your submissions dated March 19, 2008.

These "Changes Being Effected" supplemental new drug applications provide for class-labeling changes under ADVERSE REACTIONS, Extrapyramidal Symptoms. The following subsection has been added:

> **Dystonia** - *Class Effect:* Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first few days of treatment. Dystonic symptoms include: spasm of the neck muscles, sometimes progressing to tightness of the throat, swallowing difficulty, difficulty breathing, and/or protrusion of the tongue. While these symptoms can occur at low doses, they occur more frequently and with greater severity with high potency and at higher doses of first generation antipsychotic drugs. An elevated risk of acute dystonia is observed in males and younger age groups.

We have completed our review of these supplemental new drug applications and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 19, 2008.

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 this NDA and a copy to the following address:

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

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, email CAPT Steven D. Hardeman, R.Ph., Chief, Project Management Staff, at Steven.Hardeman@FDA.HHS.GOV.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry 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/

Thomas Laughren
5/16/2008 12:09:07 PM