DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-825 / S-026
NDA 20-919 / S-016

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

Dear Ms. De Micco:

Please refer to your supplemental new drug applications dated July 30, 2007, received July 31, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for GEODON (ziprasidone HCl) Capsules and GEODON (ziprasidone mesylate) for Injection.

We acknowledge receipt of your submission dated September 14, 2007.

These "Changes Being Effected" supplemental new drug applications provide for the addition of the terms, facial droop, tardive dyskinesia, swollen tongue, enuresis, and urinary incontinence under the Other Events Observed During Post-marketing Use subsection of ADVERSE REACTIONS.

In addition, mania/hypomania was moved from Nervous System Disorders to Psychiatric Disorders per the MedDRA dictionary and syncope was moved from Nervous System Disorders to Vascular Disorders based on Pfizer's PSUR analysis.

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 September 14, 2007.

Since facial droop is a symptomatic descriptor, whereas facial palsy/paresis can also be a diagnostic descriptor, separating the cases of facial droop from facial palsy/paralysis may be indicated. Thus, we request that you consider splitting the term into "facial droop, facial palsy/paresis" to more accurately reflect the findings of the six cases reviewed.

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 New 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
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