DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-825/S-024
NDA 20-919/S-014

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

Dear Ms. De Micco:

We acknowledge receipt of your supplemental new drug applications dated December 19, 2006, received December 21, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Geodon (ziprasidone HCl) Capsules (NDA 20-825) and Geodon (ziprasidone mesylate) Injection (NDA 20-919).

These supplements, submitted under "Changes Being Effected", provide for the following revisions to labeling:

1. A reference to the **ADVERSE REACTIONS- Other Events Observed During Post-marketing Use** under the **WARNNINGS- QT Prolongation and Risk of Sudden Death** section.

2. Revisions to the **ADVERSE REACTIONS- Other Events Observed During Post-marketing Use** section.

3. Revisions to the **OVERDOSAGE** section.

4. Revisions to the **DOSAGE AND ADMINISTRATION- Preparation for Administration** section.

5. Revisions to the **Storage and Handling** section to reflect the standard USP controlled room temperature language.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, these applications are approved effective on the date of this letter.

Additionally, since this approval letter supersedes the labeling revisions proposed in supplemental applications 20-825/S-014 & 20-919/S-004, we are going to administratively close these supplements and retain them in our files.

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, e-mail Keith Kiedrow, Pharm.D. at Keith.Kiedrow@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

Attachment

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
5/24/2007 08:12:47 AM