DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-825 / S-021
NDA 20-919 / S-012

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

Dear Ms. De Micco

Please refer to your supplemental new drug applications dated November 9, 2006, received November 13, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Geodon (ziprasidone HCl) Capsules and Geodon (ziprasidone mesylate) Injection.

These supplemental new drug applications provide for an update to the Patient Summary of Information. These revisions include the addition of the black box warning and the indication for manic and mixed episodes associated with bipolar disorder. Also, some of the language from the previously-approved patient labeling was revised to be more patient-friendly.

We have completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the submitted labeling text. The final printed labeling (FPL) must be identical to the package insert and patient package insert submitted November 9, 2006 (copy attached).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 20-825/S-021 and NDA 20-919/S-012**." Approval of these submissions by FDA is not required before the labeling is used.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, email 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 Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

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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