DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-825 / S-015 / S-017
NDA 20-919 / S-005 / S-006

Pfizer, Inc.
Attention: Mojgan Moghaddassi, Pharm.D.
235 East 42nd Street
New York, NY 10017-5755

Dear Dr. Moghaddassi:

Please refer to your supplemental new drug applications dated April 22, 2005, received April 25, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Geodon (ziprasidone HCl) Capsules and Geodon (ziprasidone mesylate) Injection.

We also acknowledge receipt of your supplements dated May 11, 2005, received May 12, 2005.

- Supplemental new drug applications NDA 20-825/S-015 and NDA 20-919/S-005, submitted as "Changes Being Effected," provide for revised labeling to include a Boxed Warning and Bolded Warning regarding increased mortality in elderly patients with dementia related psychosis.

- Supplemental new drug applications NDA 20-825/S-017 and NDA 20-919/S-006, submitted as "Changes Being Effected," provide for revised labeling in PRECAUTIONS to move Dysphagia after Seizures and to include a reference to the Boxed Warning after Dysphagia.

We have completed our review of these supplemental new drug applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 11, 2005 (attached).

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, call CAPT Steven D. Hardeman, R.Ph., Acting Chief, Project Management Staff, at (301) 594-5525.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Acting 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

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