DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-483 / S-003

Pfizer, Inc.
Attention: Eileen De Micco
Worldwide Regulatory Affairs & Quality Assurance
235 East 42nd Street
New York, NY 10017

Dear Ms. De Micco:

Please refer to your supplemental new drug application dated and received on May 5, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for GEODON (ziprasidone) Oral Suspension, 10 mg/mL [NDA 21-483].

We acknowledge receipt of your submissions dated June 17, 2009, July 13, 2009, July 15, 2009, and July 28 2009, to the supplement referenced above.

Reference is made to our letter dated April 5, 2009, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for the entire class of antipsychotic drugs. This information pertains to the risk of leukopenia, neutropenia, and agranulocytosis.

We also refer you to the letter we sent on June 2, 2009, informing you that we determined that a 30-day extension of the discussion period was warranted to allow us to complete our review and reach agreement on the content of the labeling. We also refer to modified labeling language that we sent to you via email on June 9, 2009. In addition, we refer to the letter we sent you dated July 19, 2009, informing you that we determined that an additional 30-day extension of the discussion period was warranted.

This supplemental new drug application, as amended, provides for the addition of the subsection PRECAUTIONS/ Leukopenia, Neutropenia and Agranulocytosis to the labeling for GEODON (ziprasidone).

We have completed our review of this supplemental application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text (text for the package insert).

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, **"SPL for approved supplement NDA 21-483 / S-003."**

In addition, within 21 days of the date of this letter, amend any pending applications for this NDA with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

Failure to make these changes within the specified period of time could make your product misbranded under 21 USC 321(n) and 352(a).

We note that Geodon (ziprasidone) Oral Suspension, 10 mg/mL, has not been marketed since the initial approval of this dosage form on March 29, 2006. If and when you market this dosage form, given the time elapsed since initial approval, you must submit a supplemental NDA to update the manufacturing and controls processes for this dosage form, including all labels and labeling [container, carton, package insert]. The updated package insert must include the new PRECAUTIONS language approved today.

LETTERS TO HEALTH CARE PROFESSIONALS

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 these NDAs and a copy to the following address:

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

REPORTING REQUIREMENTS

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, please contact Doris J. Bates, Ph.D., Safety Regulatory Project Manager, at (301)796-2260.

Sincerely,

{See appended electronic signature page}

Thomas P. Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Package Insert labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DORIS J BATES
08/06/2009

MITCHELL V Mathis
08/07/2009
For Dr. Laughren