DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDAs 20825/S-046, 20919/S-030, 21483/S-009

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attn: Lisha Cole, Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Ms. Cole:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received on February 16, 2012, submitted under section 505(b) of the Federal Food Drug, and Cosmetic Act (FDCA) for Geodon (ziprasidone HCl) 20 mg, 40 mg, 60 mg, 80 mg Capsules (N 20825), Geodon (ziprasidone mesylate) 20 mg/mL Injection (N 20919), and Geodon (ziprasidone HCl) Oral Suspension (N 21483).

These Prior Approval supplemental new drug applications provide for revisions to the Warning/Precautions – Hyperprolactinemia section (5.11) of labeling. These supplements also propose revisions under Full Prescribing Information to the Indications and Usage (section 1), Dosage and Administration (section 2), and Clinical Studies (section 14).

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), 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 and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for these NDAs, including pending CBE supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave.
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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, call Sonny Saini, Pharm.D., MBA, Regulatory Project Manager, at (301) 796-0532.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
CAPT, USPHS
Director (acting)
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

MITCHELL V Mathis
03/01/2013