DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20825/S-053
NDA 20919/S-040
NDA 21483/S-013

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Mary Boylan-Bost
Director, US Regulatory Cluster Lead
235 East 42nd Street
New York, NY 10017

Dear Ms. Boylan-Bost:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received November 10, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Geodon (ziprasidone) 20 mg, 40 mg, 60 mg, and 80 mg Capsules (NDA 20825), Geodon (ziprasidone hydrochloride) 10 mg/ml oral suspension (NDA 21483), and Geodon (ziprasidone mesylate) 20 mg/ml injection (NDA 20919).

We acknowledge receipt of your amendment dated December 3, 2014.

We also refer to our letter dated October 10, 2014 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Geodon (ziprasidone). This information pertains to the association between the use of ziprasidone and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

These supplemental new drug applications provide for the following revisions to the labeling for ziprasidone consistent with our October 10, 2014 letter:

- Revisions to **Highlights of Prescribing Information**
- Addition of a new subsection under **Warnings and Precautions** entitled **Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)**
- Revisions to the **Adverse Reactions-Postmarketing Experience** section
- Addition of a new subsection under **Patient Counseling Information** entitled **DRESS**
- Revisions to the Patient Package Insert.

APPROVAL & LABELING

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

Additionally, we note that you have revised Section 7.3 and reported it as an annual reportable change under § 314.70(d). These changes do not qualify to be submitted as such. Therefore, we have removed these changes from the attached product labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 that includes labeling changes for this NDA, including 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, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Simran Parihar, PharmD, Regulatory Project Manager, at (301) 796-7545 or email simran.parihar@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
CAPT, USPHS
Director
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
12/10/2014