DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-825 / S-009

Pfizer, Inc.
Attention: Mr. Brian Green
Associate Director I
Regulatory Strategy, Policy and Registration
Worldwide Regulatory Affairs
50 Pequot Avenue
New London, Connecticut 06320

Dear Mr. Green:

Please refer to your supplemental new drug application dated October 20, 2003, received October 21, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Geodon® (ziprasidone HCl) Capsules.

We also acknowledge receipt of your submissions dated February 20, 2004, May 14, 2004, and June 23, 2004.

This supplemental new drug application provides for the use of Geodon® Capsules as monotherapy in the treatment of acute manic or mixed episodes in Bipolar I Disorder, with or without psychotic features.

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

Pediatric Research Equity Act (PREA) Requirements: Phase 4 Commitment: Partial Waiver, Partial Deferral
All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred.

We are waiving this requirement for children below the age of 10 years. We are deferring submission of your pediatric studies for ages 10 to 17 years (children and adolescents) until June 30, 2008 (see below). Your deferred pediatric studies required under Section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing commitments shall be reported annually according to 21 CFR 314.81. The associated commitment is listed below.

1. *Deferred pediatric studies under PREA.*
   You are required to assess the safety and effectiveness of Geodon as a treatment for bipolar disorder in pediatric patients ages 10 to 17 (children and adolescents).

   Final Report Submission: February 11, 2008

Please submit study protocols to your IND for this product. Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment, whether submitted to the IND or the NDA, must be clearly designated "**Required Pediatric Study Commitments**".

Pediatric Exclusivity
Please note that Proposed Pediatric Study Requests and Pediatric Written Requests, which apply to pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act, are distinct from, and may need to be developed ***in addition to,*** pediatric studies under PREA as described above. Satisfaction of the requirements in Section 2 of PREA alone may not qualify you for pediatric exclusivity.

Additional Phase 4 Commitment (Clinical)
We remind you of your additional postmarketing commitment, as agreed in our teleconference of August 17, 2004. This commitment is listed below.

2. *Clinical Efficacy and Safety: Adult clinical study/ies to address short-term efficacy and safety of ziprasidone as add-on therapy in bipolar disorder and long-term efficacy and safety of ziprasidone in bipolar disorder, including lower doses than were studied in the acute mania studies.*

   You have agreed to submit the results of a clinical study or studies examining the short-term efficacy and safety of ziprasidone as add-on therapy in bipolar patients currently taking mood stabilizers (e.g., lithium, valproate) and long-term efficacy and safety of ziprasidone in bipolar disorder. This study or studies will explore lower dose ranges for ziprasidone than were studied in the acute mania studies.

   Final Report Submission: On or before March 31, 2008.

Submit clinical protocols to your IND for this product. Please submit all final study reports to this NDA, including any final reports intended to support clinical efficacy claims or changes in labeling. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary for each commitment in your annual report to this NDA. The status summary should include:

- expected final report submission dates,
- any changes in plans since the last annual report,
- and, for clinical studies, the number of patients entered into each study.

All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol**", "**Postmarketing Study Final Report**", or "**Postmarketing Study Correspondence**."

Labeling
The final printed labeling (FPL) must be identical to the enclosed agreed-upon labeling (text for the package insert) and submitted labeling (immediate container and carton labels submitted December 22, 2003). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-427**." Approval of this submission by FDA is not required before the labeling is used.

Introductory Promotional Materials
In addition, please submit three copies of the introductory promotional materials that you propose to use for this product in this indication. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert(s) directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 call Doris J. Bates, Ph.D., Regulatory Project Manager, at 301-594-2850.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: agreed-upon labeling

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

/s/

Russell Katz
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