



NDA 20-919/S-022

Pfizer, Inc.

Attention: Mary Boylan-Bost, Associate Director, Worldwide Regulatory Strategy  
235 East 42<sup>nd</sup> Street  
New York, NY 10017

Dear Ms. Boylan-Bost:

Please refer to your supplemental new drug application dated August 21, 2008, received August 21, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Geodon (ziprasidone meyclate) Injection, 20 mg/mL.

This "Prior Approval" supplemental new drug application provides for an alternate manufacturing and stability testing site for the drug product.

We completed our review of this supplemental new drug application and it is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Teshara G. Bouie, Regulatory Health Project Manager, at (301) 796-1649.

Sincerely,

*{See appended electronic signature page}*

James D. Vidra, Ph.D.  
Branch Chief  
Branch VII, Division of Post-Marketing Evaluation  
Office of New Drug Quality Assessment  
Center for Drug Evaluation and Research

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/s/

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Jim Vidra  
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