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APPLICATION NUMBER:

21-483

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-483

Pfizer Global Research & Development
Attention: Christopher L. McCawley, MS, VMD
Worldwide Regulatory Affairs
50 Pequot Avenue
New London, CT 06320

Dear Dr. McCawley:

Please refer to your new drug application (NDA) dated September 26, 2002, received September 27, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Geodon (ziprasidone HCL) Oral Suspension 10 mg/ml.

Your submission of September 29, 2005, constituted a complete response to our November 21, 2003, action letter.

This new drug application provides for the use of Geodon (ziprasidone HCL) Oral Suspension for the treatment of schizophrenia and for the treatment of acute manic or mixed episodes associated with bipolar disorder, with or without psychotic features.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text (email of March 20, 2006).

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Marketing the products 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*. For administrative purposes, designate this submission "**FPL for approved NDA 21-483.**" Approval of this submission by FDA is not required before the labeling is used.

A 24 month expiry date is granted based upon the available stability data.

The regulatory test methods have been validated and they have been found suitable for analysis of the drug product.

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 the pediatric study requirement for this application.

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 Keith Kiedrow, Pharm.D., Regulatory Project Manager, at (301) 796-1924.

Sincerely,

{See appended electronic signature page}

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

Enclosure