



NDA 20-825

Pfizer Central Research
Attention: Charles A. Ritrovato, Pharm.D.
Eastern Point Road
Groton, CT 06340

Dear Dr. Ritrovato:

Please refer to your new drug application (NDA) dated March 18, 1997, received March 17, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ziprasidone 20, 40, 60, 80 mg Capsules.

We acknowledge receipt of the following submissions:

September 15, 2000	October 3, 2000	October 20, 2000
October 24, 2000	November 21, 2000	November 28, 2000
December 1, 2000	December 12, 2000	December 22, 2000
January 2, 2001	January 25, 2001	

Your submission of October 20, 2000 constituted a complete response to our action letter of September 8, 2000.

This new drug application provides for the use of ziprasidone 20, 40, 60, 80 mg Capsules for the treatment of schizophrenia.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). 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 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 20-825." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitments in your submission dated October 20, 2000.

These commitments are listed below.

1. A Dose Response Study for QTc Effect
2. A Study of Sudden Unexpected Death with Ziprasidone and other Atypical Antipsychotics
3. Studies to Demonstrate Possible Advantages for Ziprasidone

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, 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."**

In our action letter of September 8, 2000, we requested that you rapidly notify the Agency of specific adverse events (photosensitivity reaction, jaundice, hepatitis, increased transaminases, ketoacidosis, hyperosmolar coma, and marked glucose intolerance). Your proposal to submit monthly line listings of these events is acceptable.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, 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 (63 *FR* 66632)(21 CFR 314.55 (or 601.27)). The Agency has not made a determination if a health benefit would be gained by studying ziprasidone in pediatric patients for its approved indications. FDA is deferring the requirement for submission of the pediatric assessments of safety and effectiveness because pediatric studies should be delayed until additional safety data have been collected and reviewed. FDA will inform you on or before June 1, 2001 whether pediatric studies are required under the rule. If FDA determines at that time that pediatric studies are necessary, FDA will also set a specific time at which you must submit the required assessments.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

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

As stated in the action letter of September 8, 2000, the proprietary name "Zeldox" is not in compliance with 21 CFR 201.10(c)(5). This regulation prohibits the designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient. However, your proposed alternative proprietary name "Geodon" is acceptable. Please note, if you choose not to use "Geodon" as the proprietary name for this product, the name you choose and its use in the label must conform to the specifications under 21 CFR 201.10 and 201.15. Please submit any proprietary name to the Agency for our review prior to its implementation.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Steven D. Hardeman, R.Ph., Senior Regulatory Project Manager, at (301) 594-5525.

Sincerely,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Attachment

/s/

Robert Temple

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