CLINICAL REVIEW

Application Type	NDA [redacted] (b) (4)
Submission Number	020592
Submission Code	SE5 040/041
Letter Date	2/5/2008
Stamp Date	2/5/2008
PDUFA Goal Date	8/5/2008
Reviewer Name	Cara Alfaro, Pharm.D.
Review Completion Date	7/14/2008
Established Name	Olanzapine
Trade Name	Zyprexa
Therapeutic Class	Antipsychotic
Applicant	Eli Lilly & Co
Priority Designation	S
Formulation	Oral tablets
Dosing Regimen	2.5 – 5 mg starting, maximum dose 20 mg/day
Indications	Treatment of Bipolar I Disorder (040) and Schizophrenia (041)
Intended Population	Adolescents

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(b) (4)

1 EXECUTIVE SUMMARY

1.1 Recommendation on Regulatory Action

This is a review (b) (4) for NDAs 20-592 SE5-040 (b) (4) and SE5-041 (b) (4)

(b) (4)

1.2 Recommendation on Postmarketing Actions

1.2.1 Risk Management Activity

The Sponsor submitted a "risk management plan" document, however, it was not a typical risk management plan. The Sponsor has proposed (b) (4) labeling changes and some further clinical trials to address the safety risks of olanzapine in both adults and adolescents.

1.2.2 Required Phase 4 Commitments

The Sponsor is planning to conduct a 52-week open-label safety study (Study F1D-MC-HGMX) in adolescent subjects with bipolar disorder or schizophrenia (see Section 7 of review - Studies to be Conducted In Adolescents). This study is being considered as a Phase 4 commitment. As of this time, the protocol for this study has not been submitted.
No additional Phase 4 commitments are recommended.

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/s/

Cara Alfaro
7/14/2008 12:33:38 PM
PHARMACIST

Ni Aye Khin
7/18/2008 09:57:26 AM
MEDICAL OFFICER
I concur with Dr. Alfaro's recommendations; see memo to file for additional comments.