CLINICAL REVIEW

Application Type NDA

(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

Clinical Review
Cara Alfaro, Pharm.D.
NDA 020592 SE5 040/041 –
Zyprexa (olanzapine) tablets

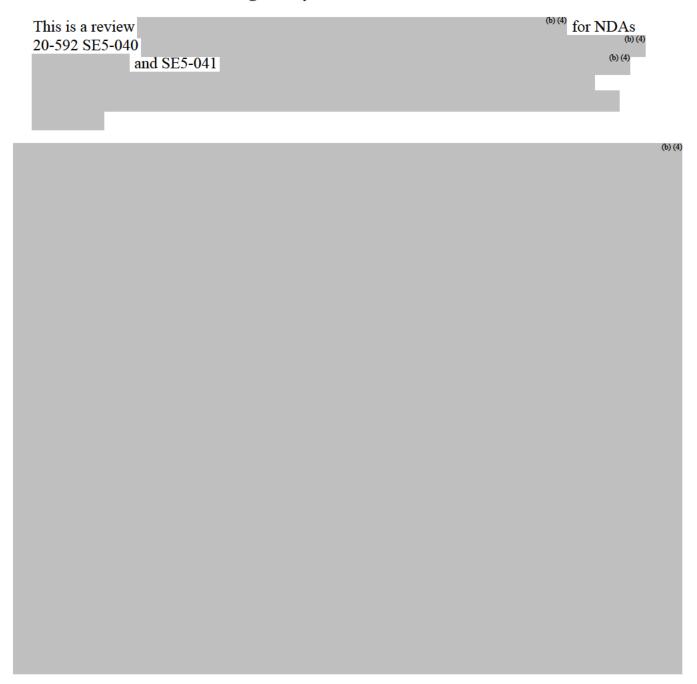
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1 EXECUTIVE SUMMARY

1.1 Recommendation on Regulatory Action



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 [10] 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.