

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

020592Orig1s040s041

CHEMISTRY REVIEW(S)

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
 FOOD AND DRUG ADMINISTRATION
 OFFICE OF NEW DRUG QUALITY ASSESSMENT
 POST-MARKETING EVALUATION
 CMC ASSESSMENT FORM**

APPLICANT: LILLY	NDA NUMBER: 020592 020592	DOC TYPE: SE5 SE5	SEQ NUMBER: 040 041	SUBMISSION TYPE: ORIGINAL
PROPRIETARY NAME: ZYPREXA(OLANZAPINE) ORAL TABS 2.5MG/5MG/		ESTABLISHED NAME: OLANZAPINE		
DOSAGE FORM: TAB		STRENGTH/POTENCY: 2.5; 5; 7.5; AND 10 MG	PHARMACOLOGICAL CATEGORY:	
LETTER DATE: 10/30/2006	STAMP DATE: 10/31/2006	PDUFA GOAL DATE: 4/30/2007	SUBMISSION (CHECK ONE) FIRM: PA FINAL: PA	
DIVISION IV BRANCH: VII	OND DIVISION: 130	MANAGED BY: OND	PAL: Brown MEDIA SUBMISSION: Electronic	
SUPPLEMENT PROVIDES FOR: fulfillment of FDA's request for pediatric studies. 11/15/06 amendment to includes the Environmental Assessment for both Zyprexa indications and request a waiver from the requirement in the new Physicians Labeling Rule that the Highlights section of labeling in the PLR format be limited to one-half page.				
BUNDLED: No				
CHANGE CATEGORY: Efficacy Supplement				
LABELING INVOLVED: Yes - PI only	PAT: No	COMPARABILITY PROTOCOL: No	PHASE 4 COMMITMENT: Np	
REVIEW PATH: 6 - OND Multi-Discipline Review				
CONSULTS: NA				
JUSTIFICATION/COMMENTS: 1/12/2007 - BROWNJA				
<p>1. The applicant has requested a categorical exclusion from submitting an environmental assessment for the use of Zyprexa in the treatment of schizophrenia. The active ingredient in Zyprexa is olanzapine and the expected concentration of olanzapine at the point of entry into the aquatic environment would be ^{(b) (4)} μg/L or less which is less than 1 part per billion (1μg/L) which qualifies for a categorical exclusion as described in 21 CFR 25.31(b). The applicant has also stated that there are no extraordinary circumstances known to exist for this proposed action. The applicant's request for a categorical exclusion is granted.</p> <p>2. There are no CMC labeling changes.</p> <p>3. From a CMC standpoint, this supplement can be approved.</p>				
PAL ACTION: Recommend Approval				
BRANCH CHIEF: James Vidra				

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this page is the manifestation of the electronic signature.**

/s/

Janice Brown
1/17/2007 02:49:46 PM
CHEMIST

Jim Vidra
1/17/2007 03:50:48 PM
CHEMIST