

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-148

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: Eli Lilly and Co.	NDA NUMBER: 22-148	DOC TYPE: N-000 Type 6 NDA	SEQ NUMBER: 000	SUBMISSION TYPE: ORIGINAL
PROPRIETARY NAME: Cymbalta		ESTABLISHED NAME: Duloxetine Hydrochloride		
DOSAGE FORM: Capsules	STRENGTH/POTENCY: 20, 30, 60 MG		PHARMACOLOGICAL CATEGORY:	
LETTER DATE: 08/14/2007	STAMP DATE: 8/14/2007	PDUFA GOAL DATE: 06/14/2008	SUBMISSION (CHECK ONE) FIRM: PA FINAL: PA	
DIVISION IV BRANCH: VII	OND DIVISION: 170	MANAGED BY: OND	PAL: Ramesh Raghavachari MEDIA SUBMISSION: Electronic	
SUPPLEMENT PROVIDES FOR: Indication for the of Fibromyalgia				
BUNDLED: No				
CHANGE CATEGORY: Type -6 NDA				
LABELING INVOLVED: No	PAT: No		COMPARABILITY PROTOCOL: No	PHASE 4 COMMITMENT:
REVIEW PATH: 6- Multidisciplinary review				
CONSULTS: EA from OPS				
5/20/2008- RAGHAVACHARI –				
<p>Review: The applicant has submitted this as a Type 6 NDA. This is an approved drug under NDA 21-427 in a different clinical division (HFD-130). This NDA is indicated for the of fibromyalgia. There are no CMC related changes submitted in this application. The applicant has referenced NDA 21-427 for CMC related information in this NDA. However, a complete Environmental Assessment has been provided in this submission. This EA was consulted with OPS Immediate Office. Based on the review from OPS consult dated May 13, 2008, the Environmental Assessment provided by the applicant is adequate.</p>				
<p>From CMC point of view this application is recommended for approval.</p>				
PAL ACTION: Recommended for approval from CMC point of view.				
BRANCH CHIEF: James D. Vidra				
COMMENTS:				
<i>EA adequate. CMC point of view recommended for approval.</i>				
BRANCH CHIEF ACTION: Recommends approval.				
REVIEWER: Ramesh Raghavachari				
REVIEWER ACTION:				
<i>From CMC point of view, recommended for approval</i>				

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

/s/

Ramesh Raghavachari
5/20/2008 04:59:31 PM
CHEMIST

Jim Vidra
5/21/2008 01:11:05 PM
CHEMIST