

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
022516Orig1s000

CHEMISTRY REVIEW(S)

MEMO TO FILE

To: NDA 22-516 for Cymbalta® (duloxetine HCl) capsules, 20, 30, (b) (4) 60 mg
From: Danae Christodoulou, Ph.D. – PAL, ONDQA, DPA I, Branch II
Through: Prasad Peri, Ph.D. – Acting Branch Chief, ONDQA, DPA I, Branch II;
Don Henry, Project Manager, ONDQA
Date: March 10, 2010
Subject: NDA 22-516 – CMC recommendation

CMC of the current NDA is supported by the previously approved NDAs 21-247 (anxiety disorder), 21-733 (diabetic neuropathy) and 22-148 (fibromyalgia), by Eli-Lilly.

Review of the submitted Environmental Assessment was completed on November 2, 2009, by Emily McVey, Ph.D., and a FONSI was recommended.

On March 15, 2010, the Office of Compliance issued an overall ACCEPTABLE cGMP recommendation for the NDA, based on profile of the currently used facilities (see attached EER summary report).

There are no pending CMC issues with respect to this application and approval is recommended from a CMC perspective.

**FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT**

Application:	NDA 22516/000	Sponsor:	ELI LILLY AND CO
Org. Code:	170		ELI LILLY CORPORATE CENTER
Priority:	6		INDIANAPOLIS, IN 46285
Stamp Date:	15-MAY-2009	Brand Name:	CYMBALTA
PDUFA Date:	15-MAR-2010	Estab. Name:	
Action Goal:		Generic Name:	DULOXETINE HCL POWDER
District Goal:	14-JAN-2010	Product Number; Dosage Form; Ingredient; Strengths	001; CAPSULE; DULOXETINE HYDROCHLORIDE; 20MG 002; CAPSULE; DULOXETINE HYDROCHLORIDE; 30MG 003; CAPSULE; DULOXETINE HYDROCHLORIDE; 60MG
FDA Contacts:	D. HENRY	Project Manager	301-796-4227
	D. CHRISTODOULOU	Team Leader	301-796-1342

Overall Recommendation: ACCEPTABLE on 15-MAR-2010 by M. STOCK (HFD-320) 301-796-4753

Establishment: CFN: (b) (4) FEI: (b) (4)
(b) (4)

DMF No: AADA:

Responsibilities:

Profile: OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 10-MAR-2010

Decision: ACCEPTABLE

Reason: BASED ON PROFILE

Establishment: CFN: (b) (4) FEI: (b) (4)
(b) (4)

DMF No: AADA:

Responsibilities:

Profile: CAPSULES, PROMPT RELEASE OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 15-MAR-2010

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

**FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT**

Establishment: CFN: 1819470 FEI: 1819470
ELI LILLY AND COMPANY
LILLY CORPORATE CENTER
INDIANAPOLIS, IN 462850001

DMF No: AADA:

Responsibilities: (b) (4)

Profile: CAPSULES, PROMPT RELEASE OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 08-MAR-2010

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

Establishment: CFN: 1813682 FEI: 1813682
ELI LILLY CO/TIPPECANOE
BOX 685 LILLY RD
LAFAYETTE, IN 47902

DMF No: AADA:

Responsibilities: (b) (4)

Profile: (b) (4) OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 08-MAR-2010

Decision: ACCEPTABLE

Reason: BASED ON PROFILE

**FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT**

Establishment: CFN: 2619243 FEI: 2619243
LILLY DEL CARIBE INC
CARR 3 KM 12.6
CAROLINA, PR 00985

DMF No: AADA:
Responsibilities: (b) (4)

Profile: CAPSULES, PROMPT RELEASE OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 15-MAR-2010
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION

Establishment: CFN: FEI: 3005303436
LILLY DEL CARIBE INC
CARR 53 KM 82 EXIT JOBOS 83
GUAYAMA, PR 00784

DMF No: AADA:
Responsibilities: (b) (4)

Profile: OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 15-MAR-2010
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION

Establishment: CFN: (b) (4) FEI: (b) (4)
(b) (4)

DMF No: AADA:
Responsibilities: (b) (4)

Profile: OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 08-MAR-2010
Decision: ACCEPTABLE
Reason: BASED ON PROFILE

**FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT**

Establishment:	CFN: (b) (4)	FEI: (b) (4)	
	(b) (4)		
DMF No:			AADA:
Responsibilities:			
Profile:	CAPSULES, PROMPT RELEASE		OAI Status: NONE
Last Milestone:	OC RECOMMENDATION		
Milestone Date:	08-MAR-2010		
Decision:	ACCEPTABLE		
Reason:	BASED ON PROFILE		
Establishment:	CFN: (b) (4)	FEI: (b) (4)	
	(b) (4)		
DMF No:			AADA:
Responsibilities:			
Profile:	CAPSULES, PROMPT RELEASE		OAI Status: NONE
Last Milestone:	OC RECOMMENDATION		
Milestone Date:	10-MAR-2010		
Decision:	ACCEPTABLE		
Reason:	BASED ON PROFILE		

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22516	ORIG-1	ELI LILLY AND CO	CYMBALTA
NDA-22516	GI-1	ELI LILLY AND CO	CYMBALTA

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DANAE D CHRISTODOULOU
03/15/2010

PRASAD PERI
03/15/2010
I concur