

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
022516Orig1s000

**RISK ASSESSMENT and RISK MITIGATION
REVIEW(S)**



**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology**

Date: February 19, 2010
Bob Rappaport, MD, Director

To: **Division of Anesthesia, Analgesia and Rheumatology
Products (DAARP)**

Through: Claudia Karwoski, PharmD, Director
Division of Risk Management (DRISK)
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From: Jessica Diaz, BSN, RN
Patient Product Information Reviewer
Division of Risk Management (DRISK)

Subject: DRISK Review of Patient Labeling (Medication Guide),
(b) (4)

Drug Name(s): CYMBALTA (duloxetine hydrochloride) Capsules
Application Type/Number: NDA 22-516 reference to NDA 21-427
Applicant/sponsor: Eli Lilly and Company

OSE RCM #: 2009-1205

1 INTRODUCTION

This review is written in response to a request by the Division of Anesthesia, Analgesia and Rheumatology Products (DAARP) for the Division of Risk Management (DRISK) to review the Applicant's proposed Medication Guide (MG) [REDACTED] (b) (4) supporting document for CYMBALTA (duloxetine hydrochloride) Capsules.

2 MATERIAL REVIEWED

[REDACTED] (b) (4)

- Comprehensive Medication Guide Notification Letter dated April 16, 2009 from DPP

3 DISCUSSION

CYMBALTA (duloxetine hydrochloride) Capsules was approved on August 3, 2004 with a single issue Medication Guide for the antidepressant class of drugs regarding the suicidality risk. The Division of Psychiatry Products (DPP) has determined all current generation drugs indicated to treat Major Depressive Disorder will be required to have a comprehensive Medication Guide as part of the approved drug label because the class poses a serious and significant public health concern that requires distribution of comprehensive patient information. The Applicant was notified of this requirement on April 16, 2009. This labeling change is not being required under the Food and Drug Administration Amendments Act (FDAAA) of 2007. The comprehensive MGs will include class language regarding the suicidality risk that is common to all products.

[REDACTED] (b) (4) in response to the letter above [REDACTED] (b) (4) the Applicant submitted a comprehensive MG. Because the details of the MG initiative in DPP are still under discussion, DAARP determined that the current one-issue MG is sufficient at this time [REDACTED] (b) (4). Our review of the comprehensive MG will be provided at a later date pending the outcome of above issues.

[REDACTED] (b) (4) It is important to note that the SWAT team made a determination that the conversion of a one-issue MG to a comprehensive MG would not trigger a REMS for the products in the class because there was no new safety information as the basis to require a REMS.

In the case of the currently approved Cymbalta MG, no new safety information is being added to the single issue MG that warrants conversion of the MG to a MG-only REMS. [REDACTED] (b) (4)

[REDACTED]

4 CONCLUSIONS AND RECOMMENDATIONS

DRISK does not believe that a REMS should be required for Cymbalta at this time [REDACTED] (b) (4). The currently approved one-issue MG is found to be acceptable until the DPP and DRISK develop an acceptable comprehensive MG for all the drugs in the class. [REDACTED] (b) (4)

[REDACTED]

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21427	ORIG-1	ELI LILLY AND CO	CYMBALTA(DULOXETINE HCL)20,30,40,60MG
NDA-22516	ORIG-1	ELI LILLY AND CO	CYMBALTA

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/s/

SHAWNA L HUTCHINS
02/19/2010

CLAUDIA B KARWOSKI
02/19/2010
concur