

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**022255Orig1s000**

**OTHER REVIEW(S)**

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**MEMORANDUM**

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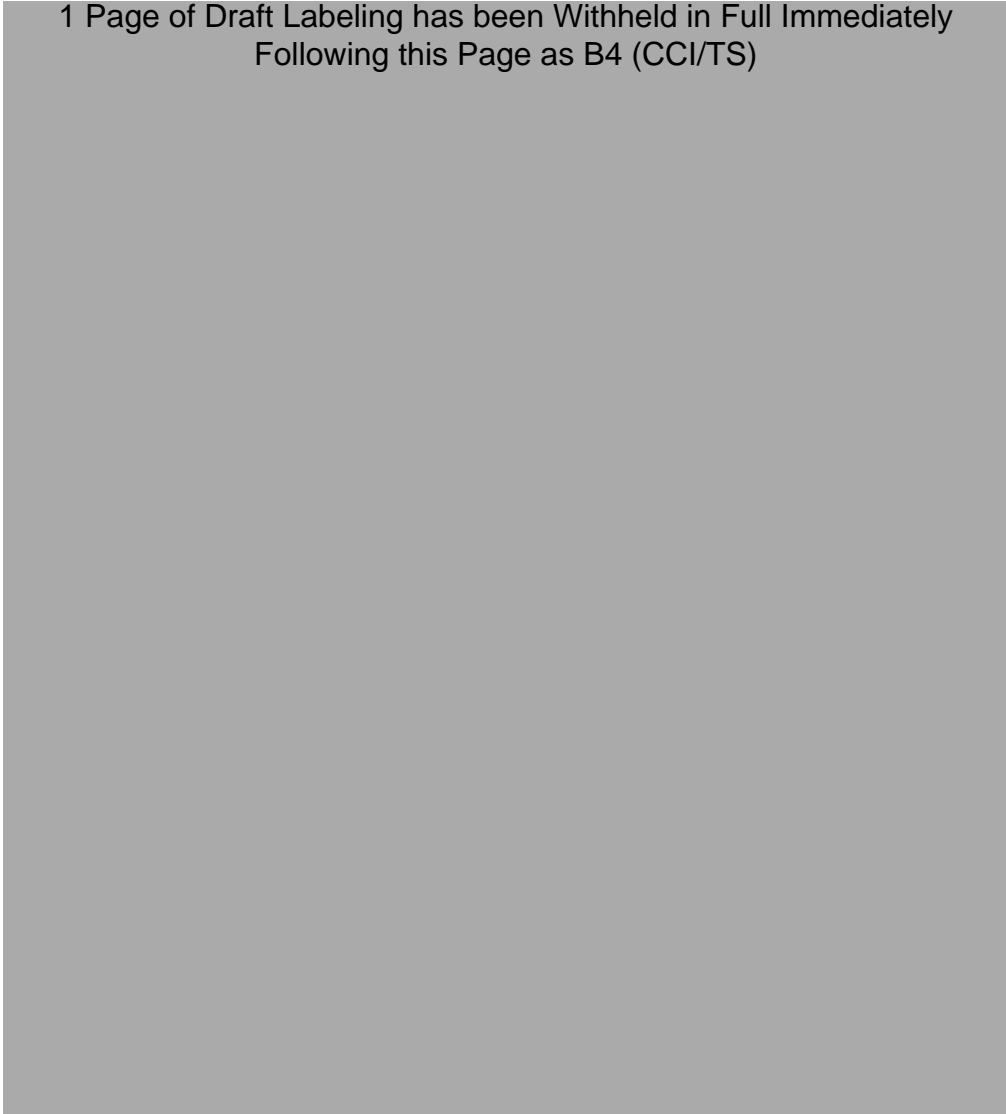
**TO:** NDA 22-255  
**FROM:** Wendy I. Wilson-Lee, Review Chemist  
**SUBJECT:** CMC Review of Revised Carton and Container Labels  
**DATE:** 4/19/2010  
**CC:** Susan Daugherty, HFD 120 RPM; Don Henry, ONDQA PM; Martha Heimann, ONDQA CMC Lead; Ramesh Sood, ONDQA Branch Chief

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Revised Carton and Container Labels

Schwarz provided revised carton and container labels based on FDA comments forwarded to the sponsor on 14-APR-2010. Based on further review, and in concert with DMEPA, we requested the sponsor remove the expression of total lacosamide content per total volume as it may confuse the patient. Figures 1 and 2 represent the final draft carton and container labels.

1 Page of Draft Labeling has been Withheld in Full Immediately  
Following this Page as B4 (CCI/TS)



Overall Recommendation

**The revised carton and container labels are adequate, from a CMC perspective.**

Wendy I. Wilson-Lee

Wendy I. Wilson-Lee, Ph.D.  
Review Chemist  
ONDQA DPA-I

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22255	ORIG-1	SCHWARZ BIOSCIENCES INC	VIMPAT

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

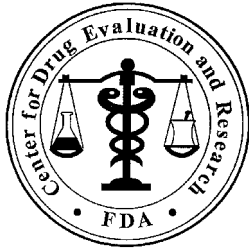
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/s/

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WENDY I WILSON  
04/19/2010

MARTHA R HEIMANN  
04/19/2010  
for Ramesh Sood



**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: April 7, 2010

To: Russell Katz, MD, Director  
Division of Neurology Products

Thru: Carlos Mena-Grillasca, RPh, Team Leader  
Denise Toyer, PharmD, Deputy Director  
Carol Holquist, RPh, Director  
Division of Medication Error Prevention and Analysis

From: Judy Park, PharmD, Safety Evaluator  
Division of Medication Error Prevention and Analysis

Subject: Medication Error and Labeling Review

Drug Name(s): Vimpat (Lacosamide) Oral Solution  
10 mg/mL

Application Type/Number: NDA 022255

Applicant: UCB, Inc.

OSE RCM #: 2009-2157 and 2009-2158

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