

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
NDA 22-253 & 22-254

CHEMISTRY REVIEW(S)

MEMORANDUM

TO: NDA 22-254
FROM: Wendy I. Wilson, Review Chemist
SUBJECT: CMC Review of Revised Labeling
DATE: 10/23/2008
CC: Jacqueline Ware, HFD 120 RPM; Scott Goldie, ONDQA PM; Martha Heimann, ONDQA PAL; Ramesh Sood, ONDQA Branch Chief; Blair Fraser, ONDQA Division Director

Revised Labeling

Schwarz incorporated all of the CMC recommendations concerning the carton container labels during the initial CMC review cycle. As part of that review, we recommended that the sponsor _____

b(4)

Overall Recommendation

We recommend that Schwarz revise the labeling _____

b(4)

Wendy I. Wilson

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

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

/s/

Wendy I. Wilson
10/23/2008 04:09:43 PM
CHEMIST

Ramesh Sood
10/24/2008 09:38:16 AM
CHEMIST

MEMORANDUM DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: July 16, 2008

FROM: Prafull Shiromani, Ph.D.
Reviewing Chemist
Division of Neurology Products, HFD-120

b(4)

TO: File NDA 22-253 _____

SUBJECT: Approval recommendation for Vimpat® (Lacosamide) Tablets, (NDA 22-253
_____, Schwarz Biosciences, Inc.)

b(4)

This memo recommends the approval of Vimpat® (Lacosamide) Tablets from CMC perspective based on the overall acceptable establishment report from the Office of Compliance, the summary of which is attached. All other CMC related issues had been resolved as per earlier CMC reviews.

Prafull Shiromani
Chemist

15-JUL-2008

FDA CDER BCS

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

Application : NDA 22253/000
Org Code : 120
Priority : 18

Sponsor: SCHWAB BIOSCIENCES
NO CITY, XX

Stamp Date : 28-SEP-2007
PDUFA Date : 28-JUL-2008
Action Goal :
District Goal: 29-MAY-2008

Brand Name : LACOSAMIDE (SPN927) TABLETS
Etab. Name:
Generic Name: LACOSAMIDE
Dosage Form: (TABLET)
Strength : 50, 100, 150, 200, 250, 300

FDA Contacts: S. GOLDIE Project Manager 301-796-1053
E. SHIRKANI Review Chemist 301-796-2133
M. HELMANN Team Leader 301-796-1678

Overall Recommendation: ACCEPTABLE on 15-JUL-2008 by S. ADAMS (HFD-325) 301-796-31

Establishment : CFN :

FPI :

b(4)

/ / /

b(4)

OSF No:

AADA:

b(4)

Responsibilities:

Profile : CSN OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 15-APR-08

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