CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022255Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

27 March 2010

NDA: 22-255 – Resubmission, Class 2 response

Drug Product Name
Proprietary: Lacosamide Oral Syrup
Non-proprietary: (R) -2-acetomido-N-benzyl-3-methoxypropionamide
Drug Product Priority Classification: S1

Review Number: 2

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
October 16, 2009	October 17, 2009	February 18, 2010	February 24, 2010

Submission History (for amendments only)

Submit Date(s)	Microbiology Review #	Review Date(s)
September 28, 2007	1	May 31, 2008

Applicant/Sponsor
Name: Schwarz Biosciences
Address: P.O.Box 110167, Research Triangle Park, NC 27709
Representative: Susan Tegtmeyer, Senior Manager, Reg. Affairs
Telephone: 770-970-8654 (phone), 770-970-8345 (fax)

Name of Reviewer: Vinayak B. Pawar, Ph.D.

Conclusion: The application is recommended for approval from microbiology product quality standpoint.

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original NDA

2. SUBMISSION PROVIDES FOR: A change (b) (4) in the reformulated oral solution.

3. MANUFACTURING SITE: Schwarz Pharma Manufacturing Inc., 1101 C Avenue West, Seymour, IN 47274.

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: 10mg/mL

5. METHOD(S) OF STERILIZATION: (b) (4)

6. PHARMACOLOGICAL CATEGORY: For treatment of partial-onset seizures.

B. SUPPORTING/RELATED DOCUMENTS: NDA 22-253 & NDA 22-255

C. REMARKS: The Re-submitted NDA 22-255 (October 16, 2009) is intended to be a full response to the FDA's complete response letter dated October 28, 2008. Although there were no microbiology product quality deficiencies in the original submission, the re-submission is being reviewed due to changes made (b) (4) . During the review of the Lacosamide oral solution application in Europe, the EMEA requested the removal of (b) (4) from the formulation (June 2008). For consistency, it was also removed from the proposed US formulation. Therefore, in the re-submission, the reformulation of the oral syrup Lacosamide (SPM927) includes removal of (b) (4) and a change in (b) (4) level. The re-submission is in electronic format in EDR. Initial Quality Assessment has been filed by Martha Heinman on October 30, 2007. No IQA was filed for the re-submission.

filename: C:\my documents\review\supplement\N022255R2

Executive Summary

I. Recommendations

A. Recommendation on Approvability – The re-submission is recommended for approval from microbiology product quality standpoint.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable - NA

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – (b) (4)

(b) (4)

The resubmission has a change in formulation (b) (4)

B. Brief Description of Microbiology Deficiencies – None.

C. Assessment of Risk Due to Microbiology Deficiencies – None.

III. Administrative

A. Reviewer's Signature _____

Primary Reviewer, Vinayak B. Pawar, Ph.D.

B. Endorsement Block _____

Secondary concurrence, Bryan S. Riley, Ph.D.

C. CC Block

N/A

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

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/s/

VINAYAK B PAWAR
03/30/2010

BRYAN S RILEY
03/31/2010
I concur.

Product Quality Microbiology Review

31 May 2008

NDA: 22-255

Drug Product Name
Proprietary: Lacosamide Oral Syrup
Non-proprietary: (R) -2-acetomido-N-benzyl-3-methoxypropionamide
Drug Product Priority Classification: S1

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
September 28, 2007	October 1, 2007	November 20, 2007	November 21, 2007

Submission History (for amendments only) - N/A

Applicant/Sponsor
Name: Schwarz Biosciences
Address: P.O.Box 110167, Research Triangle Park, NC 27709
Representative: Alan L. Blumberg, Sr. Dir. Global Reg. Affairs
Telephone: 919-767-2513 (phone), 919-767-3139 (fax)

Name of Reviewer: Vinayak B. Pawar, Ph.D.

Conclusion: The application is recommended for approval from microbiology product quality standpoint.

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original NDA

2. SUBMISSION PROVIDES FOR: An Oral form of a drug previously approved in a tablet form.

3. MANUFACTURING SITE: Schwarz Pharma Manufacturing Inc., 1101 C Avenue West, Seymour, IN 47274.

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: 10mg/mL

5. METHOD(S) OF STERILIZATION: (b) (4)

6. PHARMACOLOGICAL CATEGORY: For treatment of partial-onset seizures.

B. SUPPORTING/RELATED DOCUMENTS: NDA 22-253 & NDA 22-255

C. REMARKS: The consult requests review of an original NDA 22-255 for an oral syrup form of Lacosamide (SPM927). This application is a GRMP pilot application. The submission is in electronic form in EDR. Initial Quality Assessment has been filed by Martha Heinman on October 30, 2007.

filename: C:\my documents\review\supplement\N022255R1

Executive Summary

I. Recommendations

A. Recommendation on Approvability – The application is recommended for approval from microbiology product quality standpoint.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable - NA

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – (b) (4)

(b) (4)

B. Brief Description of Microbiology Deficiencies – None.

C. Assessment of Risk Due to Microbiology Deficiencies – None.

III. Administrative

A. Reviewer's Signature _____

Vinayak B. Pawar, Ph.D.

B. Endorsement Block _____

James McVey

C. CC Block

N/A

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/s/

Vinayak Pawar
6/5/2008 03:35:59 PM
MICROBIOLOGIST

Recommended for approval from microbiology product quality standpoint.

James McVey
6/5/2008 03:41:32 PM
MICROBIOLOGIST
I concur.