CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 22-253 & 22-254

MICROBIOLOGY REVIEW(S)



Product Quality Microbiology Review

1 June 2008

NDA:

22-254

Drug Product Name

Proprietary:

Lacosamide

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,	October 1, 2007	November 20,	November 21,
2007		2007	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.



C.

Product Quality Microbiology Data Sheet

TYPE OF SUBMISSION: Original NDA A. 1. 2. SUBMISSION PROVIDES FOR: An injectable form of a drug previously approved in a tablet form. b(4)3. **MANUFACTURING SITE:** DOSAGE FORM, ROUTE OF ADMINISTRATION AND 4. STRENGTH/POTENCY: 10mg/mL b(4)5. **METHOD(S) OF STERILIZATION:** PHARMACOLOGICAL CATEGORY: For treatment of partial-onset 6. seizures. b(4) B. **SUPPORTING/RELATED DOCUMENTS:** NDA 22-253 /

REMARKS: The consult requests review of an original NDA 22-254 for an injectable form of Lacosamide (SPM927) Injection. 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.

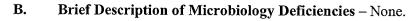
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APPEARS THIS WAY ON ORIGINAL



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 –



- C. Assessment of Risk Due to Microbiology Deficiencies None.
- III. Administrative

A.	Reviewer's Signature		
		Vinavak B Payyar Ph D	

B. Endorsement Block ______ James McVey

C. CC Block N/A



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	Trade Secret / Confidential (b4)
· .	Draft Labeling (b4)
	Draft Labeling (b5)
	Deliberative Process (b5)

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