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

filename: C:\my documents\review\NDA\N022254R1

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 –**

/ / / /

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

14 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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