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

<table>
<thead>
<tr>
<th>Letter</th>
<th>Stamp</th>
<th>Review Request</th>
<th>Assigned to Reviewer</th>
</tr>
</thead>
</table>

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: __________

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

5. METHOD(S) OF STERILIZATION: __________


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

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
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 –

   ![Image]

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
Page(s) Withheld

[Checkmark] Trade Secret / Confidential (b4)

Draft Labeling (b4)

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/s/

Vinayak Pawar
6/4/2008 03:09:05 PM
MICROBIOLOGIST

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

James McVey
MICROBIOLOGIST
I concur