CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-623

MICROBIOLOGY REVIEW

Product Quality Microbiology Review
Review for HFD-170

17 DECEMBER 2003

NDA: 21-623

Drug Product Name
Proprietary: S-Caine Patch
Non-proprietary: lidocaine 70 mg/tetracaine 70 mg
Drug Product Priority Classification: S

Review Number: 1

Subject of this Review
Submission Date: 31 March 2003
Receipt Date: 4 April 2003
Consult Date: 2 October 2003
Date Assigned for Review: 20 October 2003

Submission History (for amendments only)
Date(s) of Previous Submission(s): N/A
Date(s) of Previous Micro Review(s): N/A

Applicant/Sponsor
Name: ZARS Inc.
Address: 350 West 800 North, Suite 320, Salt Lake City, Utah 84103
Representative: T. Andrew Crockett
Telephone:

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

A. **1.** **TYPE OF SUPPLEMENT:** N/A

2. **SUPPLEMENT PROVIDES FOR:** N/A

3. **MANUFACTURING SITE:** Tapemark Company
1685 Marthaler Lane
West St. Paul, MN 55118

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Topical patch, 70 mg lidocaine and 70 mg tetracaine

5. **METHOD(S) OF STERILIZATION:** N/A

6. **PHARMACOLOGICAL CATEGORY:** Anesthetic

B. **SUPPORTING/RELATED DOCUMENTS:** N/A

C. **REMARKS:** none

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Executive Summary

I. Recommendations

A. Recommendation on Approvability – This submission is recommended for approval on the basis of product quality microbiology.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable – N/A

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – The drug product is a non-sterile transdermal patch with a microbial limits release specification.

B. Brief Description of Microbiology Deficiencies – N/A

C. Assessment of Risk Due to Microbiology Deficiencies – The drug product has appropriate microbial limits specifications and presents minimal risk from the standpoint of product quality microbiology.

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block
Bryan S. Riley, Ph.D. (Microbiology Reviewer)
Peter H. Cooney, Ph.D. (Microbiology Supervisor)

C. CC Block
N/A

1 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Microbiology- 7

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

/s/

Bryan Riley
1/23/04 08:25:19 AM
MICROBIOLOGIST

Peter Cooney
1/23/04 09:21:46 AM
MICROBIOLOGIST