

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-504

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

Review for HFD-170

2 JULY 2003

NDA: 21-504

Drug Product Name

Proprietary: Northstar Lidocaine Inotophoretic Drug Delivery System

Non-proprietary: N/A

Drug Product Priority Classification: S

Review Number: 1

Subject of this Review

Submission Date: 9 May 2002

Receipt Date: 9 May 2003

Consult Date: 16 April 2003

Date Assigned for Review: 30 June 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: Vyteris, Inc.

Address: 13-01 Pollitt Dr. Fair Lawn, NJ 07410

Representative: James P. Burns, Jr. Ph.D.

Telephone: 609-951-6803

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:** Vysteris, Inc.
13-01 Pollitt Drive
Fair Lawn, NJ 07410
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Topical Iontophoretic Patch, ~ mg lidocaine HCl – ~ mg epinephrine bitartrate
5. **METHOD(S) OF STERILIZATION:** N/A
6. **PHARMACOLOGICAL CATEGORY:** Dermal Anesthetic
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** N/A

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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 topical patch. The contents of the patch are preserved and have a microbial limits specification.
- B. **Brief Description of Microbiology Deficiencies** – N/A
- C. **Assessment of Risk Due to Microbiology Deficiencies** – The drug product is preserved and has an appropriate microbial limits specification for a topical product. Therefore, the product presents a 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

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___ § 552(b)(4) Trade Secret / Confidential

___ § 552(b)(5) Deliberative Process

___ § 552(b)(4) Draft Labeling

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/s/

Bryan Riley
7/3/03 10:12:29 AM
MICROBIOLOGIST

Peter Cooney
7/3/03 10:17:13 AM
MICROBIOLOGIST