

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-451

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

Review for HFD-170

22 October 2002

NDA: 21-451

Drug Product Name

Proprietary: Oraqix™ Peridontal Gel

Non-proprietary: lidocaine 2.5% and prilocaine 2.5% peridontal gel

Drug Product Classification: Topical

Review Number: 1

Subject of this Review

Submission Date: 21 January 2002

Receipt Date: 22 January 2002

Consult Date: 16 October 2002

Date Assigned for Review: 21 October 2002

Applicant/Sponsor

Name: Densply Pharmaceutical

Address: Concord Executive Center, 3427 Concord Road, York, PA
17402

Representative: Lee A. Zagar

Telephone: (717) 757-0200

Name of Reviewer: Paul Stinavage

Conclusion: The application is recommended for approval on the basis of microbiological quality of the drug product.

Product Quality Microbiology Data Sheet

- A.
1. TYPE OF SUPPLEMENT: N/A
 2. SUPPLEMENT PROVIDES FOR: N/A
 3. MANUFACTURING SITE: AstraZeneca, Bjorkborn, Sweden
 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Oral Topical
 5. METHOD(S) OF STERILIZATION: N/A
 6. PHARMACOLOGICAL CATEGORY: The product is intended for localized anesthesia in periodontal pockets for scaling, and/or root planing.

B. SUPPORTING/RELATED DOCUMENTS:

- C. REMARKS: The product is to be manufactured by:
AstraZeneca Liquid Production Services (LPS)
Karlskoga Plant
Bjorkborn
S-691 27 Karlskoga
Sweden

The product is not manufactured as a sterile product but conforms to microbiological quality specifications. The product is to be applied to periodontal pockets in the oral cavity. In light of the microbiological flora present in the oral cavity product sterility is not indicated.

filename: n21451.doc

Executive Summary**I. Recommendations**

- A. Recommendation on Approvability** – The application is recommended for approval on the basis of microbiological quality of the drug product.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -**

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology –**
- B. Brief Description of Microbiology Deficiencies – none**

III. Administrative

- A. Reviewer's Signature** _____
- B. Endorsement Block**
 - P. Stinavage
 - P.H. Cooney
- C. CC Block**
 - cc:
 - Original NDA 21-451
 - HFD-170/Division File/NDA 21-451/K. Compton

1 Page(s) Withheld

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

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

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

/s/

Paul Stinavage
11/14/02 10:35:44 AM
MICROBIOLOGIST
Oral preparation, no need for product sterility.

Peter Cooney
11/14/02 10:58:48 AM
MICROBIOLOGIST