CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-470

MICROBIOLOGY REVIEW

Product Quality Microbiology Review
Review for HFD-540

15 OCTOBER 2002

NDA: 21-470

Drug Product Name
Proprietary: Finacea Gel, 15%
Non-proprietary: azelaic acid
Drug Product Classification: S

Review Number: 1

Subject of this Review
Submission Date: 20 March 2002
Receipt Date: 21 March 2002
Consult Date: 24 April 2002
Date Assigned for Review: 24 April 2002

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: Berlex Laboratories
Address: 340 Changebridge Rd; Montville, NJ 07045
Representative: John Hegerty, Regulatory Associate
Telephone: 973-487-2166

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:** Schering SpA
Via E. Schering 21
20090 Segrate
Milano, Italy

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Non-sterile Gel for topical application, 15%

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

6. **PHARMACOLOGICAL CATEGORY:** Treatment of rosacea

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

C. **REMARKS:** The drug product is a non-sterile, preserved, gel. The application was submitted as an electronic file (1 compact disk).

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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, preserved cream.

B. Brief Description of Microbiology Deficiencies – N/A

C. Assessment of Risk Due to Microbiology Deficiencies – The drug product has appropriate microbial limit specifications and is adequately preserved. Therefore, the drug 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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/s/

Bryan Riley
10/18/02 09:37:54 AM
MICROBIOLOGIST

Peter Cooney
10/18/02 01:51:40 PM
MICROBIOLOGIST