CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-852

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review
Review for HFD-540

29 JUL 2005

NDA: 21-852
21-852 BI

Drug Product Name
Proprietary: Dovobet® Ointment
Non-proprietary: Calcipotriene hydrate and betamethasone dipropionate ointment
Drug Product Priority Classification: 4S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
09-MAR-2005	09-MAR-2005	23-MAY-2005	06-JUN-2005
13-JUL-2005	14-JUL-2005	19-JUL-2005	19-JUL-2005

Submission History (for amendments only) – N/A

Applicant/Sponsor
Name: LEO Pharmaceutical Products Ltd.
Address: Industriparken 55
DK-2750 Ballerup
Denmark

Representative: Gail Glifort, RAC
Consultant, PAREXEL Consulting
Telephone: (919) 294-5099
E-mail: gail.glifort@parexel.com

Name of Reviewer: Anastasia G. Lolas

Conclusion: Recommended for approval based on microbiological product quality

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUBMISSION:** New drug application

2. **SUBMISSION PROVIDES FOR:** Product quality microbiology for a non-aqueous based ointment for topical skin application

3. **MANUFACTURING SITE:**
Manufacturing and testing site: LEO Laboratories Ltd. (LEO Pharma)
285 Cashel Road, Dublin 12
Ireland

Stability testing: LEO Laboratories Ltd. (LEO Pharma)
Industriparken 55
DK-2750 Ballerup
Denmark

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**

- Ointment
- Topical dermatologic
- 0.005% calcipotriene and — betamethasone
- 3, 15, 30, 60 and — aluminum tubes

5. **METHOD(S) OF STERILIZATION:** N/A, drug product is non-sterile

6. **PHARMACOLOGICAL CATEGORY:** Treatment of psoriasis vulgaris

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

C. **REMARKS:** Ms. Gail Glifort was contacted via e-mail on June 29, 2005 to provide information on: in-house protocols and procedures for testing for microbial limits; validation of the test methods; raw data on materials/excipients and finished product with action limits; sampling plan. An electronic response was received on July 13 and a minor amendment was submitted on the same day.

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Executive Summary

I. Recommendations

A. Recommendation on Approvability – Recommended for approval based on microbiological product quality

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 submission includes microbial test methods, specifications and action limits for the drug product and its excipients.

B. Brief Description of Microbiology Deficiencies – N/A

C. Assessment of Risk Due to Microbiology Deficiencies – N/A

III. Administrative

A. Reviewer's Signature _____
Anastasia G. Lolas

B. Endorsement Block
David Hussong, Ph.D.
Microbiology Supervisor

C. CC Block
In DFS

5 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Microbiology- 1a