

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-502

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

22-November-2005

NDA: See below

Drug Product Name

NDA	Proprietary	Non-Proprietary
[_____]	
21-502	SPF 15 Daily Use Sunscreen	Ecamsule 2%/Avobenzone/Octocrylene
[_____]	

Drug Product Priority Classification: Standard

Review Number: 1

Dates of Submission(s) Covered by this Review

NDA	Letter Date	Stamp Date	Consult Sent	Assigned to Reviewer
[_____]			
21-502	5/12/05	5/12/05	11/18/05	11/21/05
[_____]			

Submission History (for amendments only): Not applicable

Applicant/Sponsor

Name: L'Oreal USA Products, Inc.
Address: 111 L'Oreal Way
Clark, NJ 07066
Representative: Jean R. Grieve
Telephone: (732) 680 5562

Name of Reviewer: Stephen E. Langille, Ph.D.

Conclusion: Recommended for approval.

Product Quality Microbiology Data Sheet

- A.
1. TYPE OF SUBMISSION: Original NDAs
 2. SUBMISSION PROVIDES FOR: Microbial limits and preservative effectiveness for topical creams.
 3. MANUFACTURING SITE: []
 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:
 - Semisolid
 - Topical[]
 5. METHOD(S) OF STERILIZATION: Non-sterile drug product
 6. PHARMACOLOGICAL CATEGORY: Sun screen
- B. SUPPORTING/RELATED DOCUMENTS: None
- C. REMARKS: None

filename: []

Executive Summary**I. Recommendations**

- A. Recommendation on Approvability –**
NDA: — 21-502 [] are recommended for approval from the standpoint of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -**
Not applicable

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -**
The drug products are all non-sterile topical creams containing methylparaben and propylparaben —
- B. Brief Description of Microbiology Deficiencies -**
No deficiencies were identified based upon the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies -**
Not applicable

III. Administrative

- A. Reviewer's Signature** _____
- B. Endorsement Block**
Bryan Riley, Ph.D.
- C. CC Block**
N/A

2 Page(s) Withheld

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

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

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/s/

Stephen Langille
11/29/2005 09:15:10 AM
MICROBIOLOGIST

Bryan Riley
11/30/2005 08:15:45 AM
MICROBIOLOGIST