

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
NDA 21-501

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

22-November-2005

NDA: See below

Drug Product Name

NDA	Proprietary	Non-Proprietary
21-501	SPF 15 Water Resistant Lotion Sunscreen	Ecamsule 3%/Avobenzone/Octocrylene
21-502	SPF 15 Daily Use Lotion Sunscreen	Ecamsule 2%/Avobenzone/Octocrylene
21-471	— SPF 20 Water Resistant	— SPF 20 Water Resistant

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
21-501	5/16/05	5/16/05	11/18/05	11/21/05
21-502	5/12/05	5/12/05	11/18/05	11/21/05
21-471	9/27/05	9/28/05	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 effectiveness for topical creams.
3. MANUFACTURING SITE: *1 1 1*
4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:
- Semisolid
 - Topical
 - Various strengths
5. METHOD(S) OF STERILIZATION: Non-sterile drug product
6. PHARMACOLOGICAL CATEGORY: Sun screen
- B. SUPPORTING/RELATED DOCUMENTS: None
- C. REMARKS: None

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Executive Summary

I. Recommendations

- A. **Recommendation on Approvability –**
NDAs 21-501, 21-502, and — are recommended for approval from the standpoint of product quality microbiology. b(4)
- 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 b(4)
- 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

/ Trade Secret / Confidential (b4)

 Draft Labeling (b4)

 Draft Labeling (b5)

 Deliberative Process (b5)

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/s/

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

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