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RESEARCH**

*APPLICATION NUMBER:*  
**21-471**

**MICROBIOLOGY REVIEW**

# 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.

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## 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
    - Various strengths
  5. METHOD(S) OF STERILIZATION: Non-sterile drug product
  6. PHARMACOLOGICAL CATEGORY: Sun screen
- B. SUPPORTING/RELATED DOCUMENTS: None
- C. REMARKS: None

filename: N021501r1.doc

**APPEARS THIS WAY  
ON ORIGINAL**

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## **Executive Summary**

### **I. Recommendations**

- A. Recommendation on Approvability –**  
NDAs 21-501, 21-502, and 21-503 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 preservatives.
- 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

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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