

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number** 21-142

**MICROBIOLOGY REVIEW(S)**

NOV 2 1999

REVIEW FOR HFD-540  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF  
MICROBIOLOGIST'S REVIEW # 1 OF NDA

October 12, 1999

A. 1. NDA 21-142

SPONSOR Connetics Corporation  
3400 West Bayshore Road  
Palo Alto, CA 94303

2. PRODUCT NAMES: OLUX™ Foam (0.05% clobetasol propionate)
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Foam, Topical
4. METHOD(S) OF STERILIZATION: NA
5. PHARMACOLOGICAL CATEGORY: Corticosteroid
6. DRUG PRIORITY CLASSIFICATION:

- B. 1. DATE OF INITIAL SUBMISSION: July 29, 1999
2. DATE OF AMENDMENT: NA
  3. RELATED DOCUMENTS: none
  4. ASSIGNED FOR REVIEW: August 18, 1999

C. REMARKS: The proposed indication is 1 \_\_\_\_\_

1. This review addresses the antimicrobial effectiveness test.

D. CONCLUSIONS: This submission is recommended for approval on the basis of product quality microbiology.

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10-12-99

Bryan Riley, Ph.D.

Pat 11/2/99

cc: Original NDA 21-142  
HFD 540/Consult File  
HFD 540/Project Manager  
HFD 540/Rev Chemist  
HFD 805/Consult File  
HFD 805/B. Riley

Drafted by: B. Riley, 10/12/99  
R/D initialed by: P. Cooney,

APPEARS THIS WAY  
ON ORIGINAL

**THIS SECTION  
WAS  
DETERMINED  
NOT  
TO BE  
RELEASABLE**

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