

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number** 20-985

**MICROBIOLOGY REVIEW(S)**

HFD 540  
LOTWAK

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

FEB 23 2000

February 17, 2000

A. 1. NDA 20-985

SPONSOR Dermik Laboratories Inc.  
500 Arcola Road  
Collegeville, PA 19426

2. PRODUCT NAMES \_\_\_\_\_ Cream (fluorouracil)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 0.5%, Topical Cream

4. METHOD(S) OF STERILIZATION: NA

5. PHARMACOLOGICAL CATEGORY: Antimetabolite/Cytotoxic

6. DRUG PRIORITY CLASSIFICATION:

B. 1. DATE OF INITIAL SUBMISSION: October 28, 1999

2. DATE OF AMENDMENT: NA

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: December 17, 1999

C. REMARKS: The drug product is a non-sterile, preserved, topical cream.

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

[ /S/ ]

2-17-00

Bryan Riley, Ph.D.

- cc:
- HFD 540/Consult File
  - HFD 540/V. Lutwak
  - HFD 540/Rev Chemist
  - HFD 805/Consult File
  - HFD 805/B. Riley

Drafted by: B. Riley, 2/17/00  
R/D initialed by: P. Cooney,

[ /S/ ] for PNC 2/23/2000

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