

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-145

MICROBIOLOGY REVIEW(S)

M. Wright

DEC - 6 1999

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

December 6, 1999

A. 1. NDA 21-145

SPONSOR Westwood-Squibb Colton Holdings Partnership
100 Forest Avenue
Buffalo, New York 14213-1091

- 2. PRODUCT NAMES: Vaniqa™ (Eflornithine Hydrochloride 15% Cream)
- 3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Topical Cream
- 4. METHOD(S) OF STERILIZATION: NA
- 5. PHARMACOLOGICAL CATEGORY: Ornithine Decarboxylase Inhibitor
- 6. DRUG PRIORITY CLASSIFICATION:

- B. 1. DATE OF INITIAL SUBMISSION: September 24, 1999
- 2. DATE OF AMENDMENT: NA
- 3. RELATED DOCUMENTS: none
- 4. ASSIGNED FOR REVIEW: October 28, 1999

C. REMARKS: The drug product is a non-sterile topical cream. This review examines the drug products microbial limit specifications and the antimicrobial effectiveness test.

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

15/ 12-6-99

Bryan Riley, Ph.D. ✓
15/ 12/4/99

cc:

HFD 540/Consult File
HFD 540/M. Wright
HFD 540/Rev Chemist
HFD 805/Consult File
HFD 805/B. Riley

Drafted by: B. Riley, 12/6/99
R/D initialed by: P. Cooney,

APPEARS THIS WAY
ON ORIGINAL

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