

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-145/S-005

Trade Name: Vaniqa Cream 13.9%

Generic Name: (eflornithine HCl)

Sponsor: Bristol-Myers Squibb Company

Approval Date: September 5, 2001

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APPLICATION NUMBER:

21-145/S-005

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Reviews / Information Included in this NDA Review.

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APPLICATION NUMBER:

21-145/S-005

APPROVAL LETTER



NDA 21-145/S-005

Bristol-Myers Squibb Co.
Attention: William J. Regan
Director, CMC for Marketed Products
P.O. Box 5400
Princeton, NJ 08543-5400

Dear Mr. Regan:

Please refer to your supplemental new drug application dated May 4, 2001, received May 7, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vaniqa (eflornithine hydrochloride) Cream, 13.9%.

We acknowledge receipt of your submission dated May 4, 2001.

This "Changes Being Effected" supplemental new drug application provides for

We have completed the review of this supplemental application, and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Millie Wright, Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader for the
Division of Dermatologic & Dental Drug Products,
(HFD-540)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Wilson H. DeCamp
9/5/01 01:42:41 PM
approved

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APPLICATION NUMBER:

21-145/S-005

CHEMISTRY REVIEW(S)

18. **CONCLUSIONS AND RECOMMENDATIONS**

Recommend approval letter to issue for this supplement.

cc: Orig: NDA 21-145
 HFD-540 HFD-540/Cook
 HFD-540/Hill HFD-540/Wright
 HFD-540/EGPappas HFD-540/WHDeCamp:R/D initialed __

19. **REVIEWER**

NAME	SIGNATURE	DATE COMPLETED
Ernest G. Pappas		09/5/01

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/s/

Ernest G. Pappas
9/5/01 12:59:57 PM
CHEMIST

Revised Chem Review per instruction. Recommended approval.

Wilson H. DeCamp
9/5/01 01:28:40 PM
CHEMIST
concur with review; AP letter may be prepared

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APPLICATION NUMBER:

21-145/S-005

**ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS**



NDA 21-145/S-005

CBE-0 SUPPLEMENT

Bristol-Myers Squibb Pharmaceutical Research
Attention: William J. Regan
Director, CMC for Marketed Products
PO Box 5400
Princeton, NJ 08543-5400

Dear Mr. Regan:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Vaniqa (eflornithine hydrochloride) Cream, 13.9%

NDA Number: 21-145

Supplement Number: S-005

Date of Supplement: May 4, 2001

Date of Receipt: May 7, 2001

This supplemental application, submitted as a "Supplement - Changes Being Effectuated" supplement, provides

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on July 6, 2001 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be November 7, 2001.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Dermatologic & Dental Drug
Products, HFD-540
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Dermatologic & Dental Drug
Products, HFD-540
9201 Corporate Blvd.
Rockville, Maryland 20850-3202

If you have any questions, call Millie Wright, Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Mary Jean Kozma-Fornaro
Supervisor, Project Management Staff
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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/s/

Mildred Wright
7/18/01 11:01:59 AM
Signed for Mary Jean Kozma-Fornaro