CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-145/S-003

Trade Name: Vaniqa Cream 13.9%

Generic Name: (eflornithine HCl)

Sponsor: Bristol-Myers Squibb Company

Approval Date: June 29, 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-145/S-003

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	**X**
Approvable Letter	
Labeling	
Medical Review(s)	
Chemistry Review(s)	**X**
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	**X**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-145/S-003

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-145/S-003

Bristol-Myers Squibb Company
Attention: William J. Regan
Director - CMC Marketed Products,
Regulatory Sciences and Outcome Research
P. O. Box 4000
Princeton, NJ 08543-4000

Dear: Mr. Regan

Please refer to your supplemental new drug application dated February 16, 2001, received February 23, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vaniqa (eflornithine hydrochloride) Cream 13.9%.

This "Changes Being Effected" supplemental new drug application provides for the ——— ——— as an additional site of ———.

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, Consumer Safety Officer, at (301) 443-4250.

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Wilson H. DeCamp
6/29/01 12:20:53 PM
approved

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-145/S-003

CHEMISTRY REVIEW(S)

NDA SUPPLEMENT REVIEW

CHEMIST'S REVIEW 1. **ORGANIZATION** 2. **NDA NUMBER**

DDDDP (HFD-540) 21-145

3. **NAME & ADDRESS OF APPLICANT** 4. **AF NUMBER**

Bristol-Myers Squibb Company
Mr. William Reagan
Director Regulatory Affairs, CMC
P.O. Box 5400
Princeton, NJ 08543-5400

5. SUPPLEMENT(s) NUMBER(s)DATE(s)
SCM 003 2 /16 /01

6. **NAME OF DRUG**
Vaniqa

7. **NONPROPRIETARY NAME**
eflornithine hydrochloride

8. **SUPPLEMENT(s) PROVIDES FOR:**

9. **AMENDMENTS AND OTHER (REPORTS, etc.) DATES**
none

10. **PHARMACOLOGICAL CATEGORY**
Excessive facial hair in women

11. **HOW DISPENSED**
xxx Rx OTC

12. **RELATED IND/NDA/DMF(s)**

13. **DOSAGE FORM(s)**
Cream

14. **POTENCY(ies)**
13.9 %

15. **CHEMICAL NAME AND STRUCTURE**

m.w. .
CAS Registry No. - -

16. RECORDS AND REPORTS
CURRENT
x Yes No
REVIEWED
x Yes No

17. **COMMENTS**

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		06/28/01

DISTRIBUTION ORIGINAL JACKET REVIEWER DIVISION FILE

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/s/

Ernest G. Pappas
6/29/01 09:42:17 AM
CHEMIST
Recommend approval for supplement

Wilson H. DeCamp
6/29/01 12:29:37 PM
CHEMIST
concur; AP letter may be issued

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-145/S-003

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-145/S-003

Bristol-Myers Squibb Company
Attention: William J. Regan, Director
CMC Marketed Products, Regulatory Sciences and Outcomes Research
P.O. Box 4000
Princeton, New Jersey 08543-4000

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 HCl) Topical Cream, 13.9%

NDA Number: 21-145

Supplement number: S-003

Date of supplement: February 16, 2001

Date of receipt: February 23, 2001

This supplemental application, submitted as "Supplement - Changes Being Effected in 30 days," proposes the following change: [redacted]

Unless we notify you within 60 days of the 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 April 24, 2001 in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Dermatologic and Dental Drug Products, HFD-540
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Division of Dermatologic and Dental Drug Products
Attention: Document Room
9201 Corporate Boulevard
Rockville, Maryland 20850

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

Sincerely yours,

Mary J. Kozm-Fornaro
Supervisor, Project Management Staff
Division of Dermatologic and Dental
Drug Products, HFD-540
Office of Drug Evaluation V
Center for Drug Evaluation and Research

/s/

Mildred Wright
2/26/01 09:49:41 AM