CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-145/S-002

Trade Name: Vaniqa Cream 13.9%

Generic Name: (eflornithine HCl)

Sponsor: Bristol-Myers Squibb Company

Approval Date: June 25, 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-145/S-002

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**

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APPLICATION NUMBER:

21-145/S-002

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-145/S-002

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 January 22, 2001, received January 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 in 30 days" supplemental new drug application provides for a new physician sample of the drug product to be [redacted].

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 yours,

{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
6/25/01 03:32:51 PM
approved

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APPLICATION NUMBER:

21-145/S-002

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)
SCP 002 1 /22 /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		06/11/01

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/s/

Ernest G. Pappas
6/11/01 02:18:08 PM
CHEMIST
My review for ready for signature; recommend approval.

Wilson H. DeCamp
6/18/01 11:23:46 AM
CHEMIST
concur with review; AP letter may be forwarded

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APPLICATION NUMBER:

21-145/S-002

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

Div. File

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-145/S-002

FEB 5 2001

Bristol-Myers Squibb Company
P. O. Box 5400
Princeton, NJ 08543-5400

Attention: William J. Regan, Director- CMC Marketed Products, Regulatory Sciences and Outcomes Research

Dear Mr. Regan:

We acknowledge receipt of your supplemental application for the following:

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

NDA Number: 21-145

Supplement Number: S-002

Date of Supplement: January 22, 2001

Date of Receipt: January 23, 2001

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on March 24, 2001, in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Dermatologic and Dental Drug Products, HFD-540
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

Mary J. Kozma-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

cc:
Original NDA 21-145/S-002
HFD-540/Div. Files
HFD-540/CSO/M. Wright

SUPPLEMENT ACKNOWLEDGEMENT