

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**21-145/S-001**

***Trade Name:*** Vaniqa Cream 13.9%

***Generic Name:*** (eflornithine HCl)

***Sponsor:*** Bristol-Myers Squibb Company

***Approval Date:*** December 15, 2000

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*APPLICATION NUMBER:*

**21-145/S-001**

## CONTENTS

### Reviews / Information Included in this NDA Review.

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

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**APPROVAL LETTER**



NDA 21-145/S-001

Bristol-Myers Squibb Company  
Attention: William J. Regan  
Director CMC for Marketed Products,  
North America Worldwide Regulatory Affairs  
P.O. Box 5400  
Princeton, New Jersey 08543-5400

Dear Mr. Regan:

Please refer to your supplemental new drug application dated August 2, 2000, received August 2, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vaniqa (eflornithine HCl) Cream, 13.9%.

We acknowledge receipt of your submission dated August 17, 2000.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an \_\_\_\_\_  
\_\_\_\_\_ for the \_\_\_\_\_, in the \_\_\_\_\_ of  
the active pharmaceutical ingredient, eflornithine hydrochloride.

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,

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

/s/

-----  
Wilson H. DeCamp  
12/15/00 03:08:55 PM  
Approved

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**CHEMISTRY REVIEW(S)**

**NDA SUPPLEMENT REVIEW**

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<b>CHEMIST'S REVIEW</b>	<b>1. ORGANIZATION</b> DDDP(HFD-540)	<b>2. NDA NUMBER</b> 21-145
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<b>3. NAME &amp; ADDRESS OF APPLICANT</b>	<b>4. AF NUMBER</b>
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Bristol-Myers Squibb  
Attention: William J. Regan  
Director CMC for Marketed Products, North America  
P.O. Box 5400  
Princeton, NJ 08543-5400

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**5. SUPPLEMENT(s)  
NUMBER(s)DATE(s)**  
SCM-001 8 /2/00

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<b>6. NAME OF DRUG</b> Vaniqa	<b>7. NONPROPRIETARY NAME</b> Eflornithine Hydrochloride
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<b>8. SUPPLEMENT(s) PROVIDES FOR:</b>	<b>9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES</b> 8/17/00
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the active pharmaceutical ingredient, eflornithine hydrochloride.

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<b>10. PHARMACOLOGICAL CATEGORY</b>	<b>11. HOW DISPENSED</b> x Rx    OTC	<b>12. RELATED IND/NDA/DMF(s)</b>
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<b>13. DOSAGE FORM(s)</b> Cream	<b>14. POTENCY(ies)</b>
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**15. CHEMICAL NAME AND STRUCTURE**

m.w. :  
CAS Registry No. - -

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

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**17. COMMENTS**

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EER was requested on 10/4/00 \_\_\_\_\_ were  
found acceptable for GMPs (see memo from the Office of Compliance).

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 \_

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<b>19. REVIEWER</b>	
<b>NAME</b>	<b>SIGNATURE</b>
	<b>DATE COMPLETED</b>
Ernest G. Pappas	12/15/00

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DISTRIBUTION ORIGINAL JACKET REVIEWER DIVISION

FDA CDER EES  
ESTABLISHMENT EVALUATION REQUEST  
SUMMARY REPORT

Application: NDA 21145/001	Priority: 3S	Org Code: 540
Stamp: 02-AUG-2000 Regulatory Due: 02-FEB-2001	Action Goal:	District Goal: 29-DEC-2000
Applicant: WESTWOOD SQUIBB CLTN C/O BRISTOL MEYERS SQUIBB RT 206 PRINCETON, NJ 085434000	Brand Name: VANIQA(EFLORNITHINE HCL)13.9% TOPICAL CR	
	Established Name:	
	Generic Name: EFLORNITHINE HCL	
	Dosage Form: CRM (CREAM)	
	Strength:	

FDA Contacts: M. WRIGHT (HFD-540)	301-827-2084 , Project Manager
E. PAPPAS (HFD-540)	301-827-2066 , Review Chemist
W. DECAMP II (HFD-540)	301-827-2041 , Team Leader

Overall Recommendation:

**ACCEPTABLE on 28-NOV-2000 by J. D AMBROGIO(HFD-324)301-827-0062**

Establishment: /	DMF No:
	AADA No:

Profile: CSN	OAI Status: NONE	Responsibilities: /
Last Milestone: OC RECOMMENDATION		
Milestone Date: 28-NOV-2000		
Decision: ACCEPTABLE		
Reason: DISTRICT RECOMMENDATION		

/s/

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Ernie Pappas  
12/15/00 08:37:10 AM  
CHEMIST  
goal date 2-Feb-01  
recommend approval

Wilson H. DeCamp  
12/15/00 08:40:20 AM  
CHEMIST  
concur with review

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**ADMINISTRATIVE and CORRESPONDENCE  
DOCUMENTS**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Div. File  
1  
MKE02

Food and Drug Administration  
Rockville MD 20857

NDA 21-145/S-001

Bristol-Myers Squibb Company  
P.O. Box 4000  
Princeton, NJ 08543-4000

AUG 8 2000

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-001

Date of Supplement: August 2, 2000

Date of Receipt: August 2, 2000

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on October 1, 2000 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* 8/7/00

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

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cc:

Original NDA 21-145/S-001  
HFD-540/Div. Files  
HFD-540/CSO/M. Wright

SUPPLEMENT ACKNOWLEDGEMENT