

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-026

**RISK ASSESSMENT and RISK MITIGATION
REVIEW(S)**

REQUEST FOR CONSULTATION

TO (Division/Office): Office of Drug Safety/Division of Medication Errors and Technical Support/

FROM: Division of Dermatology and Dental Products/
Mildred Wright, PM

DATE
January 30, 2006

IND NO.

NDA NO
21-026

TYPE OF DOCUMENT AZ

DATE OF DOCUMENT
August 16, 2005

NAME OF DRUG
miconazole nitrate ointment, 0.25%

PRIORITY CONSIDERATION
Standard

CLASSIFICATION OF DRUG

DESIRED COMPLETION DATE
ASAP

NAME OF FIRM: Barrier Therapeutics, Inc..

REASON FOR REQUEST

I. GENERAL

- NEW PROTOCOL
- PROGRESS REPORT
- NEW CORRESPONDENCE
- DRUG ADVERTISING
- ADVERSE REACTION REPORT
- MANUFACTURING CHANGE/ADDITION
- MEETING PLANNED BY

- PRE-NDA MEETING
- END OF PHASE II MEETING
- RESUBMISSION
- SAFETY/EFFICACY
- PAPER NDA
- CONTROL SUPPLEMENT

- RESPONSE TO DEFICIENCY LETTER
- FINAL PRINTED LABELING
- LABELING REVISION
- ORIGINAL NEW CORRESPONDENCE
- FORMULATIVE REVIEW
- xx OTHER (SPECIFY BELOW):

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH

STATISTICAL APPLICATION BRANCH

- TYPE A OR B NDA REVIEW
- END OF PHASE II MEETING
- CONTROLLED STUDIES
- PROTOCOL REVIEW

OR (SPECIFY BELOW):

- CHEMISTRY REVIEW
- PHARMACOLOGY
- BIOPHARMACEUTICS
- OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- DISSOLUTION
- BIOAVAILABILITY STUDIES
- PHASE IV STUDIES

- DEFICIENCY LETTER RESPONSE
- PROTOCOL-BIOPHARMACEUTICS
- IN-VIVO WAIVER REQUEST

IV. DRUG EXPERIENCE

- PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- CASE REPORTS OF SPECIFIC REACTIONS (List below)
- COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP

- REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- SUMMARY OF ADVERSE EXPERIENCE
- POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

CLINICAL

PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS: See Attached. If you have questions, please call Millie Wright at (301)976-1027 or e-mail—wrightm ;
Thanks, Millie

SIGNATURE OF REQUESTER

METHOD OF DELIVERY (Check one)
X MAIL

HAND

SIGNATURE OF RECEIVER

SIGNATURE OF DELIVERER

January 30, 2006

DMETS/NDA 21-026/tradename consult

Hi,

As requested another consult for the Vusion tradename. We will be taking an action on the above NDA February 16, 2006, if not sooner. We sent you a tradename consult and got back your review, dated September 15, 2005, in which you stated that Vusion was acceptable. We also have a December 13, 2005 reivew from Nora Roselle, commenting on the labeling. I

Draft labeling below.

Millie

1/25/2006 Draft label

b(4)

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b Draft Labeling

 Deliberative Process

Withheld Track Number: Risk Assessment / Risk Mitigation-

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/s/

Mildred Wright
1/30/2006 01:42:10 PM

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		REQUEST FOR CONSULTATION			
) (Division/Office): Division of Surveillance, Research and Communication Support, HFD-410			FROM: Millie Wright, Project Manager Division of Dermatologic and Dental Drug Products/HFD-540		
DATE: April 25, 2005	IND NO.	NDA NO. 21-026	TYPE OF DOCUMENT NDA AZ	DATE OF DOCUMENT: April 15, 2005	
NAME OF DRUG: miconazole nitrate		PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG:	DESIRED COMPLETION DATE: PDUFA/5/24/05	
NAME OF FIRM: Barrier Therapeutics, Inc.					
REASON FOR REQUEST					
I. GENERAL					
<input type="checkbox"/> NEW PROTOCOL <input type="checkbox"/> PROGRESS REPORT <input type="checkbox"/> NEW CORRESPONDENCE <input type="checkbox"/> DRUG ADVERTISING <input type="checkbox"/> ADVERSE REACTION REPORT <input type="checkbox"/> MANUFACTURING CHANGE/ADDITION <input type="checkbox"/> MEETING PLANNED BY		<input type="checkbox"/> PRE-NDA MEETING <input type="checkbox"/> END OF PHASE II MEETING <input type="checkbox"/> RESUBMISSION <input type="checkbox"/> SAFETY/EFFICACY <input type="checkbox"/> PAPER NDA <input type="checkbox"/> CONTROL SUPPLEMENT		<input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER <input type="checkbox"/> FINAL PRINTED LABELING <input type="checkbox"/> LABELING REVISION <input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE <input type="checkbox"/> FORMULATIVE REVIEW <input checked="" type="checkbox"/> OTHER (SPECIFY BELOW):	
II. BIOMETRICS					
STATISTICAL EVALUATION BRANCH			STATISTICAL APPLICATION BRANCH		
<input type="checkbox"/> TYPE A OR B NDA REVIEW <input type="checkbox"/> END OF PHASE II MEETING <input type="checkbox"/> CONTROLLED STUDIES <input type="checkbox"/> PROTOCOL REVIEW <input type="checkbox"/> OTHER (SPECIFY BELOW):			<input type="checkbox"/> CHEMISTRY REVIEW <input type="checkbox"/> PHARMACOLOGY <input type="checkbox"/> BIOPHARMACEUTICS <input type="checkbox"/> OTHER (SPECIFY BELOW):		
III. BIOPHARMACEUTICS					
<input type="checkbox"/> DISSOLUTION <input type="checkbox"/> BIOAVAILABILITY STUDIES <input type="checkbox"/> PHASE IV STUDIES			<input type="checkbox"/> DEFICIENCY LETTER RESPONSE <input type="checkbox"/> PROTOCOL-BIOPHARMACEUTICS <input type="checkbox"/> IN-VIVO WAIVER REQUEST		
IV. DRUG EXPERIENCE					
<input type="checkbox"/> PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL <input type="checkbox"/> DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES <input type="checkbox"/> CASE REPORTS OF SPECIFIC REACTIONS (List below) <input type="checkbox"/> COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP			<input type="checkbox"/> REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY <input type="checkbox"/> SUMMARY OF ADVERSE EXPERIENCE <input type="checkbox"/> POISON RISK ANALYSIS		
V. SCIENTIFIC INVESTIGATIONS					
<input type="checkbox"/> CLINICAL			<input type="checkbox"/> PRECLINICAL		
COMMENTS/SPECIAL INSTRUCTIONS: Please see attached. If you have questions, please contact Millie Wright at 827-2084 or e-mail Wrightm					
SIGNATURE OF REQUESTER			METHOD OF DELIVERY (Check one) x <input type="checkbox"/> MAIL <input type="checkbox"/> HAND		
SIGNATURE OF RECEIVER			SIGNATURE OF DELIVERER		

April 25, 2005

NDA 21-026/ODS/DSRCS consult

We had to request that the Sponsor reformat their Patient Information Leaflet. We only received this last week. I apologize for the late date of your receipt. Please take a look at it and provide any comments that you have. We are still drafting the PI. I will attach a draft of the PI and PPI (Derm/Dental has not edited the PPI yet, but it does include Marilyn Pitt's comments.). Thanks for your input.

Millie

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO (Division/Office): Division of Pediatric Drug Development//HFD-960 /
Lisa Mathis, M.D., Acting D.D./ Grace Carmouze, PM

FROM: HFD 540/Division of Dermatologic and Dental Drug
Products/Jonathan Wilkin, M.D., D.D./ Millie Wright, PM

DATE April 21, 2005	IND NO.	NDA NO. 21-026	TYPE OF DOCUMENT MP	DATE OF DOCUMENT 11/24/04
NAME OF DRUG Zimycan (miconazole nitrate), Ointment, 0.25%		PRIORITY CONSIDERATION Standard	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE ASAP/PDUFA date 5/24/05

NAME OF FIRM: Barrier Therapeutics, Inc.

REASON FOR REQUEST

I. GENERAL

- | | | |
|--|--|--|
| <input type="checkbox"/> NEW PROTOCOL | <input type="checkbox"/> PRE-NDA MEETING | <input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER |
| <input type="checkbox"/> PROGRESS REPORT | <input type="checkbox"/> END OF PHASE II MEETING | <input type="checkbox"/> FINAL PRINTED LABELING |
| <input type="checkbox"/> NEW CORRESPONDENCE | <input type="checkbox"/> RESUBMISSION | <input type="checkbox"/> LABELING REVISION |
| <input type="checkbox"/> DRUG ADVERTISING | <input type="checkbox"/> SAFETY/EFFICACY | <input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE |
| <input type="checkbox"/> ADVERSE REACTION REPORT | <input type="checkbox"/> PAPER NDA | <input type="checkbox"/> FORMULATIVE REVIEW |
| <input type="checkbox"/> MANUFACTURING CHANGE/ADDITION | <input type="checkbox"/> CONTROL SUPPLEMENT | <input checked="" type="checkbox"/> OTHER (SPECIFY BELOW): |
| <input type="checkbox"/> MEETING PLANNED BY | | |

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH /PE A OR B NDA REVIEW _ND OF PHASE II MEETING <input type="checkbox"/> CONTROLLED STUDIES <input type="checkbox"/> PROTOCOL REVIEW (SPECIFY BELOW):	STATISTICAL APPLICATION BRANCH <input type="checkbox"/> CHEMISTRY REVIEW <input type="checkbox"/> PHARMACOLOGY <input type="checkbox"/> BIOPHARMACEUTICS <input type="checkbox"/> OTHER (SPECIFY BELOW):
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III. BIOPHARMACEUTICS

- | | |
|--|---|
| <input type="checkbox"/> DISSOLUTION | <input type="checkbox"/> DEFICIENCY LETTER RESPONSE |
| <input type="checkbox"/> BIOAVAILABILITY STUDIES | <input type="checkbox"/> PROTOCOL-BIOPHARMACEUTICS |
| <input type="checkbox"/> PHASE IV STUDIES | <input type="checkbox"/> IN-VIVO WAIVER REQUEST |

IV. DRUG EXPERIENCE

- | | |
|--|--|
| <input type="checkbox"/> PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL | <input type="checkbox"/> REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY |
| <input type="checkbox"/> DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES | <input type="checkbox"/> SUMMARY OF ADVERSE EXPERIENCE |
| <input type="checkbox"/> CASE REPORTS OF SPECIFIC REACTIONS (List below) | <input type="checkbox"/> POISON RISK ANALYSIS |
| <input type="checkbox"/> COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP | |

V. SCIENTIFIC INVESTIGATIONS

<input type="checkbox"/> CLINICAL	<input type="checkbox"/> PRECLINICAL
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COMMENTS/SPECIAL INSTRUCTIONS: See Attached. Thanks, Millie

SIGNATURE OF REQUESTER	METHOD OF DELIVERY (Check one) <input checked="" type="checkbox"/> MAIL <input type="checkbox"/> HAND
SIGNATURE OF RECEIVER	SIGNATURE OF DELIVERER

April 21, 2005

HFD-960/ NDA 21-026 Zimycan (miconazole nitrate) Ointments, 0.25% consult

Attached you will find the PPI for the above NDA. This is an AZ in response to our NA letter. We just received the PPI on April 19th. Therefore, you will not find our labeling changes because we haven't made them. We wanted to send this to you as a draft to give you time to think about your concerns. The indication is diaper dermatitis complicated by candidiasis. We have begun revising the PI and I will attach that also. Once we edit the PPI, I will forward it to you.

Thank you for your assistance,

Millie

827-2084

Attachments (2)

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/s/

Grace Carmouze
5/19/05 05:39:45 PM
comments forwarded by Lisa Mathis.

MEMO

To: Stanka Kukich, MD
Acting Director, Division of Dermatology and Dental Products, (HFD-540)

From: Nora Roselle, PharmD
Safety Evaluator, Division of Medication Errors and Technical Support, Office of Drug Safety

Through: Alina Mahmud, RPh, MS, Team Leader
Denise P. Toyer, PharmD, Deputy Director
Carol A. Holquist, RPh, Director
Division of Medication Errors and Technical Support, Office of Drug Safety, HFD-420

Date: November 30, 2005

Re: ODS Consult 04-0271-3, Vusion (0.25% Miconazole Nitrate/15% Zinc Oxide/81.35% White Petrolatum) Ointment; NDA 21-026.

This memorandum is in response to a November 23, 2005 request from the Division of Dermatology and Dental Products for a review of the container label, carton and insert labeling of Vusion.

In the review of the labels and labeling, DMETS has attempted to focus on safety issues relating to possible medication errors. DMETS has identified the following areas of possible improvement, which might minimize potential user error.

A. CONTAINER LABEL (30 g Tube)

b(4)

1. The proprietary name is difficult to read as it currently appears in a blue font against a blue background. This color combination does not provide sufficient color contrast for maximum readability. Revise accordingly so that the proprietary name has sufficient contrast and increased readability so that it is the most prominent information on the label, along with the established name.
2. Furthermore, the "V" in Vusion is printed in a lighter blue font color than the rest of the tradename, drawing the eye to the second half of the tradename. Please revise so that the entire tradename is printed in the same color.
3. The font size of the established name is small and difficult to read. Please ensure that the information is prominent and legible and meets 21 CFR 201.10(g)(2). Additionally, half of the established name appears in black ink in a blue box. This color combination is difficult to read and highlights only one portion of the established name. Revise to include the entire established name in the colored area and revise the background or color of the text.
4. The graphic design to the left of the tradename distracts from the most important information on the label (proprietary and established names). DMETS recommends removing the graphic design from the label.
5. The statement "For Dermatological Use Only" is not prominent on the label and blends in with other information written in gray font. Increase the prominence of these statements by bolding and/or

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/s/

Nora L. Roselle
12/13/2005 10:02:06 AM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
12/13/2005 11:12:09 AM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
12/13/2005 11:18:33 AM
DRUG SAFETY OFFICE REVIEWER