

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-026

PROPRIETARY NAME REVIEW(S)

MEMO

To: Stanka Kukich, M.D.
Acting Director, Division of Dermatology and Dental Products, HFD-540

From: Alina R. Mahmud, RPh, M.S.
Team Leader, Division of Medication Errors and Technical Support, Office of Drug Safety
HFD-420

Through: 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: February 2, 2005

Re: ODS Consult 04-0271-4
Vusion (miconazole nitrate ointment) 0.25%; NDA 21-026

This memorandum is in response to a January 30, 2006 request from your Division for a re-review of the proprietary name, Vusion. Specifically, DMETS was requested to re-review the potential for confusion between the proprietary names Vusion and Fuzeon. The proposed proprietary name, Vusion, was found acceptable by DMETS in a review dated June 8, 2005 (ODS consult 04-0271-2). Container labels and package insert labeling were reviewed in a consult dated November 30, 2005 (ODS consult 04-0271-3), however only revised insert labeling has been submitted for review at this time.

DMETS has not identified any additional proprietary names since the completion of the last consult dated June 8, 2005, however, DMETS will re-review the potential for confusion between Fuzeon and Vusion. Fuzeon contains enfuvirtide for the treatment of human immunodeficiency virus. The products differ in dosing regimen (90 mg twice daily compared to with every diaper change), dosage form (lyophilized powder in vials compared to an ointment), route of administration (subcutaneous compared with topical), packaging and dispensing amount (60 vial convenience kit, single vials compared with 5 gram and 30 gram tubes), patient population (adults compared to infants), and indication of use (HIV compared with diaper rash). In addition, Fuzeon is a medication that requires education for proper use; thus a new patient will be fully informed on the preparation and administration of Fuzeon. Another obstacle for confusion is the cost. Due to the cost most pharmacies will not keep this medication stocked. Thus, an order would lead to questions and possible prior authorization. Although it is likely that an order for Vusion may be phoned in without any further product identification characteristics (such as strength, dose, directions for use, quantity), it is unlikely that the same would occur with Fuzeon. Post-Marketing experience has shown that most HIV medications are accompanied with specific directions for use as well as dispensing quantities. Therefore, multiple errors must occur for a health care professional to dispense the incorrect medication as well as for the patient to actually administer the medication. DMETS believes that the likelihood for confusion is minimal due to the differences in product characteristics and specialty of use of Fuzeon.

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In summary, DMETS has no objections to the proprietary name Vusion. The package insert labeling was reviewed and DMETS has no comments at this time. Additionally, DDMAC has no objections to the name from a promotional perspective. We consider this a final review. However, if the approval of the NDA is delayed beyond 90 days from the date of this review, the name must be re-evaluated. A re-review of the name before the NDA approval will rule out any objections based upon approvals of other proprietary and/or established names from the signature date of this document.

If you have any questions or need clarification, please contact DMETS Project Manager, Diane Smith, at 301-796-0538.

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/s/

Alina Mahmud
2/13/2006 10:50:43 AM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
2/13/2006 02:20:07 PM
DRUG SAFETY OFFICE REVIEWER
Also signing for Carol Holquist, DMETS Director, in her
absence

CONSULTATION RESPONSE

**DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF DRUG SAFETY
(DMETS; HFD-420)**

DATE RECEIVED: May 20, 2005	DESIRED COMPLETION DATE: June 21, 2005	ODS CONSULT #: 04-0271-2
DATE OF DOCUMENT: May 6, 2004		

TO: Jonathan Wilkin, MD
Director, Division of Dermatology and Dental Products
HFD-540

THROUGH: Mildred Wright
Project Manager
HFD-540

PRODUCT NAME: Vusion (alternate name) (Miconazole Nitrate Ointment) 0.25%	NDA SPONSOR: Barrier Therapeutics, Inc.
NDA#: 21-026	

SAFETY EVALUATOR: Kimberly Culley, RPh

RECOMMENDATIONS:

1. DMETS does not recommend the use of the proprietary name . However, DMETS has no objections to **b(4)** the use of the proprietary name, Vusion. This is considered a tentative decision and the firm should be notified that this name with its associated labels and labeling must be re-evaluated approximately 90 days prior to the expected approval of the NDA. A re-review of the name prior to NDA approval will rule out any objections based upon approvals of other proprietary or established names from the signature date of this document.
2. DMETS request submittal of the labels and labeling for review and comment, when available.
3. DDMAC finds the proprietary names . Vusion acceptable from a promotional perspective. **b(4)**

Denise Toyer, PharmD Deputy Director Division of Medication Errors and Technical Support Office of Drug Safety	Carol Holquist, RPh Director Division of Medication Errors and Technical Support Office of Drug Safety Phone: (301) 827-3242 Fax: (301) 443-9664
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Division of Medication Errors and Technical Support (DMETS)
Office of Drug Safety
HFD-420; PKLN Rm. 6-34
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE OF REVIEW: June 8, 2005
NDA# 21-026
NAME OF DRUG: Vusion (alternate name) **b(4)**
NDA HOLDER: Barrier Therapeutics, Inc.

I. INTRODUCTION:

This consult was written in response to a request from the Division of Dermatologic and Dental Drug Products (HFD-540), for assessment of the proprietary names () and "Vusion" in regard to potential name confusion with other proprietary or established drug names. Container labels and carton labeling were not submitted for review and comment at this time. The package insert was previously reviewed by DMETS (see ODS consult 04-0271, December 2004). **b(4)**

This is the second name submission for this application. In December 2004, DMETS reviewed the proposed name Zimycan and found the name unacceptable due to orthographic similarities with Lumigan. The sponsor submitted a rebuttal, but the name was again found unacceptable (ODS consult 04-0271-1, March 2005).

PRODUCT INFORMATION

contains 0.25% miconazole nitrate in a zinc oxide and petrolatum base for the treatment of diaper dermatitis complicated by candidiasis. () is a synthetic antifungal agent that should be applied to the entire affected area with each diaper change. The product should not be rubbed into the skin, just gently applied to clean skin. Symptomatic relief should be seen within 72 hours, but treatment should be continued for 7 days. () ointment will be available in 5 and 30 gram aluminum tubes. **b(4)**

II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of several standard published drug product reference texts^{1,2} as well as several FDA databases³ for existing drug names which sound-alike or look-alike to () vusion to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted⁴. The Saegis⁵ Pharma-In-Use database was searched for drug names with potential for confusion. An expert panel discussion was conducted to review all findings from the searches. In addition, **b(4)**

¹ MICROMEDEX Integrated Index, 2005 MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.

² Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.

³ AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-05 Drugs@fda.gov, and the electronic online version of the FDA Orange Book.

⁴ WWW location <http://www.uspto.gov/tmdb/index.html>.

⁵ Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at www.thomson-thomson.com

DMETS conducted three prescription analysis studies consisting of two written prescription studies (inpatient and outpatient) and one verbal prescription study, involving health care practitioners within FDA. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name.

A. EXPERT PANEL DISCUSSION (EPD)

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary names _____ and Vusion. Potential concerns regarding drug marketing and promotion related to the proposed name were also discussed. This group is composed of DMETS Medication Errors Prevention Staff and representation from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The group relies on their clinical and other professional experiences and a number of standard references when making a decision on the acceptability of a proprietary name. **b(4)**

1. DDMAC finds the proprietary names _____ and Vusion acceptable from a promotional perspective. **b(4)**
2. The Expert Panel and independent analysis identified five proprietary names that may be potentially confused with _____. The products are listed in table 1 (see below), along with the dosage forms available and usual dosage.
3. The Expert Panel and independent analysis identified four proprietary names that may be potentially confused with Vusion. The products are listed in table 2 (see page 4), along with the dosage forms available and usual dosage.

Table 1: Potential Sound-Alike/Look-Alike Names for _____ Identified by DMETS Expert Panel **b(4)**
and Independent Review

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*Frequently used, not all-inclusive.
 **L/A (look-alike), S/A (sound-alike)

Table 2: Potential Sound-Alike/Look-Alike Names for **Vusion** Identified by DMETS Expert Panel and Independent Review

Product Name	Established name, Dosage Form(s), Strength(s)	Usual adult dose*	Other**
Vusion	Miconazole Nitrate Ointment, 0.25% 5 gram / 15 gram	Apply to affected area at each diaper change	
Visine® (OTC Product line)	Tetrahydrozoline Hydrochloride 0.05% (original)	1 to 2 drops in affected eye four times daily	LA
Fuzeon®	Enfuvirtide for Injection, 90 mg/mL Convenience kit contains 60 single-use clear glass vials, 2 cartons of 30 each with 60 vials of sterile water for injection (2, 30 vials) with 60 syringes	90 mg twice daily subcutaneously into the upper arm, anterior thigh or abdomen.	LA/SA
Visken®	Pindolol Tablets, 5 mg and 10 mg	5 mg twice daily to a maximum of 60 mg daily.	LA
Vumon®	Teniposide Injection, 50 mg/5 mL	<u>ALL failing cytarabine</u> : 165 mg/m ² (plus cytarabine 300 mg/m ²) intravenously twice weekly for 8 to 9 doses. <u>ALL refractory to vincristine and prednisone</u> : 250 mg/m ² with vincristine 1.5 mg/m ² weekly for 4 to 8 weeks (with prednisone therapy).	LA/SA
Vision Blue®	Trypan Blue Ophthalmic Solution, 0.06% 0.5 mL	<u>After opening eye, an air bubble is injected into the anterior chamber of the eye to minimize dilution of VisionBlue. It is then applied onto the anterior lens capsule using a blunt cannula</u>	LA

*Frequently used, not all-inclusive.
 **L/A (look-alike), S/A (sound-alike)

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B. PHONETIC and ORTHOGRAPHIC COMPUTER ANALYSIS (POCA)

As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion. All names considered to have significant phonetic or orthographic similarities to **Vusion** and **Vusion** were discussed by the Expert Panel (EPD). b(4)

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C. PRESCRIPTION ANALYSIS STUDIES

Methodology:

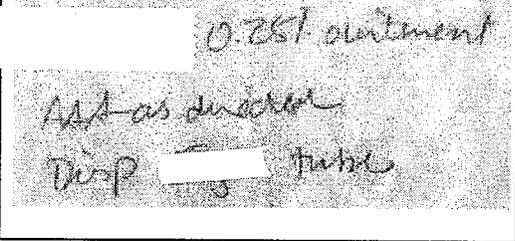
Six separate studies were conducted (3 for each proposed drug name) within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion and Vusion with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. Each set of three studies employed a total of 121 health care professionals (pharmacists, physicians, and nurses) for each. This exercise was conducted in an attempt to simulate the prescription ordering process. An inpatient order and outpatient prescriptions were written for each name, which consisted of a combination of marketed and unapproved drug products and a prescription for [redacted] and Vusion (see page 6). The prescriptions were optically scanned and one was delivered to a random sample of the participating health professionals via e-mail. In addition, the outpatient orders were recorded on voice mail, which were sent to a random sample of the participating health professionals for their review and interpretation. After receiving either the written or verbal prescription orders, the participants sent their interpretations of the orders via e-mail to the medication error staff.

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1.

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a. STUDIES

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
<p>Outpatient RX:</p> 	<p>0.25% ointment Apply to diaper rash area as directed Dispense [redacted] tube</p>
<p>Inpatient RX:</p> 	

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b. RESULTS

None of the interpretations of the proposed name overlap, sound similar, or look similar to any currently marketed U.S. product. See appendix A for the complete listing of interpretations from the verbal and written studies.

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2. VUSION

a. STUDIES

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
<p>Outpatient RX:</p> <p><i>Vusion 0.25% ointment apply to diaper rash area as directed 30 gm</i></p>	<p>Vusion .25% Ointment 30 gram Apply to diaper rash area as directed</p>
<p>Inpatient RX:</p> <p><i>Vusion 0.25% ointment apply to diaper rash area p.m. as</i></p>	

b. RESULTS

From the inpatient study, one respondent interpreted the proposed name as the word "version" and another as the word "fusion." In addition, six participants of the voice study interpreted the name as "fusion." In this voice study, two respondents interpreted the proposed name as the medical term "effusion" and one as "porfusion", which is similar to the medical term, "perfusion." In the outpatient study, two respondents interpreted the proposed name as the word "vision." See appendix B for the complete listing of interpretations from the verbal and written studies.

D. SAFETY EVALUATOR RISK ASSESSMENT

1. **b(4)**

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2 Page(s) Withheld

2 Trade Secret / Confidential

 Draft Labeling

 Deliberative Process

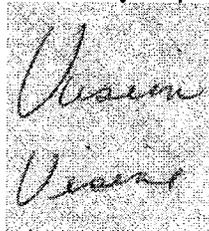
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2. VUSION

In reviewing the proprietary name Vusion, the primary concerns related to look-alike and sound-alike confusion with Visine, Fuzeon, Visken, and Vumon.

Additionally, DMETS conducted prescription studies to simulate the prescription ordering process. In this case, there was no confirmation that Vusion could be confused with the aforementioned names. However, six respondents from the verbal study and one respondent from the inpatient study misinterpreted the name of Vusion for fusion, which is verbally similar to the marketed drug product, Fuzeon. One respondent interpreted the proposed name as the word "version"; while two respondents interpreted the proposed name as the medical term, effusion. Two respondents interpreted the proposed name as the word "vision" and one respondent interpreted the proposed name as Porfusion, which is similar to the medical term perfusion. Although many of the misinterpretations involved medical terminology, DMETS can not conceive a situation where confusion would result from this type of misinterpretation. Thus, the medical terms will not be discussed further.

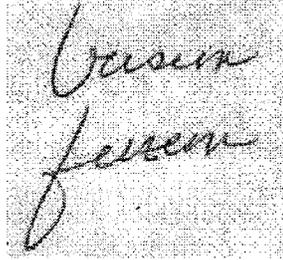
- a. Visine (original) may look similar to Vusion when scripted. The Visine product line also includes Visine A.C., Visine Tears, Visine-A, Visine L.R., Visine Advanced Relief, Visine for Contacts and Visine Pure Tears. However, the modifiers should help to distinguish the product names from Vusion. Therefore, only the original Visine will be discussed. Visine contains tetrahydrozoline 0.05% for the relief of redness of the eye due to minor eye irritation. The product is available in 0.5 ounce (15 mL) and 1 ounce (30 ml) bottles. The recommended dosage is one to two drops in the affected eye up to 4 times daily. Both names begin with "V" and share a central "si", which may be compounded by the possibility for the first "i" of Visine to resemble the "u" of Vusion (see below). However, the concluding "e" of Visine may help to differentiate the two names.



The image shows two lines of handwritten text in cursive script. The top line reads "Vusion" and the bottom line reads "Visine". The letters are written in a fluid, connected style, illustrating the visual similarity between the two names when written by hand.

The products share possible order amounts/dispensing quantities as both can be ordered as #1 and of "30" if you omit the descriptors of milliliter and grams and single strength status. Additionally, both products are available in a single strength, and thus, the drug may be dispensed without indication of strength. Despite these similarities, they differ in most product characteristics as shown by the following: dose (one to two drops compared to an application), route of administration (ocular compared with topical), dosage form (solution compared to ointment), prescription status (over-the-counter compared to prescription only), frequency of administration (up to four times per day compared to with every diaper change), patient population (adults compared to primarily infants), and indication of use (eye redness compared with diaper rash). Of importance for this name pair, is the likelihood that a prescription will be written for Visine. This OTC product is not commonly recommended by physicians, thus the possibility for prescriptions to be written for insurance or tracking purposes would be unlikely. In part, this is due to the multitude of better options in the marketplace, both over-the-counter (Vasocon-A) and prescription status (Naphcon Forte). If the order was misinterpreted and completed with Vusion, the differing dosage forms should help to alleviate error in patient use as a caregiver would be expecting a cream/ointment for diaper rash irritation and a patient would expect an eye drop for irritation or dryness. In addition, Vusion should be used predominantly in the pediatrics, a population in which Visine would not be used or recommended. Due to the differing directions for use, dosage forms, indication of use, and prescription status, DMETS believed the possibility for confusion to be minimal.

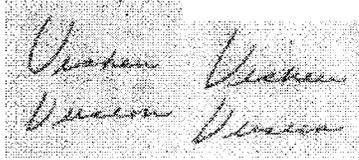
- b. Fuzeon may look and sound similar to Vusion when written and spoken. In the verbal studies, six participants identified Fusion, which is similar to Fuzeon. Fuzeon contains enfuvirtide for the treatment of human immunodeficiency disease. Recommended dosing is 90 mg twice daily subcutaneously. Fuzeon is available as a convenience kit containing 60 count of each of the following: single-use clear glass vials, vials of sterile water for injection and syringes. The orthographic similarities stem from the likeness of a lower case, scripted "f" with the "v" of Vusion. In addition, the "eon" of Fuzeon will look identical to the "ion" of Vusion when scripted. However, the "z" may serve to differentiate the two names when scripted with a downstroke; but if written as a printed "z" it may resemble the "s" of Vusion. The auditory similarities relate to where the reader places emphasis and how the reader pronounces Vusion; whether noted as VU-Z-ON or VU-JEN. If pronounced as the first, the names would only differ by the leading letter of "F" and "V", which are not immensely distinct in speech.



Additionally, both products are only available in one strength, and thus, the drug may be dispensed without indication of strength. Despite these similarities, the products differ in dosing regimen (90 mg twice daily compared to with every diaper change), dosage form (lyophilized powder in vials compared to an ointment), route of administration (subcutaneous compared with topical), dispensing amount (60 vial convenience kit, single vials compared with 5 gram and 30 gram tubes), patient population (adults compared to infants), and indication of use (HIV compared with diaper rash). In addition, Fuzeon is a medication that requires education for proper use; thus often specialty pharmacies are the care centers for this drug product; however, it can be obtained through any pharmacy. Another obstacle for confusion is the cost. Due to the cost, most pharmacies will not keep this medication stocked. b(4)

Thus, an order would lead to questions and a special order of the medication. Although there is a likeness in the name, the likelihood for confusion should be low due to the differences in product characteristics and specialty of use of Fuzeon.

- c. Visken may look similar to Vusion when written. Visken contains pindolol in 5 mg and 10 mg tablets for the management of hypertension. Recommended initial dosing is 5 mg twice daily, up to 60 mg per day (increased at 10 mg per day increments). The orthographic similarities stem from the shared leading "V", central "s" and concluding "n." However, the upstroke of the "k" of Visken should help to differentiate the names.



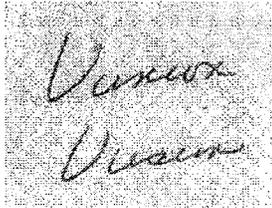
In addition, the products differ in all characteristics as shown by the following: strength (5 mg, 10 mg compared to 0.25%), dosage form (tablets compared to ointment), dosage regimen (5 to 30 mg tablet twice daily compared to with each diaper change), route of administration (oral compared with topical), and indication of use (hypertension compared with diaper rash). Due to the differing characteristics, DMETS believes the possibility for confusion to be minimal.

- d. VisionBlue may look similar to Vusion. Two respondents of the prescription studies interpreted the name as "vision"; thus, leading to the potential association. VisionBlue contains trypan blue as an ophthalmic solution to aid in ophthalmic surgery by staining the anterior capsule of the lens. VisionBlue is packaged in a glass syringe (containing 0.5 mL) with an attached blunt cannula. The orthographic similarities stem from the shared leading "V" and central "sion". However, the concluding "blue" of VisionBlue would need to be omitted for confusion to occur.



Furthermore, the drug products differ in strength (0.06% to 0.25%), dosage form (ophthalmic solution compared to ointment), dosage regimen (one time use compared to with each diaper change), route of administration (ocular compared with topical), and indication of use (staining the anterior lens capsule during cataract surgery compared with diaper rash). The context of use is also a differentiating factor, since VisionBlue will be used in ophthalmic surgery and likely ordered with a pharmacy requisition form, not an individual order. So, although the two drug products are single strengths and thus, can have an order completed accurately without indication of strength; the context of use and different routes of administration should differentiate the two drug products.

- e. Vumon may look and sound similar to Vusion when scripted and spoken. Vumon contains teniposide for induction therapy in patients with refractory childhood acute lymphoblastic leukemia (ALL). Vumon should be used with other approved anticancer agents. Vumon is available as 50 mg/5 mL ampules. The recommended dosing is as follows: for ALL patients failing cytarabine- 165 mg/m² (plus cytarabine 300 mg/m²) intravenously twice weekly for 8 to 9 doses and for ALL patients refractory to vincristine and prednisone- 250 mg/m² with vincristine 1.5 mg/m² weekly for 4 to 8 weeks with prednisone therapy. The orthographic and auditory similarities stem from the shared lead "Vu" and concluding "n." The orthographic similarities are further compounded by the possibility for the central "m" or "s" to appear similar.

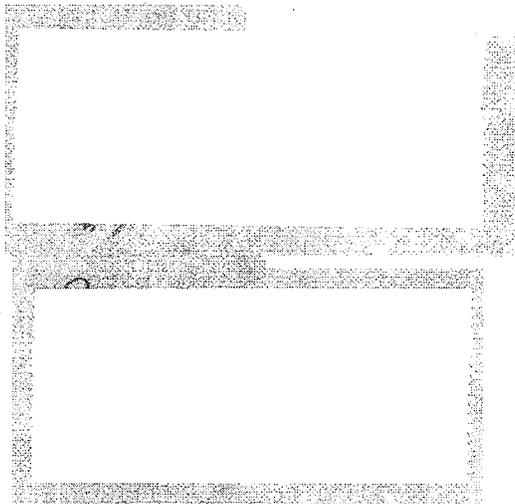


However, the products share no overlapping characteristics as shown by the following: route of administration (intravenous compared to topical), strength (50 mg/5 mL, 10 mg per mL compared to 0.25%), dosage regimen (165 to 250 mg/m² twice weekly with other medications compared to with each diaper change), dispensing amount (total dose required compared to 5 gm and 30 gram), context of use (infusion treatment likely to occur in a physician's office/clinic or hospital compared to primary outpatient use), and indication (leukemia compared to diaper rash). Since DMETS can find no method for the prescription to overlap for a verbal or written order, primarily since a dose must be entered for Vumon, the likelihood for confusion is minimal.

III. COMMENTS TO THE SPONSOR:

DMETS does not recommend the use of the proprietary name . However, DMETS has no objections to the use of the proprietary name Vusion. In reviewing the proprietary name the primary concerns related to look-alike and/or sound-alike confusion

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indication of use of diaper rash would be indicative of an innate irritation of the skin, which could be as severe as erosions of the skin. In light of this, the occlusive environment of the diaper and the increased absorption of an infant's skin due to irritation, DMETS is concerned with the possible outcomes if confusion occurs between the two names. **b(4)**

IV. RECOMMENDATIONS:

A. DMETS does not recommend the use of the proprietary name, . However, DMETS has no objections to the use of the proprietary name, Vusion from a safety perspective. This is considered a final decision. However, if the approval of this application is delayed beyond 90 days from the signature date of this document, the name must be re-evaluated. A re-review of the name will rule out any objections based upon approval of other proprietary or established names from the signature date of this document. **b(4)**

B. DMETS request submittal of the labels and labeling for review and comment, when available.

C. DDMAC finds the proprietary names and Vusion acceptable from a promotional perspective. **b(4)**

DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Diane Smith, project manager, at 301-827-1998.

Kimberly Culley, RPh
Safety Evaluator
Division of Medication Errors and Technical Support
Office of Drug Safety

Concur:

Alina Mahmud, RPh, MS
Team Leader
Division of Medication Errors and Technical Support
Office of Drug Safety

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Appendix B. Prescription Study Results (Vusion)

Inpatient	Outpatient	Voice
Vusion	Vusion	Vusion
Uvusion	Vusion	Vusion
Vusion	Vusion	Fusion
Vusion	Vusion	Effusion
Vusion	Vusion	Fusion
Vusion	Vusion	Fusion
Vusion	Vusion	Vusion
Vusion	Vusion	Vusion
Vusion	Vusion	Vuzion
Vusion	Vusion	Fusion
Vusion	Vusion	Vusion
Vusion	Vusion	Vusion
Version	Vusion	Vusion
Virision	Vusion	Vusion
Vusion	Vusion	Porfusion
Vusion	Vusion	Effusion
Vusion	Vusion	vusion
Vusion	Vision	Vusion
Vusion	Vusion	Fusion
Vusion	Vusion	Fusion
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Kimberly Culley
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Denise Toyer
9/15/2005 03:28:08 PM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
9/15/2005 03:38:12 PM
DRUG SAFETY OFFICE REVIEWER