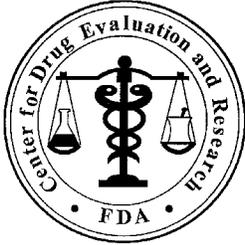


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

050803Orig1s000

PROPRIETARY NAME REVIEW(S)



Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date: April 20, 2010

To: Susan Walker, MD, Director
Division of Dermatology and Dental Products

Through: Denise Toyer, PharmD., Deputy Director
Division of Medication Error Prevention and Analysis

From: Zachary Oleszczuk, PharmD., Safety Evaluator
Division of Medication Error Prevention and Analysis

Subject: Proprietary Name Review

Drug Name(s): Veltin (Clindamycin and Trentinoin) Gel
1% /0.025%

Application Type/Number: NDA 050803

Applicant: Stiefel Laboratories, Inc.

OSE RCM #: 2010-668

1 INTRODUCTION

This re-assessment of the proprietary name is written in response to the anticipated approval of NDA 050803 within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Veltin, acceptable in OSE Review #2009-2212, dated February 4, 2010. The Division of Dermatology and Dental Products did not have any concerns with the proposed name, Veltin during the previous review of the proposed name and the Division of Drug Marketing, Advertising and Communication (DDMAC) found the name acceptable from a promotional perspective on November 26, 2009.

2 METHODS

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see Section 5) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the completion of the previous OSE proprietary name review. We used the same search criteria outlined in OSE Review #2009-2212, dated February 4, 2010, for the proposed proprietary name, Veltin. None of Veltin's product characteristics have been altered since our previous review thus, we did not re-evaluate previous names of concern. Additionally, DMEPA searches the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

3 RESULTS

DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of April 8, 2010.

Additionally, the searches of the databases did not yield any additional names thought to look or sound similar to Veltin and represent a potential source of drug name confusion.

4 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Veltin, is not vulnerable to name confusion that could lead to medication errors, nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Veltin, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Dermatology and Dental Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

5 REFERENCES

1. Oleszczuk, Z. OSE Review #2009-2212: Proprietary Name Review for Veltin. February 4, 2010.

2. **Drugs@FDA** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present.

Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.

3. **USAN Stems** (<http://www.ama-assn.org/ama/pub/category/4782.html>)

USAN Stems List contains all the recognized USAN stems.

4. **Division of Medication Error Prevention and Analysis proprietary name requests**

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
----- NDA-50803	----- ORIG-1	----- STIEFEL A GSK CO	----- Veltin

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

/s/

ZACHARY A OLESZCZUK
04/20/2010

DENISE P TOYER
04/21/2010

CONSULTATION RESPONSE

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

DATE RECEIVED: March 31, 3005	DESIRED COMPLETION DATE: May 20, 2005	ODS CONSULT #: 05-0086
DATE OF DOCUMENT: March 2, 2005	PDUFA DATE: June 25, 2005	

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

THROUGH: Margo Owens
Project Manager, Division of Dermatology and Dental Drug Products
HFD-540

PRODUCT NAME: Veltin (Clindamycin and Tretinoin Gel) 1%/0.025%	NDA SPONSOR: Connetics Corporation
NDA#: 50-803	

SAFETY EVALUATOR: Kristina C. Arnwine, PharmD

RECOMMENDATIONS:

1. DMETS has no objections to the use of the proprietary name, Veltin. 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.
2. DMETS recommends implementation of the label and labeling revisions outlined in section III of this review to minimize potential errors with the use of this product.
3. DDMAC finds the proprietary name Veltin acceptable from a promotional perspective

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Office of Drug Safety

**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: May 16, 2005
NDA#: 50-803
NAME OF DRUG: Veltin (Clindamycin and Tretinoin Gel) 1%/0.025%
NDA HOLDER: Connetics Corporation

I. INTRODUCTION:

This consult was written in response to a request from the Division of Dermatology and Dental Drug Products (HFD-540), for assessment of the proprietary name Veltin regarding potential name confusion with other proprietary or established drug names. Container labels, carton and insert labeling were provided for review and comment. The sponsor also submitted, for review, an independent name analysis conducted (b) (4).

The sponsor originally submitted the proprietary name Velac, however, DMETS found it unacceptable due to potential sound-alike and/or look-alike with Penlac, Carac, and Velnac (See ODS Consult 04-0275 dated February 10, 2005). Thus, the sponsor submitted the proprietary names, (b) (4) and Veltin, for review and comment. (b) (4)

Therefore, only Veltin will be reviewed by DMETS from a safety perspective.

PRODUCT INFORMATION

Veltin is a topical antibiotic/retinoid combination gel indicated for the topical treatment of acne vulgaris. Veltin should be applied to affected areas once daily in the evening. Veltin is supplied in 30 gram aluminum tubes.

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 Veltin 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

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 98-04, and the electronic online version of the FDA Orange Book.

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, 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 name Veltin. 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.

1. DDMAC finds the proprietary name, Veltin, acceptable from a promotional perspective.
2. The Expert Panel identified seven proprietary names that were thought to have the potential for confusion with Veltin. These products are listed in table 1 (see below), along with the dosage forms available and usual dosage.

Table 1: Potential Sound-Alike/Look-Alike Names Identified by DMETS Expert Panel

Product Name	Dosage form(s), Established name	Usual adult dose*	Other**
Veltin	Clindamycin/Tretinoin Gel, 1%/0.025%	Apply to affected area every evening	
Feldene	Piroxicam Capsules: 10 mg and 20 mg	10 mg to 20 mg by mouth once daily	SA
Ultane	Sevoflurane Liquid for Inhalation: 100%	Inspired concentrations of up to 5% sevoflurane in oxygen or in combination with oxygen/nitrous oxide	LA
Veltin	Thiometon Insecticide	Thiometon is a colorless oil with a characteristic odor. It is used as an insecticide	SA
Vantin	Cefpodoxime Tablets: 100 mg and 200 mg Powder for Oral Suspension: 50 mg/5 mL and 100 mg/5 mL	100 mg to 200 mg by mouth twice daily	LA
Ceftin	Cefuroxime Tablets: 250 mg and 500 mg Powder for Oral Suspension: 125 mg/ 5 mL and 250 mg/5 mL	250 mg to 500 mg by mouth twice daily	LA
Ultiva	Remifentanyl Powder for Injection 1 mg, 2 mg, and 5 mg	0.25 mcg/kg/min to 1 mcg/kg/min by continuous IV infusion	LA
Ultram	Tramadol Tablets: 50 mg	50 to 100 mg PO every 4 to 6 hours as needed, not to exceed 400 mg/day	SA/LA
*Frequently used, not all-inclusive. **L/A (look-alike), S/A (sound-alike)			

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

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. The phonetic search module returns a numeric score to the search engine based on the phonetic similarity to the input text. Likewise, an orthographic algorithm exists which operates in a similar fashion. All names considered to have significant phonetic or orthographic similarities to Veltin were discussed by the Expert Panel (EPD).

C. PRESCRIPTION ANALYSIS STUDIES

1. Methodology:

Three separate studies were conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Veltin 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. These studies employed a total of 119 health care professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the prescription ordering process. An inpatient order and outpatient prescriptions were written, each consisting of a combination of marketed and unapproved drug products and a prescription for Veltin (see below). These prescriptions were optically scanned and one prescription was delivered to a random sample of the participating health professionals via e-mail. In addition, the outpatient orders were recorded on voice mail. The voice mail messages were then sent to a random sample of the participating health professionals for their interpretations and review. 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.

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
<p><u>Outpatient RX:</u></p> 	<p>“The first one is Veltin, as directed. Number 1.”</p>
<p><u>Inpatient RX:</u></p> 	

2. Results:

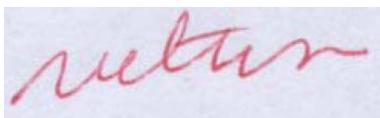
None of the interpretations of the proposed name overlap, sound similar, or look similar to any currently marketed U.S. product. See appendix A for the complete listing of interpretations from the verbal and written studies.

D. SAFETY EVALUATOR RISK ASSESSMENT

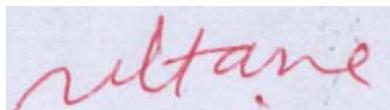
In reviewing the proprietary name, Veltin, the primary concerns related to look-alike and sound-alike confusion with Feldene, Ultane, Veltin, Vantin, Ceftin, Ultiva, and Ultram. Upon further review of the names gathered from EPD, and POCA, DMETS notes the name Veltin is an exact match for the proposed proprietary name, however it will not be reviewed further. It is not considered to be a safety risk for confusion with the proposed proprietary name due to the fact that Veltin is an insecticide which would have no medicinal use, and thus not be prescribed either verbally or in writing.

DMETS conducted prescription studies to simulate the prescription ordering process. In this case, there was no confirmation that the proposed name could be confused with any of the aforementioned names. However, negative findings are not predicative as to what may occur once the drug is widely prescribed, as these studies have limitations primarily due to a small sample size. The majority of misinterpretations were misspelled/phonetic variations of the proposed name, Veltin.

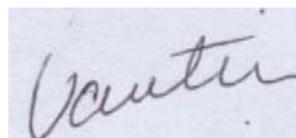
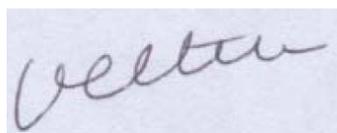
1. Veltin and Feldene can sound similar when pronounced. Feldene is a non-steroidal anti-inflammatory agent indicated for the treatment of osteoarthritis and rheumatoid arthritis. The beginnings of each name can sound similar ('VELL' vs. 'FELL') and both names contain two syllables which are the primary contributions to the sound-alike characteristics of each name. In addition it is possible for the last syllable of each name to sound slightly similar depending on how it is pronounced ('tinn' vs. 'dean'). The only product characteristic that Veltin and Feldene overlap is the dosing frequency (once daily). Veltin and Feldene do not overlap with respect to route of administration (topical vs. oral), dosage form (gel vs. capsule), and the usual dose (sufficient amount vs. 10 mg to 20 mg). Although Veltin is a combination product whose ingredients' strengths differ from each other (i.e. 1% and 0.025%), Veltin is only available in one combination of strengths and thus the strength may be omitted on a prescription. Conversely, since Feldene is available in two different strengths (i.e. 10 mg and 20 mg), a product strength must be indicated on a prescription order, which will help differentiate Veltin from Feldene. Overall, despite the sound-alike characteristics between Veltin and Feldene, the differing product characteristics decrease the potential for sound-alike confusion between the name pair.
2. Veltin and Ultane can look similar when scripted. Ultane is a general anesthetic indicated for use in general anesthesia induction during inpatient or outpatient surgery and general anesthesia maintenance during inpatient or outpatient surgery. The beginnings and endings of Veltin and Ultane ('Velt' vs. 'Ult') and ('in' vs. 'ane') can look similar depending on how they are scripted (see below). Veltin and Ultane do not overlap with respect to any product characteristics including route of administration (topical vs. respiratory), dosage form (gel vs. liquid for inhalation), dosing frequency (once daily vs. once), usual dose (sufficient amount vs. 5%), and product strength (1%/0.025% vs. 100%). Furthermore, Veltin will most likely primarily be used in the outpatient setting. Although Ultane can be used for both inpatient and outpatient surgery, Ultane will most likely be dispensed directly to the operating room or surgical clinic and not to the patient, thereby decreasing the potential for confusion between the two names. Overall, the differing product characteristics decrease the potential for name confusion between Veltin and Ultane.



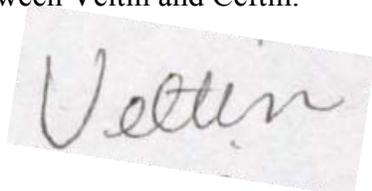
5



3. Veltin and Vantin can look similar when scripted. Vantin is a semi-synthetic cephalosporin antibiotic indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of microorganisms including *Escherichia coli*, *Haemophilus influenzae*, *Staphylococcus aureus*, *Streptococcus pneumoniae*, and *Neisseria gonorrhoeae* among others. Veltin and Vantin both begin with the letter 'V' and end with the letters 'tin' which are the principal contributions to the look-alike characteristics of the names (see page 6). In addition, the second and third letters of each name (-el- vs. -an-) can also look similar depending on how they are scripted. Veltin and Vantin do not overlap with regards to any product characteristics such as route of administration (topical vs. oral), dosage form (topical gel vs. tablets and powder for oral suspension), or usual dose (sufficient amount vs. 100 mg to 200 mg). Furthermore, the two products have differing dosing frequencies (once daily vs. twice daily) and product strengths (1%/0.025% vs. 100 mg, 200 mg, 50 mg/5 mL, and 100 mg/5 mL). As such, prescription orders for Vantin would require to have a specified dosing frequency and product strength, thereby further distinguishing the two products. Overall, despite the orthographic similarities between the two names, the differing product characteristics between Veltin and Vantin decrease the potential for medication errors due to look-alike confusion between the name pair.



4. Veltin and Ceftin can look similar when scripted. Ceftin is a second-generation cephalosporin antibiotic indicated for the treatment of mild to moderate infections with susceptible microorganisms such as *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Escherichia coli*, *Klebsiella pneumoniae*, and *Neisseria gonorrhoeae*, among others. The last three letters of each name are identical ('tin'). In addition, the second and third letters of each name (-el- vs. -ef-) can look similar depending on how they are scripted (see below). However, the first letter of each name ('V' vs. 'C') is orthographically different. Veltin and Ceftin do not overlap with regard product characteristics such as route of administration (topical vs. oral) and dosage form (topical gel vs. tablets and powder for oral suspension). Although Veltin is a combination product whose ingredients' strengths differ from each other (i.e. 1% and 0.025%), Veltin is only available in one combination of strengths and thus the strength may be omitted on a prescription. Conversely, since Ceftin is available in four different strengths (i.e. 250 mg, 500 mg, 125 mg/5 mL and 250 mg/5 mL) with a range of doses (i.e. 250 mg to 500 mg) a product strength and dose must be indicated on a prescription order, which will help differentiate Veltin from Ceftin. In addition, since Ceftin has a dosing frequency of twice daily, this will also most likely be included on a prescription order, and thus will differ from Veltin's dosing frequency of once daily. Overall, the differing product strengths, usual doses, and dosing frequencies decrease the potential for name confusion between Veltin and Ceftin.



5. Veltin and Ultiva can look similar when scripted. Ultiva is an opiate agonist for use during general anesthesia and monitored anesthesia care. The first letter of each name ('V' vs. 'U') can look similar and both names contain the letters 'lti' which are the principal contributions

to the look-alike characteristics of each name. In addition, the last letter of each name ('n' vs. 'a') can look similar depending on how they are scripted (see below). Veltin and Ultiva do not overlap with respect to product characteristics such as route of administration (topical vs. intravenous), dosage form (topical gel vs. injection), and dosing frequency (once daily vs. as needed during surgery). Furthermore, since Ultiva's dosing is based on the patients weight

(i.e. 0.25 mcg/kg/min to 1 mcg/kg/min) and Ultiva has more than one product strength (1%/0.025% vs. 1 mg, 2 mg, and 5 mg), both the desired dose and product strength must be specified on a prescription order which will help to differentiate the two product names. Although Ultiva can be used for both inpatient and outpatient surgery, Ultiva will most likely be dispensed directly to the operating room or surgical clinic and not to the patient, thereby decreasing the potential for confusion between the two names. Overall, despite the orthographic similarity between Veltin and Ultiva, the differing product characteristics decrease the potential for name confusion between the name pair.



6. Veltin and Ultram can look similar when scripted. Ultram is a centrally-acting analgesic indicated for moderate or moderately severe pain. The first letter of each name ('V' vs. 'U') can look similar when scripted and both names contain the letters 'lt' which are the principal contributions to the look-alike characteristics of each name (see below). However, the endings of each name are orthographically different ('in' vs. 'ram'). Veltin and Ultram do not overlap with respect to product characteristics including route of administration (topical vs. oral), dosage form (topical gel vs. tablet), or product strength (1%/0.025% vs. 50 mg). Since Ultram has a range of doses (i.e. 50 mg to 100 mg) a dose must be indicated on a prescription order, which will help differentiate Veltin from Ultram. In addition, since Ultram has a dosing frequency of every 4 to 6 hours, this will also most likely be included on a prescription order, and thus will differ from Veltin's dosing frequency of once daily. Overall, the orthographically different endings of each name, along with the differing product characteristics decrease the potential for name confusion between Veltin and Ultram.



F. INDEPENDENT NAME ANALYSIS

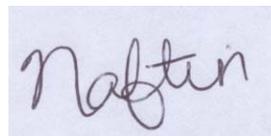
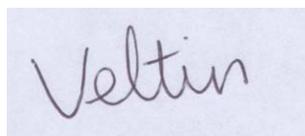
The analysis conducted (b) (4) discusses the potential for Veltin to be confused with the proprietary names Altinac, Beldin, Celontin, Foltrin, Gel-Tin, Iletin, (b) (4) V-Cillin, Valium, Valorin, Valtrex, Vectrin, Velcade, Velosef, Velosulin, Velsar, Voltaren, Retin-A, Veetids, Velban, Ventolin, Naftin, Veltane, Valnac, and Deltalin that were not identified as potential sound or look-alike products by DMETS. Upon evaluation of the twenty-five aforementioned proprietary names submitted (b) (4), DMETS considered the proprietary names Naftin, Veltane, Valnac, and Deltalin to need further evaluation (See Table 2, page 8). Upon further review of Veltane and Deltalin, DMETS learned that both products are no longer marketed, and are not found in commonly used references such as Drug Facts & Comparisons, Epocrates, Physician's Desk Reference, the Orange Book, or the Red Book, and thus will not be reviewed further.

Table 2: Potential Sound-Alike/Look-Alike Names Identified by (b) (4)

Product Name	Dosage form(s), Established name	Usual adult dose*	Other**
Veltin	Clindamycin/Tretinoin Gel, 1%/0.025%	Apply to affected area every evening	
Naftin	Naftifine Hydrochloride Topical Gel & Topical Cream, 1%	Sufficient amount to affected area once daily (cream) or twice daily (gel)	LA
Valnac	Betamethasone Valerate Topical Cream, 0.1%	Apply sparingly to affected area 2 to 4 times daily	LA
Veltane	Brompheniramine Maleate Tablet, 4 mg	One to two tablets every 12 hours	SA/LA
Deltalin	Ergocalciferol Capsule, 50,000 IU	50,000 IU to 200,000 IU by mouth daily	SA/LA

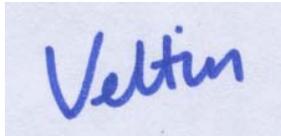
*Frequently used, not all-inclusive.
 **L/A (look-alike), S/A (sound-alike)

1. Veltin can look similar to Naftin when scripted. Naftin is a topical antifungal agent indicated for tinea pedis, tinea cruris and tinea corporis. The endings of each name are identical (-tin) which is the principal contributions to the look-alike characteristics of each name. However, the beginnings of each name ('Vel' vs. 'Naf') are different, which may help to distinguish the two names. Veltin and Naftin overlap with respect to product characteristics such as route of administration (topical), and usual dose (sufficient amount). Although Veltin is a combination product whose ingredients' strengths differ from each other (i.e. 1% and 0.025%), Veltin is only available in one combination of strengths. Similarly, Naftin is only available in one strength. Therefore, the strength can be omitted on an order for either product, and the medication could still be dispensed. Veltin and Naftin are both available in gel formulations, however Naftin is also available in a cream formulation, thus a dosage form would have to be specified on prescription orders for Naftin. Veltin gel and the cream formulation of Naftin overlap with respect to dosing frequency (once daily), however, the dosing frequency of Veltin gel and the gel formulation of Naftin differs (once daily vs. twice daily). Overall, the orthographic differences in the beginnings of each name, along with the availability of multiple dosage forms of Naftin decrease the potential for look-alike confusion between Veltin and Naftin.



2. Veltin can look similar to Valnac when scripted. Valnac is a topical corticosteroid indicated for relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. The beginnings of each name are similar ('Vel' vs. 'Val') which is the principal contribution to the look-alike characteristics of each name. However, the endings of each name are orthographically different ('tin' vs. 'nac'), which may help to distinguish the two names from each other. Veltin and Valnac overlap with respect to product characteristics such as route of administration (topical) and usual dose (sufficient amount). In addition, although Veltin is a combination product whose ingredients' strengths differ from each other (i.e. 1% and 0.025%), Veltin is only available in one combination of strengths. Similarly, Valnac is only available in one strength (0.1%). Therefore, the strength can be omitted on an order for either product, and the medication could still be dispensed. Although the dosage forms of Veltin and Valnac differ (gel vs. cream), both are topical agents, and each product is only available in their respective dosage form, thereby allowing the dosage form to be omitted from the prescription. However, Veltin and Valnac differ with regard to dosing frequency (once daily vs. two to four times daily). Overall, the orthographic differences in the

endings along with the differing dosing frequencies decrease the potential for look-alike confusion between Veltin and Valnac.



Following review of the proprietary name analysis submitted by (b) (4) DMETS concurs that none of the aforementioned names poses a significant safety risk due to a low potential for look-alike and/or sound-alike confusion as well as differences in product characteristics. We concur with the overall findings of the study.

III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES:

In the review of the container labels, carton and insert labeling of Veltin, 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. GENERAL COMMENTS

1. We note the sponsor has proposed the exact same layout for their product line of topical foams. This approach will likely lead to medication errors among these products due to their similarity in appearance. The FDA receives many errors involving similar labeling across manufacturers' product lines. The sponsor needs to revise this product labeling to help minimize the similarity among these products. For example, the purple color stripe design is distracting and interferes with the readability of the proprietary and established names. This same stripe appears for other foams marketed by Connetics such as Extina, Olux, and Luxiq.
2. Revise the established name and strength to read as one of the following examples:

a. Veltin
(Clindamycin and Tretinoin Gel)
1%/0.025%

b. Veltin
Clindamycin 1%
and
Tretinoin 0.025%
Topical Gel

3. Increase the prominence of the established name so that it is at least ½ the size of the proprietary name.
4. Relocate the route of administration statement, "For topical use only. Not for ophthalmic use," to the principal display panel.
5. Revise the total drug content to read, "grams," instead of "g."
6. We are unable to identify from the submitted materials that the container closure is child

resistant. Please ensure that the container has a Child Resistant Closure (CRC) cap in order to be compliant with the Poison Prevention Act.

7. The dosage form, “Gel”, is printed in the same font size and type as the proprietary name and it is bigger than the established name. DMETS recommends decreasing the prominence of the dosage form. Also, the sponsor identifies their product as “Veltin Gel” on the labels and labeling, however, the proprietary name is trademarked without the dosage form. Please revise all labels and labeling so that the product is identified as “Veltin”, without its dosage form.

(b) (4)

C. CONTAINER LABEL (30 gram tube)

See General Comments A-1 through A-7.

(b) (4)

E. CARTON LABELING (30 gram tube)

See General Comments A-1 through A-7.

F. INSERT LABELING

1. See General Comment A-2.
2. In accordance with CFR 201.57(f)(2) reprint the “Information for Patients” subsection at the end of the package insert.

V. RECOMMENDATIONS:

- A. DMETS has no objections to the use of the proprietary name Veltin. DMETS considers this a final decision. However, if the approval of the NDA is delayed beyond 90 days the firm should be notified that this name with its associated labels and labeling must be re-evaluated. A re-review of the name prior to NDA approval will rule out any objections based upon approvals of other proprietary and established names from this date forward.
- B. DMETS recommends implementation of the label and labeling revisions outlined in section III of this review that might lead to safer use of the product. We would be willing to revisit these issues if the Division receives another draft of the labeling from the manufacturer.
- C. DDMAC finds the proprietary name, Veltin, acceptable from a promotional perspective.

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.

Kristina C. Arnwine, PharmD
Safety Evaluator
Division of Medication Errors and Technical Support
Office of Drug Safety

Concur: _____
Linda Kim-Jung, PharmD
Team Leader
Division of Medication Errors and Technical Support
Office of Drug Safety

Attachment A

Verbal	Inpatient Written	Outpatient Written
Veltin	Veltin	Veltin
Beltin	Veltin	Veltin
Dalton us ud	Veltin	Veltin
Delten	Veltin	Veltin
Delten	Veltin	Veltin
Deltin	Veltin	Veltin
Doltan	Veltin	Veltin
Dultin	Veltin	Veltin
Velkin	Veltin	Yeltin
Veltan	Veltin	
Veltin	Veltin	
Velton	Veltin	
Velton	Veltin	
	Veltin	
	Veltin ud	
	Veltin ud	
	Veltin ud	
	Veltrin	

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/s/

Kristina Arnwine
6/24/05 02:02:02 PM
DRUG SAFETY OFFICE REVIEWER

Linda Kim-Jung
6/24/05 02:22:11 PM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
6/24/05 02:30:19 PM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
6/24/05 02:45:19 PM
DRUG SAFETY OFFICE REVIEWER

MEMO

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

From: Kristina C. Arnwine, PharmD
Safety Evaluator, Division of Medication Errors and Technical Support, Office of Drug Safety
HFD-420

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

Date: June 21, 2005

Re: ODS Consult 05-0086-1, (b) (4) (Clindamycin and Tretinoin Gel) 1%/0.025%;
NDA 50-803

This memorandum is in response to a March 30, 2005 request from your Division for a review of the proprietary names, (b) (4) and Veltin (NDA 50-803). Upon the initial steps in the proprietary name review process (EPD), the Division of Drug Marketing, Advertising and Communications (DDMAC) did not recommend the use of the proposed proprietary name (b) (4) from a promotional perspective because it's overly fanciful and overstating the efficacy of the product.

A drug name can be considered overly fanciful if the components of the product are common substance. This combination product includes the common substances clindamycin and tretinoin. Furthermore, the name suggests (b) (4). Coupling this image with the indication to treat acne overstates the efficacy of the product.

Please note that 21 CFR 201.10(c)(3) states that a proprietary name that implies that the drug or ingredient has some unique effectiveness or composition would be misleading, if the drug or ingredient is a common substance, the limitations of which are readily recognized when the drug or ingredient is listed by its established name. In addition, the statute also provides that labeling or advertising can misbrand a product if misleading representations are made, whether through a trade name or otherwise; this includes suggestions that a drug is better, more effective, useful in a broader range of conditions or patients, safer, has fewer, or lower incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience. [21 U.S.C 321(n); see also 21 U.S.C. 352(a) & (n); 21 CFR 202.1(e)(5)(i);(e)(6)(i)].

As per email correspondence with the Division of Dermatology and Dental Drug Products Project Manager, Margo Owens, on May 16, 2005, the Division concurs with DDMAC's comments. Therefore, DMETS will not proceed with the safety review of the proposed proprietary name (b) (4) since the Division supports DDMAC's objection of the name based on promotional concerns. DDMAC finds the proprietary name Veltin acceptable from a promotional

perspective. Thus, DMETS will only proceed with the review of the proprietary name, Veltin.

If you have any questions for DDMAC, please contact the Senior Regulatory Review Officer, Debi Tran. If you have any other questions or need clarification, please contact the medication errors project manager, Diane Smith at 301-827-1998.

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/s/

Kristina Arnwine
6/24/05 10:13:48 AM
DRUG SAFETY OFFICE REVIEWER

Linda Kim-Jung
6/24/05 11:58:40 AM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
6/24/05 12:31:20 PM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
6/24/05 12:34:32 PM
DRUG SAFETY OFFICE REVIEWER

CONSULTATION RESPONSE

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

DATE RECEIVED: 10/19/04	DESIRED COMPLETION DATE: 12/29/04	ODS CONSULT #:
DATE OF DOCUMENT: 08/23/04	PDUFA DATE: 06/25/05	04-0275

TO: Jonathan Wilkin, M.D.
Director, Division of Dermatologic and Dental Drug Products
HFD-540

THROUGH: Margo Owens
Project Manager
HFD- 540

PRODUCT NAME: Velac (Clindamycin and Tretinoin Gel) 1%/0.025%	NDA SPONSOR: Connetics Corporation
NDA#: 50-803	

SAFETY EVALUATOR: Jinhee L. Jahng, Pharm.D.

RECOMMENDATIONS:

1. DMETS does not recommend the use of the proprietary name, Velac.
2. DMETS recommends implementation of the label and labeling revisions outlined in section III of this review in order to minimize potential errors with the use of this product.
3. DDMAC finds the proprietary name, Velac, acceptable from a promotional perspective.

Carol Holquist, R.Ph.
Director
Division of Medication Errors and Technical Support
Office of Drug Safety
Phone: (301) 827-3242 Fax: (301) 443-9664