

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**22-563**

**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: September 17, 2010

Application Type/Number: NDA 022563

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

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

From: Zachary Oleszczuk, PharmD, Team Leader  
Division of Medication Error Prevention and Analysis

Subject: Proprietary Name, Label and Labeling Review

Drug Name(s): Sorilux (Calcipotriene) Foam  
0.005%

Applicant: Stiefel Laboratories, Inc.

OSE RCM #: 2010-1966

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## **1 INTRODUCTION**

This re-assessment of the proposed proprietary name, Sorilux, is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Sorilux, acceptable in OSE Review #2010-165, dated April 15, 2010. DDMAC reviewed the proposed name on January 28, 2010, and had no concerns regarding the proposed name from a promotional perspective. Furthermore, the review Division did not have any concerns with the proposed name, Sorilux, during our initial review.

Additionally, the Applicant submitted revised container label and carton labeling in response to DMEPA's concern over similar tradenames between this product and Veltin, which is also a product of the Applicant (see OSE Review #2010-166, dated August 4, 2010).

## **2 METHODS AND RESULTS**

### **2.1 PROPRIETARY NAME**

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. We used the same search criteria used in OSE Review #2010-165 for the proposed proprietary name, Sorilux. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern.

Additionally, DMEPA searched the United States Adopted Names (USAN) stem list to determine if the name contains any USAN stems as of the last USAN update. 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. DMEPA staff did not identify any USAN stems in the proposed proprietary name, Sorliux, as of September 15, 2010.

However, the searches of the databases yield two new names ( (b) (4) and Corlux\*\*\* ) thought to look or sound similar to Sorilux and represent a potential source of drug name confusion.

### **2.2 LABELS AND LABELING**

The Applicant submitted revised container labels (see Appendix B) and carton labeling (see Appendix C) on September 10, 2010. DMEPA used Failure Mode and Effects Analysis (FMEA) and the Principals of Human Factors in our evaluation of the labels and labeling. We also evaluated the recommendations pertaining to the label and labeling presented in OSE Review #2010-166, dated August 4, 2010 to see if the DMEPA recommendations had been incorporated into the labels and labeling.

## **3 DISCUSSION**

### **3.1 PROPRIETARY NAME**

Failure mode and effect analysis (FMEA) was applied to determine if the proposed name could potentially be confused with either of the names identified by DMEPA and lead to medication errors. This analysis determined that the name similarity between Sorilux and the two names identified was unlikely to result in medication errors for the reasons presented in Appendix A.

### 3.2 LABELS AND LABELING

The Applicant revised the labels and labeling to incorporate all of DMEPA's recommendations. Additionally, the Applicant used the color orange to adequately differentiate this container label and carton labeling from the container label and carton labeling of Veltin.

### 4 CONCLUSIONS AND RECOMMENDATIONS

This re-review determined that the proposed name, Sorliux, 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, Sorilux, 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 Anesthesia and Analgesia Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

Additionally, the Applicant has adequately addressed all of DMEPA's concerns regarding the container label and carton labeling and we have no additional comments at this time.

### REFERENCES

1. *OSE review #2010-165, Sorilux Name Review, April 15, 2010, Duffy, F.*
2. *OSE review #2010-166, Sorilux Name Review, August 4, 2010, Oleszczuk, Z..*
3. *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.

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

USAN Stems List contains all the recognized USAN stems.

5. *Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request*

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

**APPENDICIES**

**Appendix A:** Drug names with differentiating product characteristics

Product name with potential for confusion	Similarity to Product Name	Strength	Usual Dose	Differentiating Product Characteristics Sorilux vs. product
Sorilux		0.005%	Apply to affected area twice daily	

(b) (4)

Corlux*** (mifepristone) Tablets (b) (4)	Sound	(b) (4)		<p><b><u>Dosage form:</u></b> Foam vs. tablet</p> <p><b><u>Route of administration:</u></b> Topical vs. oral</p> <p><b><u>Frequency of administration:</u></b> Twice daily vs. once daily</p> <p><b><u>Dose:</u></b> 1 application vs. 300 mg to 1,200 mg; or 1 to 4 tablets</p>
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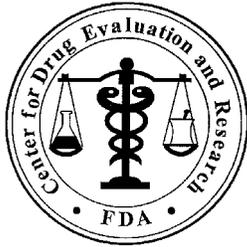
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/s/

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ZACHARY A OLESZCZUK  
09/17/2010

DENISE P TOYER  
09/22/2010



**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 15, 2010

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

Through: Zachary Oleszczuk, PharmD, Acting Team Leader  
Denise P. Toyer, PharmD, Deputy Director  
Carol A. Holquist, RPh, Director  
Division of Medication Error Prevention and Analysis (DMEPA)

From: Felicia Duffy, RN, BSN, MSED, Safety Evaluator  
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name: Sorilux (Calcipotriene) Foam  
0.005%

Application Type/Number: NDA 022563

Applicant: Stiefel Laboratories, Inc.

OSE RCM #: 2010-165

**\*\*\* This document contains proprietary and confidential information that should not be released to the public.\*\*\***

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## **EXECUTIVE SUMMARY**

Sorilux is the proposed proprietary name for Calcipotriene Foam. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name, Sorilux, conditionally acceptable for this product. The proposed proprietary name must be re-reviewed 90 days before approval of the NDA.

Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

## **1 BACKGROUND**

### **1.1 INTRODUCTION**

This review is in response to a January 15, 2010 request from Steifel Laboratories, Inc. for an assessment of the proposed proprietary name, Sorilux, regarding potential name confusion with other proprietary or established drug names in the usual practice settings.

Additionally, the container labels, carton and insert labeling are being evaluated for their potential contribution to medication errors under separate cover (OSE Review #2010-166).

### **1.2 REGULATORY HISTORY**

DMEPA previously reviewed the proposed proprietary name, Sorilux, under IND 071198 (OSE Review #2009-111, dated June 11, 2009). We found the name conditionally acceptable at that time. The product characteristics for Sorilux have not changed since the date of our last review.

### **1.3 PRODUCT INFORMATION**

Sorilux (calcipotriene 0.005%) is an antipsoriatic foam which is applied in a thin layer to affected skin twice daily. It is indicated for the topical treatment of plaque psoriasis in patients (b) (4). Sorilux will be available in a 60 gram can which can be inverted to dispense a small amount of foam into the cap of the can or directly on the affected area of the skin. The container is stored at room temperature and the product will be distributed through retail, inpatient, long-term care, and clinic pharmacy settings.

## **2 METHODS AND MATERIALS**

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1 and 2.2 identify specific information associated with the methodology for the proposed proprietary name, Sorilux.

### **2.1 SEARCH CRITERIA**

For this review, particular consideration was given to drug names beginning with the letter 'S' when searching to identify potentially similar drug names, as 75% of the confused drug names

reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.<sup>1,2</sup>

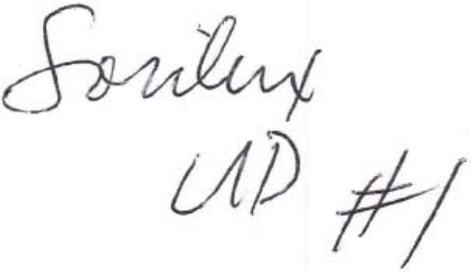
To identify drug names that may look similar to Sorilux, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (seven letters), upstrokes (2, capital letter ‘S’ and lower case letter ‘l’), downstrokes (none), cross strokes (one, lower case letter ‘x’), and dotted letters (one, lower case ‘i’). Additionally, several letters in Sorilux may be vulnerable to ambiguity when scripted (see Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Sorilux.

When searching to identify potential names that may sound similar to Sorilux, the DMEPA staff search for names with similar number of syllables (three), stresses (SOR-i-lux, sor-I-lux or sor-i-LUX), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary (see Appendix B). The Applicant provided their intended pronunciation of the proprietary name (sawr-i-luks) in the proposed name submission and, therefore, it was taken into consideration. However, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

## 2.2 FDA PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient medication order, outpatient and verbal prescriptions were communicated during the FDA prescription studies.

**Figure 1. Sorilux Study (conducted on February 1, 2010)**

HANDWRITTEN PRESCRIPTION AND MEDICATION ORDER	VERBAL PRESCRIPTION
<p><u>Outpatient Prescription:</u></p>  <p>The image shows a handwritten prescription on lined paper. The word 'Sorilux' is written in cursive. Below it, 'UD #1' is written in a similar cursive style.</p>	<p>Sorilux As directed #1</p>

<sup>1</sup> Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

<sup>2</sup> Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

<p><u>Inpatient Medication Order :</u></p> <p><i>Sorilux - apply to affected area</i></p> <p><i>As in</i></p>	
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### 3 RESULTS

#### 3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of 47 names as having some similarity to the name Sorilux. Twenty of these names (Avelox, Seradex, Sorine, Soriatane, Sarafem, (b) (4), Sorlex, Sonata, Serax, Starlix, Doribax, Dorivax, Sporanox, Scanlux<sup>\*\*\*</sup>, Solex, Soliris, Solurex, Sonorx, Serloux, and Zovirax) were identified and evaluated in our previous review and will not be discussed further since the Sorilux product characteristics have not changed.

Of the 27 remaining names, 25 were thought to look like Sorilux (Zantac, Sonahist, Lartus, Surbex-T, Lantus, Surfak, Lorabid, Surital, Focalin, Loniten, Serostim, Borofair, Surqlax, Sarilen, Sanctura, Sanorex, (b) (4)<sup>\*\*\*</sup>, Desilux<sup>\*\*\*</sup>, Subutex, Savella, Zonalon, Zoladex, (b) (4), Galvus<sup>\*\*\*</sup>, and (b) (4)). The two remaining names (Psorilys and Psorilom) were thought to sound similar to Sorilux.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name as of March 3, 2010.

#### 3.2 CDER EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (see Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Sorilux.

#### 3.3 FDA PRESCRIPTION ANALYSIS STUDIES

A total of 49 practitioners responded, but none of the responses overlapped with any existing or proposed drug names. About 61% of the participants (n=30) interpreted the name correctly as 'Sorilux', with correct interpretation occurring more frequently in the inpatient written study. The remainder of the respondents (n=19) misinterpreted the drug name. In the outpatient prescription study, the letter 'S' was misinterpreted as the letter 'F', the letter 'r' was misinterpreted as 'n', the letter 'u' was misinterpreted as 'e', and 'a'. In the verbal prescription study, the letter 'S' was misinterpreted as the letter 'Z', and the letter 'i' was misinterpreted as 'a' and 'e', and the letter 'x' was misinterpreted as 'ck'. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

#### 3.4 COMMENTS FROM THE DIVISION OF DERMATOLOGY AND DENTAL PRODUCTS

DMEPA notified the Division of Dermatology and Dental Products via e-mail that we had no objections to the proposed proprietary name, Sorilux, on March 22, 2010. Per e-mail

\*\*\*This document contains proprietary and confidential information that should not be released to the public.\*\*\*

correspondence from the Division of Dermatology and Dental Products on March 26, 2010, they indicated they had no concerns with the proposed proprietary name, Sorilux.

### **3.5 SAFETY EVALUATOR RISK ASSESSMENT**

Independent searches by the primary Safety Evaluator did not result in identification of any additional names which were thought to look and/or sound similar to Sorilux and represent a potential source of drug name confusion. Therefore, a total of 27 names were evaluated for their potential similarity to Sorilux.

## **4 DISCUSSION**

This proposed name, Sorilux, was evaluated from a promotional perspective and safety perspective. Furthermore, input from pertinent disciplines involved with the review of this application was considered accordingly.

### **4.1 PROMOTIONAL REVIEW**

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name. DMEPA and the Division of Dermatology and Dental Products concurred with the findings of the promotional assessment.

### **4.2 SAFETY REVIEW**

None of the product characteristics changed from the time of the initial review of the proposed name from IND to NDA submission. Since the proposed name was reviewed in the IND phase, 27 new names were identified as potential sources of confusion. DMEPA did not identify other aspects of the name that could function as a source of error. Thirteen of the 27 names were not evaluated further for the following reasons: three names lacked convincing orthographic and/or phonetic similarities with Sorilux, three names are foreign products, three names are proposed proprietary names that did not receive approval and have never been marketed, three names are discontinued products with no generic equivalents, and one name did not have any additional information that could be found in any of the commonly used references (see Appendices D through H).

Failure mode and effects analysis (FMEA) was then applied to determine if the proposed name could potentially be confused with the remaining 14 names and lead to medication errors. This analysis determined that the name similarity between Sorilux was unlikely to result in medication errors with any of the 14 products for the reasons presented in Appendices I through K.

## **5 CONCLUSIONS AND RECOMMENDATIONS**

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

However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding and the name must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change. If the approval of this application is delayed beyond 90 days from the signature date of this review, the proposed name must be re-

evaluated. If you have further questions or need clarifications, please contact Janet Anderson, OSE Project Manager, at 301-796-0675.

## 5.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Sorilux, and have concluded that it is acceptable. Sorilux will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

## 6 REFERENCES

1. *Micromedex Integrated Index* (<http://csi.micromedex.com>)

Contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

2. *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. This is a database which was created for the Division of Medication Error Prevention and Analysis, FDA.

3. *Drug Facts and Comparisons, online version, St. Louis, MO*  
(<http://factsandcomparisons.com>)

Drug Facts and Comparisons is a compendium organized by therapeutic course; contains monographs on prescription and OTC drugs, with charts comparing similar products.

4. *FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]*

DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. *Division of Medication Errors Prevention and Analysis proprietary name consultation 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.

6. *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.

7. *Electronic online version of the FDA Orange Book*  
(<http://www.fda.gov/cder/ob/default.htm>)

Provides a compilation of approved drug products with therapeutic equivalence evaluations.

8. *U.S. Patent and Trademark Office* (<http://www.uspto.gov>)

Provides information regarding patent and trademarks.

**9. Clinical Pharmacology Online ([www.clinicalpharmacology-ip.com](http://www.clinicalpharmacology-ip.com))**

Contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. Provides a keyword search engine.

**10. Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at ([www.thomson-thomson.com](http://www.thomson-thomson.com))**

The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

**11. Natural Medicines Comprehensive Databases ([www.naturaldatabase.com](http://www.naturaldatabase.com))**

Contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

**12. Stat!Ref ([www.statref.com](http://www.statref.com))**

Contains full-text information from approximately 30 texts. Includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolph's Pediatrics, Basic Clinical Pharmacology and Dictionary of Medical Acronyms Abbreviations.

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

List contains all the recognized USAN stems.

**14. Red Book Pharmacy's Fundamental Reference**

Contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

**15. Lexi-Comp ([www.lexi.com](http://www.lexi.com))**

A web-based searchable version of the Drug Information Handbook.

**16. Medical Abbreviations Book**

Contains commonly used medical abbreviations and their definitions.

**17. OSE review 2009-111; Proprietary Name Review: Sorilux (Calcipotriene) Foam; June 11, 2009; Fava, W.**

## APPENDICES

### **Appendix A:**

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.<sup>3</sup>

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate into the overall risk assessment.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>4</sup> DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, DMEPA staff considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and

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<sup>3</sup> National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

<sup>4</sup> Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

monitoring the impact of the medication.<sup>5</sup> DMEPA provides the product characteristics considered for this review in section one.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., “T” may look like “F,” lower case ‘a’ looks like a lower case ‘u,’ etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details). In addition, the DMEPA staff compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. If provided, DMEPA will consider the Applicant’s intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Applicant has little control over how the name will be spoken in clinical practice.

**Table 1.** Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name.

<b>Type of similarity</b>	<b>Considerations when searching the databases</b>		
	<i>Potential causes of drug name similarity</i>	<i>Attributes examined to identify similar drug names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication</li> <li>Names may look similar when scripted and lead to drug name confusion in written communication</li> </ul>
	Orthographic similarity	Similar spelling Length of the name Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may look similar when scripted, and lead to drug name confusion in written communication</li> </ul>

<sup>5</sup> Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may sound similar when pronounced and lead to drug name confusion in verbal communication</li> </ul>
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Lastly, the DMEPA staff also considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the safety of the proposed proprietary name or product based on professional experience with medication errors.

### 1. Database and Information Sources

DMEPA staff conducts searches of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the DMEPA staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel.

### 2. CDER Expert Panel Discussion

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the DMEPA staff to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

### 3. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, conducts a Failure Mode and Effects Analysis, and provides an overall risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a

systematic tool for evaluating a process and identifying where and how it might fail.<sup>6</sup> When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section one. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

***“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?”***

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

***“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”***

The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Risk Assessment:

- a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

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<sup>6</sup> Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Applicant with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant. However, the safety concerns set forth in criteria a through e are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), Joint Commission on Accreditation of Hospitals (JCOAH), and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and a preventable source of medication error that, in many instances, the Agency and/or Applicant can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Applicants have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Applicant and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Applicants' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval. (See Section 4 for limitations of the process).

**Appendix B: Letters with possible orthographic or phonetic misinterpretation**

Letters in Name Sorilux	When scripted may appear as:	When spoken may be interpreted as:
Capital 'S'	'A', 'F', lower case 'g' or 'f'	Z
Lower case 'o'	'a', 'e', 'i', or 'u'	any vowel
Lower case 'r'	'n', 'i', 'l', or 'v'	
Lower case 'i'	'e', 'l', or 'r'	any vowel
Lower case 'l'	'e' or 'i'	
Lower case 'u'	'a', 'o'	any vowel
Lower case 'x'	'l' (if uncrossed)	'ks', 'k'

**Appendix C: FDA Prescription Study Responses**

Outpatient Prescription	Inpatient Medication Order	Voice
Forilax	Sorelux	Soralux
Sonilex	Sorilux	Sorelux
Soriblex	Sorilux	Sorlox
Sorilax	Sorilux	Sorlux
Sorilerx	Sorilux	Sorlux
Sorilerx	Sorilux	Sorlux
Sorilerx	Sorilux	Sorolux
Sorilex	Sorilux	Sorrelux
Sorilux	Sorilux	sorulux
Sorilux	Sorilux	Zorlock
Sorilux	Sorilux	
Sorilux		

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**Appendix D: Proprietary names lacking convincing orthographic and phonetic similarities with Sorilux**

Proprietary Name
Borofair
(b) (4)
Zantac

**Appendix E: Foreign Proprietary names with orthographic or phonetic similarity to Sorilux**

Proprietary Name	Similarity to Sorilux	Country
Psorilys	Sound	Estonia, Slovenia
Psorilom	Sound	Russia
Sarilen	Look	Spain, Turkey

**Appendix F: Proprietary Names with similarity to Sorilux but did not receive approval**

Proprietary Name	Similarity to Sorilux	Status
(b) (4)		
Desilux*** (IND 67825)	Look	Name found unacceptable by DMEPA in 2005 Approved under the proprietary name Verdeso (NDA 21978)
Banilux*** (IND 69927)	Look	DDMAC objection 2007 Approved under the proprietary name Kapidex (NDA 22287)

\*\*\*This is proprietary and confidential information that should not be released to the public.\*\*\*

**Appendix G: Proprietary Name with orthographic similarity to Sorilux that is discontinued and has no generic equivalents available**

Proprietary Name	Similarity to Sorilux
Lorabid (loracarbef)	Look
Surital (thiamylal sodium)	Look
Sanorex (mazindol)	Look

**Appendix H: Proprietary name found in Drug Facts and Comparisons database, but no product characteristics or other information was found in any of the other commonly used databases listed in the Reference section (section 6)**

Proprietary Name	Similarity to Sorilux
Lartus	Look

**Appendix I: Proprietary names with orthographic or phonetic similarities to Sorilux but have no overlapping strength**

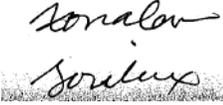
Proprietary Name	Product Strength/Established Name/Dosage Form	Usual Dose
<b>Sorilux</b>	<b>0.005% calcipotriene foam</b>	<b>Apply twice daily</b>
Focalin	2.5 mg, 5 mg, 10 mg dexamethylphenidate HCl tablets	2.5 mg to 10 mg by mouth twice daily
Loniten (discontinued, generics available)	2.5 mg, 10 mg minoxidil tablets	10 mg to 40 mg by mouth once daily
Subutex	2 mg, 8 mg buprenorphine HCl sublingual tablets	8 mg to 16 mg per day sublingually as a single dose
Savella	12.5 mg, 25 mg, 50 mg, 100 mg milnacipran HCl tablets	50 mg by mouth twice daily
Zoladex	3.6 mg, 10.8 mg goserelin acetate implant	Administer 3.6 mg or 10.8 mg subcutaneously every 28 days or 12 weeks
Galvus <sup>***</sup>	50 mg, 100 mg vildagliptin tablets	50 mg or 100 mg by mouth one or twice daily
Serostim	4 mg/vial, 5 mg/vial, 6 mg/vial somatropin recombinant injection	0.1 mg/kg/day subcutaneously (up to 6 mg)

<sup>\*\*\*</sup>This is proprietary and confidential information that should not be released to the public.<sup>\*\*\*</sup>

**Appendix J:** Drug names with single strength availability but with differentiating product characteristics

<b>Product name with potential for confusion</b>	<b>Similarity to Product Name</b>	<b>Strength</b>	<b>Usual Dose</b>	<b>Differentiating Product Characteristics Sorilux vs. product</b>
<b>Sorilux</b>		<b>0.005%</b>	Apply to affected area twice daily	
Surbex-T (vitamin B and C) tablets	Look	NA	1 tab by mouth once daily	<b><u>Dosage form:</u></b> Foam vs. tablet <b><u>Route of administration:</u></b> Topical vs. oral <b><u>Frequency of administration:</u></b> Twice daily vs. once daily
Lantus (insulin glargine) injection	Look	100 units/mL	2 units to 100 units subcutaneously once daily, dose is individualized	<b><u>Dosage form:</u></b> Foam vs. injection <b><u>Route of administration:</u></b> Topical vs. subcutaneous <b><u>Frequency of administration:</u></b> Twice daily vs. once daily
Surfak (docusate sodium) capsules	Look	240 mg	240 mg/day for several days or until bowel movements are normal	<b><u>Dosage Form:</u></b> Foam vs. capsules <b><u>Route of Administration:</u></b> Topical vs. oral <b><u>Frequency of administration:</u></b> Twice daily vs. once daily
Surqlax (docusate calcium) capsules	Look	240 mg	240 mg/day for several days or until bowel movements are normal	<b><u>Dosage Form:</u></b> Foam vs. capsules <b><u>Route of Administration:</u></b> Topical vs. oral <b><u>Frequency of administration:</u></b> Twice daily vs. once daily
Sanctura (trospium chloride) tablets	Look	20 mg	20 mg by mouth twice daily	<b><u>Dosage Form:</u></b> Foam vs. tablets <b><u>Route of Administration:</u></b> Topical vs. oral
Sonahist (chlorpheniramine ; phenylephrine) Pediatric drops	Look	1 mg/2 mg per mL	1 mL to 2 mL by mouth every 4 to 6 hours as needed	<b><u>Dosage Form:</u></b> Foam vs. pediatric drops <b><u>Route of Administration:</u></b> Topical vs. oral <b><u>Frequency of administration:</u></b> Twice daily vs. Q4-6hr prn

**Appendix K:** Products with numeric overlap in strength, dose or achievable dose

<b>Proposed name:</b> <b>Sorilux</b> <b>(calicipotriene) foam</b>	<b>Strength:</b> <b>0.005%</b>	<b>Usual Dose:</b> <b>Apply to affected area twice daily</b>
<b>Failure Mode: Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Effects</b>
<p>Zonalon (doxepin HCl) 5% cream Short-term management (up to 8 days) of moderate pruritis in adults with atopic dermatitis or lichen simplex chronicus Apply a thin film four times a day with at least a 3 to 4 hour interval between applications</p>	<p>Orthographic similarities: Both contain 7 letters; both names share the second letter ‘-o-’; and ‘-lon’ and ‘-lux’ may appear similar when scripted’. Both products will be available as a single strength Both are topical Both may be scripted with ‘use as directed’ instructions</p>	<p>Orthographic differences may help to minimize the potential for medication errors in the usual practice setting. <i>Rationale:</i> Zonalon and Sorilux are both topical products available in a single strength that may be prescribed with ‘use as directed’ instructions. Despite this similarity, orthographic differences between the names may help to minimize confusion between these two products. The first letter of each name helps to provide some visual differentiation between the two names (‘Z’ vs. ‘S’). Additionally, the last letter of each name (‘n’ vs. ‘x’) also helps to provide some orthographic difference between Zonalon and Sorilux. Therefore, the overall orthographic differences will help to minimize the potential for confusion and medication errors.</p> 

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22563	ORIG-1	STIEFEL LABORATORIES INC	CALCIPOTRIEN FOAM 0.005%

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/s/

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FELICIA DUFFY  
04/15/2010

DENISE P TOYER on behalf of ZACHARY A OLESZCZUK  
04/15/2010

DENISE P TOYER  
04/15/2010

CAROL A HOLQUIST  
04/15/2010