CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 21-501

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE
DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF DRUG SAFETY
(WO22; Mail Stop 4447)

DATE RECEIVED: January 6, 2006 **DATE OF DOCUMENT:** May 16, 2005	**DESIRED COMPLETION DATE:** January 31, 2006 **PDUFA DATE:** March 12, 2006	**ODS CONSULT #:** 06-0012 06-0043

TO: Andrea Leonard-Segal, M.D., Acting Director
Division of Nonprescription Clinical Evaluation, HFD-560

THROUGH: Alina Mahmud, RPh, MS, Team Leader
Denise Toyer, PharmD, Deputy Director
Carol Holquist, RPh, Director
Division of Medication Errors and Technical Support, HFD-420

FROM: Felicia Duffy, RN, Safety Evaluator
Division of Medication Errors and Technical Support, HFD-420

PRODUCT NAME: **UV Expert (NDA 21-501)** (Avobenzone 2%, Ecamsule 3%, Octocrylene 10% Lotion) **UV Expert (NDA 21-502)** (Avobenzone 2%, Ecamsule 2%, Octocrylene 10% Lotion) **UV Expert (NDA 21-471)** (Avobenzone 2%, Ecamsule 2%, Octocrylene 10%, Titanium Dioxide 2% Lotion)	**NDA SPONSOR:** L'Oreal USA Products **DISTRIBUTOR:** Lancôme

ECOMMENDATIONS:

1. Although we have not identified any proprietary or established names that would render the name "UV Expert" objectionable from a look-alike or sound-alike perspective, DMETS is concerned with the use of "Expert" in the name. We believe "Expert" is promotional and question what it communicates to consumers (see section III A of this review). For these reasons, DMETS does not recommend the use of the proprietary name UV Expert. However, if UV Expert is approved, we recommend r

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. Because DDMAC does not have regulatory authority to review proposed OTC proprietary names, they did not comment on the name UV Expert.

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 301-796-0538.

Division of Medication Errors and Technical Support (DMETS)
Office of Drug Safety
WO22; Mail Stop 4447
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE OF REVIEW: January 18, 2006

NDA#s: 21-501, 21-502, 21-471

NAME OF DRUG: **UV Expert 15 (NDA 21-501)**
(Avobenzone 2%, Ecamsule 3%, Octocrylene 10% Lotion)

UV Expert 15 (NDA 21-202)
(Avobenzone 2%, Ecamsule 2%, Octocrylene 10% Lotion)

UV Expert 20 (NDA 21-471)
(Avobenzone 2%, Ecamsule 3%, Octocrylene 10%, Titanium Dioxide 2% Lotion)

NDA HOLDER: L'Oreal USA Products

DISTRIBUTOR: Lancôme

I. INTRODUCTION:

This consult was written in response to a request from the Division of Nonprescription Clinical Evaluation (HFD-560) for a review of the proprietary name, "UV Expert", regarding potential name confusion with other proprietary and/or established drug names. Container labels, carton and insert labeling were provided for review and comment.

PRODUCT INFORMATION

The UV Expert products are over-the-counter (OTC) products that contain three or four ultraviolet radiation (UVR) filters providing protection throughout the ultraviolet B (UVB) and ultraviolet A (UVA) spectrum. The active ingredients include ecamsule, avobenzone, octocrylene, and/or titanium dioxide in the same or different concentrations. UV Expert is indicated for the prevention of sunburn will be available in a regular formulation and in a water resistant formulation. UV Expert is to be applied evenly [redacted] before sun exposure and as needed. The water resistant formulation is to be applied liberally 15 minutes before sun exposure and reapplied [redacted] after towel drying, swimming or perspiring. A physician should be consulted for use in children under six months of age. UV Expert will be supplied in [redacted] tubes containing 100 mL. 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 databases[3] for existing drug names which sound-alike or look-alike to UV Expert to a degree where potential confusion between drug names could occur under

[1] MICROMEDEX Integrated Index, 2006, 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], Drugs@FDA, the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, and the electronic online version of the FDA Orange Book.

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 conducted[4]. The Saegis[5] 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 UV Expert. 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. Because over-the-counter drug products are regulated by the FTC, DDMAC is unable to provide comments on the proposed trade name UV Expert.

2. The Expert Panel identified two proprietary names that were thought to have the potential for confusion with UV Expert. This product is 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	Established name, Dosage form(s)	Usual adult dose*	Other**
UV Expert SPF 15	Avobenzone/Ecamsule/Octocrylene/ Lotion 2%/2%/10% and 2%/3%/10%	Apply [redacted] before sun exposure. Water resistant. Apply liberally 15 minutes before sun exposure.	NA
UV Expert SPF 20	Avobenzone/Ecamsule/Octocrylene/ Titanium Dioxide Lotion 2%/2%/10%/2%	Apply liberally 15 minutes before sun exposure.	
UV Expert SPF 15 Sunscreen Daily UVA/UVB Protection	No information available.	No information available.	
UV Expert DNA Shield SPF 50	No information available.	No information available.	LA/SA
UV Expert Extra Large Double Protection SPF 50	No information available.	No information available.	LA/SA
*Frequently used, not all-inclusive. **L/A (look-alike), S/A (sound-alike)			

b(4)

[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

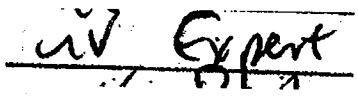
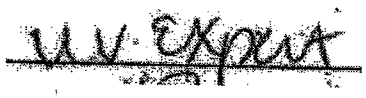
B. PHONETIC and ORTHOGRAPHIC COMPUTER ANALYSIS (POCA)

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 UV Expert were discussed by the Expert Panel.

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 UV Expert 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 125 health care professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the prescription ordering process. Two requisition prescriptions were written, each consisting of a combination of marketed and unapproved drug products and a prescription for UV Expert (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 PRESCRIPTIONS	VERBAL PRESCRIPTION
Requisition #1: 	Order Code# 12 UV Expert 12 Bottles
Requisition #2: 	

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 a complete listing of interpretations.

D. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name UV Expert, the primary concerns related to look-alike and/or sound-alike confusion with UV Expert DNA Shield and UV Expert Extra Large Double Protection.

Additionally, 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, UV Expert.

1. Nomenclature Concerns with "Expert"

   DMETS is concerned with the use of the modifier "Expert" in the proprietary name. We note the sponsor, Lancôme, uses this term with their sunscreen product line (e.g. UV Expert) and acknowledge there does not appear to be any safety concerns with the use of this modifier for this product. However, we question what "Expert" communicates to consumers and consider it promotional. DDMAC could not comment on the proprietary name UV Expert because they do not have regulatory authority to review proposed OTC proprietary names. The term "expert" has not been used in conjunction with any approved prescription drug product, and thus, this may establish precedence for other approved drug products. Although it is noted that there are no safety concerns with the use of the name "Expert" for these OTC products, DMETS notes that we would not recommend use of "Expert" for any prescription products because it is promotional. For these reasons, DMETS does not recommend the use of the proprietary name UV Expert.

2. Look-alike and Sound-Alike Concerns

   UV Expert is a sunscreen that will be distributed by Lancôme. While using the search engine www.google.com, Lancôme UV Expert products (specifically, UV Expert DNA Shield SPF 50 and UV Expert Extra Large Double Protection SPF 50) were found for purchase on websites such as www.amazon.com, www.cosmeticamerica.com and www.ebay.com. DMETS contacted Lancôme's consumer affairs via email to obtain information on the active ingredients in the Lancôme UV Expert products advertised on the aforementioned websites. The consumer affairs advisor indicated that "UV Expert has been discontinued and stock is no longer available. We have no way to obtain it for you to purchase." Thus, DMETS cannot review UV Expert DNA Shield SPF 50 and UV Expert Extra Large Double Protection SPF 50 due to lack of product availability and product information. DMETS has no objections to the proprietary name, UV Expert, from a look-alike, sound-alike standpoint. However, DMETS cautions the sponsor about the potential for consumers to confuse the discontinued Lancôme UV Expert products with the proposed Lancôme UV Expert products. For example, if a consumer previously purchased UV Expert SPF 15 Sunscreen Daily UVA/UVB Protection before it was discontinued, they may believe that the currently proposed UV Expert Sunscreen Daily Face Protection Moisturizer Lotion (SPF 15) is the same product. However, both products may have different active ingredients. It is possible that a consumer may have an allergic reaction to the proposed UV Expert product because they assumed it was the same as the discontinued product. Thus, we caution the sponsor to be aware of this potential issue.

3. Differentiation of UV Expert products that Contain Different Active Ingredients

We note that the sponsor proposes to market two products containing two different sets of active ingredients (avobenzone, ecamsule, octocrylene vs. avobenzone, ecamsule, octocrylene, titanium dioxide) and concentrations with the same proprietary name, UV Expert. This is concerning because consumers would not know by the name alone that there are different active ingredients in each. If a consumer is allergic to a specific ingredient they may not realize that the active ingredients of UV Expert may be different depending upon the SPF they choose. However, DMETS recognizes that the current practice, of naming OTC sunscreens, is to use the same proprietary name and distinguish them by using descriptors and/or the SPF number. Although DMETS does not recommend the use of the same proprietary name for products that contain different active ingredients for prescription products, we acknowledge that there is precedent for this naming convention with sunscreens in the Division of Nonprescription Clinical Evaluation. We note that the sponsor prominently displays the SPF rating on the principal display panel of each label. If the Division allows the use of the proprietary name UV Expert, DMETS recommends that the sponsor

III. COMMENTS TO THE SPONOSOR

DMETS does not recommend the use of the proprietary name UV Expert due to nomenclature concerns with the name "Expert".

A. DMETS is concerned with the use of the modifier "Expert" in the proprietary name. We note the sponsor, Lancôme, uses this term with their sunscreen product line (e.g. UV Expert) and acknowledge there does not appear to be any safety concerns with the use of this modifier for this product. However, we question what "Expert" communicates to consumers and consider it promotional. DDMAC could not comment on the proprietary name UV Expert because they do not have regulatory authority to review proposed OTC proprietary names. The term "expert" has not been used in conjunction with any approved prescription drug product, and thus this may establish precedence for other approved drug products. Although it is noted that there are no safety concerns with the use of the name "Expert" for these OTC products, DMETS notes that we would not recommend use of "Expert" for any prescription products because it is promotional. For these reasons, DMETS does not recommend the use of the proprietary name UV Expert.

In the review of the container labels, carton and insert labeling of UV Expert, 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.

1 Page(s) Withheld

_____ Trade Secret / Confidential (b4)

_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Appendix A: Prescription Study Results for UV Expert

Requisition 1	Requisition 2	Verbal
UV expert	UV Expera	UV Expert
UV Expert	UV Expera	UV Expert
UV Expert	UV Expera	UV Expert
UV Expert	UV Expert	UV Expert
UV Expert	UV Expert	UV Expert
UV Expert	UV Expert	UV Expert
UV Expert	UV Expert	UV Expert
UV Expert	UV Expert	UV Expert
UV Expert	UV Expert	UV expert
UV Expert	UV Expert	UV Expert
UV Expert	UV Expert	UV Expert
UV Expert	UV Expert	UV Expert
UV expert	UV Expert	UVExpert
UV Expert	UV Expert	
UV Expert	UV Expert	
UV Expert	UV Expert	
UV Expert	Uv Expira	
UV Expert	UV Expira	
UV Expert	UV Expua	

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

/s/

Felicia Duffy
3/8/2006 10:15:07 AM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
3/8/2006 01:20:10 PM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
3/8/2006 02:01:23 PM
DRUG SAFETY OFFICE REVIEWER

CONSULTATION RESPONSE
DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF DRUG SAFETY
(WO: 22, Mailstop 4447)

DATE RECEIVED: January 6, 2006 **DATE OF DOCUMENT:** May 16, 2005	**DESIRED COMPLETION DATE:** January 31, 2006 **PDUFA DATE**: March 16, 2006	**ODS CONSULT #:** 06-0010 06-0045

TO: Andrea Leonard Segal, M.D., Acting Director
Division of Nonprescription Clinical Evaluation, HFD-560

THROUGH: Nora Roselle, PharmD., Acting Team Leader
Denise Toyer, Pharm D., Deputy Director
Carol Holquist, RPh, Director
Division of Medication Errors and Technical Support, HFD-420

FROM: Linda M. Wisniewski, RN, Safety Evaluator
Division of Medication Errors and Technical Support, HFD-420

PRODUCT NAME: **Capital Soleil 15 (NDA 21-501)** (Avobenzone 2%, Ecamsule 3%, Octocrylene 10% Lotion) **Capital Soleil 20 (NDA 21-471)** (Avobenzone 2%, Ecamsule 3%, Octocrylene 10%, Titanium Dioxide 2% Lotion)	**NDA SPONSOR:** **L'Oreal USA Products**

ECOMMENDATIONS:

1. Although the initial consult requested a review of the tradename, Capital Soleil, upon reviewing the labels and labeling we recognize the actual product names are Capital Soleil 15 and Capital Soleil 20. The numbers 15 and 20 represent the SPF rating which effectively differentiates these two product formulations. Thus, DMETS has no objections to the use of the proprietary names Capital Soleil 15 and Capital Soleil 20.

   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. Additionally, all labeling comments in this review pertain to NDA's 21-501 and 21-502.

3. Because DDMAC does not have regulatory authority to review proposed OTC proprietary names, they did not comment on the name Capital Soleil.

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 301-796-0538.

Division of Medication Errors and Technical Support (DMETS)
Office of Drug Safety
WO: 22; Mailstop: 4447
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE OF REVIEW: January 18, 2006

NDA#: 21-501

NAME OF DRUG: **Capital Soleil 15 (NDA 21-501)**
(Avobenzone 2%, Ecamsule 3%, Octocrylene 10% Lotion)

Capital Soleil 20 (NDA 21-471)
(Avobenzone 2%, Ecamsule 3%, Octocrylene 10%, Titanium Dioxide 2% Lotion)

NDA HOLDER: L'Oreal USA Products

I. INTRODUCTION:

This consult was written in response to a request from the Division of Nonprescription Clinical Evaluation (HFD-560) for a review of the proprietary name, "Capital Soleil", regarding potential name confusion with other proprietary and/or established drug names. Capital Soleil is currently marketed by L'Oreal in Europe. Container labels, carton and insert labeling were provided for review and comment.

PRODUCT INFORMATION

Capital Soleil is an over-the-counter (OTC) product that contains three ultraviolet radiation (UVR) filters providing protection throughout the ultraviolet B (UVB) and ultraviolet A (UVA) spectrum. These active ingredients include ecamsule, avobenzone, and octocrylene. Capital Soleil is indicated for the prevention of sunburn and is to be applied liberally 15 minutes before sun exposure. Reapply after towel drying, swimming or perspiring. A physician should be consulted for use in children under six months of age. Capital Soleil will be supplied in a tube containing 100 mL.

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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 databases[3] for existing drug names which sound-alike or look-alike to Capital Soleil 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 conducted[4]. The Saegis[5] Pharma-In-Use database was searched for drug names with potential for confusion. An expert panel discussion was

[1] MICROMEDEX Integrated Index, 2006, 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], Drugs@FDA, the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, 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

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 Capital Soleil. 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. Because over-the-counter drug products are regulated by the FTC, DDMAC is unable to provide comments on the proposed trade name Capital Soleil.

2. The Expert Panel identified four proprietary names that were thought to have the potential for confusion with Capital Soleil. These products are listed in Table 1 (see page 4), 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**
Capital Soleil 15 Capital Soleil 20	Ecamsule/Avobenzone/Octocylene Lotion 3 %/2 %/10 %	Apply liberally 15 minutes before sun exposure and [redacted]	NA
Capitrol	Chloroxine Shampoo 2%	Massage thoroughly into wet scalp. Allow lather to remain on scalp for 3 minutes, rinse, and repeat. Two treatments per week.	LA/SA
Capoten	Captopril Tablets 12.5 mg, 25 mg, 50 mg, 100 mg	6.25 mg to 150 mg two to three times a day.	LA/SA
Capital with Codeine	Codeine Phosphate and Acetaminophen Suspension 12 mg/120 mg	15 mL every four hours.	LA/SA
Bain de Soleil	Mega Tan Sunscreen Lotion with Self Tanner SPF 4 Streakguarde Self Tanning Crème Dark Streakguarde Self Tanning Crème Deep Dark Radiance Eternelle Self Tanning Crème Medium Dark Radiance Eternelle Self Tanning Crème Dark Orange Gelee Sunscreen Lotion SPF 4 Special Set-Radiance Eternelle Self-Tanning Crème Dark Special Set-Radiance Eternelle Self-Tanning Crème Medium Dark	Apply as directed.	LA/SA

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

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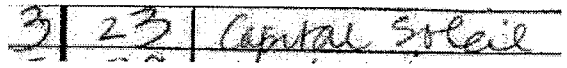
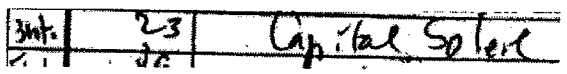
B. PHONETIC and ORTHOGRAPHIC COMPUTER ANALYSIS (POCA)

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. 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 Capital Soleil were discussed by the Expert Panel.

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 Capital Soleil 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 125 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 Capital Soleil (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
Requisition #1: 	Order Code# 23 Capital Soleil 3 Bottles
Requisition #2: 	

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 a complete listing of interpretations.

D. SAFETY EVALUATOR RISK ASSESSMENT

1. Look-alike and Sound-Alike Concerns

In reviewing the proprietary name Capital Soleil, the primary concerns related to look-alike and/or sound-alike confusion with Capitrol, Captopril, Capoten, Bain de Soleil, and Capital with Codeine.

Upon further review of the names gathered from EPD, the name Bain de Soleil was not reviewed further due to a lack of look-alike similarities with Capital Soleil as a result of the use of multiple modifiers within the Bain de Soleil product line (e.g. Mega Tan Sunscreen Lotion with Self Tanner SPF 4, Streakguarde Self Tanning Crème Dark, Streakguarde Self Tanning Crème Deep Dark, Radiance Eternelle Self Tanning Crème Medium Dark, Radiance Eternelle Self Tanning Crème Dark, Orange Gelee Sunscreen Lotion SPF 4, Special Set-Radiance Eternelle Self-Tanning Crème Dark, and Special Set-Radiance Eternelle Self-Tanning Crème Medium Dark).

Additionally, 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.

a. Capitrol was found to have look-alike and sound-alike potential with Capital Soleil if the 'Soleil" portion of the name is omitted or overlooked. Capitrol is a topical drug product and is indicated in the treatment of seborrheic dermatitis of the scalp. Both names contain six of the same letters in the same placement (C a p i t _ l vs. C a p i t _ _ l). This similarity in spelling contributes to an overall orthographic and phonetic similarity involving these two names. Both products are topically administered products that are supplied in one strength and one dosage form. This may result in either drug being ordered 'drug name use as directed', as this is not an unusual method of ordering topical products. However, Capital Soleil will be an over-the-counter product and is not likely to be stored on shelves with prescription items. This may help to prevent selection errors. DMETS believes that the different storage locations, in addition to the the entire name, Capital Soleil, will help to differentiate these two names when written.

Capital Soleil
Capital

b. Capoten may look or sound similar to Capital Soleil if the 'Soleil' portion of the name is omitted or overlooked. Capoten is indicated in the treatment of hypertension and heart failure. Both names contain the same four letters in the same placement (C a p _ t _ _). This spelling similarity may result in a similar phonetic pronunciation of each name. The upstroke for the last letter, 'l', in Capital in addition to the formal presentation of the name 'Capital Soleil', may help to differentiate these two products when written. There are differentiating product characteristics that may help to prevent error. They include dose (liberal amount vs. 6.25 mg to 150 mg), frequency of administration (before sun exposure ___ vs. two to three times daily), strength (3 %/2 %/10 % vs. 12.5

b(4)

mg, 25 mg, 50 mg, and 100 mg), route of administration (topical vs. oral), and dosage form (lotion vs. tablet). Thus, the different doses, frequencies of administration, and strengths may help to differentiate these two products when ordered.

Capital Soleil

Captopril

c. Capital with Codeine may look and sound similar to Capital Soleil if the 'Soleil' or if the 'with Codeine' portion of the name is omitted or overlooked. Capital with Codeine is indicated in the treatment of pain. The first portion of each name is identical 'Capital', however, the formal name of each product includes additional portions that are orthographically and phonetically different (Soleil vs. with Codeine). Capital Soleil consists of two words with a total of 13 letters, whereas, Capital with Codeine consists of three words and a total of 18 letters thereby providing a lengthier orthographic appearance to the name. Additionally, the phonetic difference in the pronunciation of each name is noticeable. Although the first portion of each name is identical, the second portion of the name is phonetically different. Soleil is commonly pronounced similar to 'sew lay', whereas, Codeine is commonly pronounced similar to 'co' as in 'Coke' and 'deen'. Although both products are supplied in a single strength, which may be omitted in an order for either drug, there are some product characteristics that may help to differentiate each product when written or spoken. They include dose (liberal amount vs. 15 mL), frequency of administration (15 minutes before sun exposure vs. every four hours), route of administration (topical vs. oral), dosage form (lotion vs. oral suspension) and storage location (over-the-counter products vs. controlled prescription products). Moreover, since Capital Soleil will be an over-the-counter product, it is not likely to be stored near Capital with Codeine. Thus, the second portion of each name, (Codeine vs. Soleil), in addition to differentiating product characteristics, such as dose, frequency of administration, and storage location, will help to distinguish between these two products when ordered.

Capital Soleil

Capital with Codeine

b(4)

d. Captopril may look or sound similar to Capital Soleil if the 'Soleil' portion of the name is omitted or overlooked. Captopril is indicated in the treatment of hypertension and heart failure. Both names contain the same five letters in the same sequence but in different placements (C a p _ t _ l vs. C a p t _ _ _ _ l). This spelling similarity may result in a similar phonetic pronunciation of each name. Orthographically, both names are different. Where Capital contains one downstroke for the letter 'p', Captopril contains two downstrokes for the two 'p's, thereby providing a different orthographic appearance of each name. Moreover, the complete name of the product Capital Soleil includes a second portion of the name (Soleil) which will also help to differentiate these two products when written. There are differentiating product characteristics that may help to prevent error. They include dose (liberal amount vs. 6.25 mg to 150 mg), frequency of administration (before sun exposure —— vs. two to three times daily), strength (3 %/2 %/10 % vs. 12.5 mg, 25 mg, 50 mg, and 100 mg), route of administration (topical vs. oral), and dosage form (lotion vs. tablet). Thus, the orthographic differences, in addition to the

different doses, frequencies of administration, and strengths may help to differentiate these two products when ordered.

Capital Soleil
Captopril

2. Differentation of Capital Soleil products that Contain Different Active Ingredients

We note that the sponsor proposes to market two products containing two different sets of active ingredients (avobenzone, ecamsule, octocrylene vs. avobenzone, ecamsule, octocrylene, titanium dioxide) with the same proprietary name, Capital Soleil. This is concerning because consumers would not know by the name alone that there are different active ingredients in each. If a consumer is allergic to a specific ingredient they may not realize that the active ingredients of Capital Soleil may be different depending upon the SPF they choose. However, DMETS recognizes that the current practice, of naming OTC sunscreens, is to use the same proprietary name and distinguish them by using descriptors and/or the SPF number. Although DMETS does not recommend the use of the same proprietary name for products that contain different active ingredients for prescription products, we acknowledge that there is precedent for this naming convention with sunscreens in the Division of Nonprescription Clinical Evaluation. We also note that the sponsor prominently displays the SPF rating on the Principal Display Panel of each label thereby adequately differentiating each formulation.

II. LABELING, PACKAGING, AND SAFETY RELATED ISSUES

We note that the sponsor has several pending proprietary name reviews with DMETS that may include similar labels and labeling. Therefore, we will provide General Comments, in this review, that are applicable to all of the proprietary names and address any specific comments pertinent to each proprietary name in the respective reviews.

In the review of the container labels, carton and insert labeling of Capital Soleil, 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.

1 Page(s) Withheld

_____ Trade Secret / Confidential (b4)

_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Appendix A:

ODS Consult: 06-0010 Capital Soleil

Voice	Inpatient Written	Outpatient Written
Cap Sole	Capital Solere	Capital Soleil
Capital Solay	Capilal Soleve	Capiral Soleil
Capital Solé	Capital Soeve	Capital Solei
Capital Solei	Capital Soleil	Capital Soleil
Capital Soleil	Capital Soleil	Capital Soleil
Capital Soleil	Capital Soleil	Capital Soleil
Capital Soley	Capital Solere	Capital Soleil
Capitol Solay	Capital Solere	Capital Soleil
Capitol Sole	Capital Solere	capital soleil
Capitol Solle	Capital Solere	Capital Soleil
Solay	Capital Solere	Capital Soleil
Solay	Capital Solerl	Capital Soleil
Soleil	Capital Solerl	Capital Soleil
	Capital Soleve	Capital Soleil
	Capital Solex	Capital Soleil
	Capital solution	Capital Soleil
	Capitol Soleil	Capital Soleil
	Capitol Solert	Capital Solene
	Capitol Solert	Capital Solution

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/s/

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