CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208183Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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Date of This Review:	July 20, 2015
Application Type and Number:	NDA 208183
Product Name and Strength:	Ultravate (halobetasol propionate) Lotion, 0.05%
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Ferndale Laboratories Inc.
Submission Date:	May 8, 2015
Panorama #:	2015-370482
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, RPh
DMEPA Team Leader:	Kendra Worthy, PharmD
DMEPA Associate Director:	Lubna Merchant, MS, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Ultravate, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study.

1.1 REGULATORY HISTORY

Ultravate (halobetasol dipropionate) Ointment, 0.05% (NDA 019968) was approved on December 17, 1990, whereas the cream formulation (NDA 019967) was approved on December 27, 1990.

The applicant submitted the name, Ultravate, for the lotion formulation under review for NDA 208183 on May 8, 2015.

1.2 PRODUCT INFORMATION

The following product information is provided in the May 8, 2015 proprietary name submission.

- Intended Pronunciation: uhl-trah-veyt
- Active Ingredient: halobetasol propionate
- ***Proposed Indication of Use:*** Topical treatment of plaque psoriasis in patients eighteen (18) years of age and older

  Currently Marketed: Relief of the inflammation and pruritic manifestations of corticosteroid-responsive dermatoses
- Route of Administration: Topical
- ***Proposed Dosage Form:*** Lotion
  Currently Marketed: Cream and Ointment
- Strength: 0.05%
- ***Proposed Dose and Frequency (lotion):*** Apply to the affected area twice daily***.***
  Current Dose and Frequency (cream and ointment): Apply to the affected area once or twice daily.
- How Supplied:
  Proposed: 2 g (b) (4) sample; 2 oz bottle
  Currently Marketed: 50 g tubes; 2 x 50 g tubes
- Storage:
  Proposed: 25°C (77°F); excursions permitted to 59°F and 86°F (15°C to 30°C)
  Currently Marketed: Store between 15° C and 30° C (59° F and 86° F)
- Container and Closure Systems: n/a

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Dermatology and Dental Products (DDDP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[1].

2.2.2 Components of the Proposed Proprietary Name

The applicant indicated in their submission that they have "licensed the marketing rights for this product to Ranbaxy Laboratories Inc. (Ranbaxy). The proposed proprietary name, Ultravate®, is the proprietary name currently used for Ranbaxy's line of halobetasol propionate topical dosage forms. The applicant has received authorization from Ranbaxy to use the Ultravate trade mark in connection with this application." In addition, they state that the proposed proprietary name, Ultravate, is based on its use with an existing product line for over 25 years.

Ultravate is derived from the existing product line, Ultravate (halobetasol propionate) Cream and Ointment, 0.05%. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error. Additionally, as noted above we did not retrieve any medication errors associated with name confusion with the name Ultravate.

The Applicant is proposing a new lotion dosage form for the Ultravate product line. It is a common and accepted practice to have a product line with multiple formulations/dosage forms managed under one proprietary name. Although the indications for the proposed lotion and the currently marketed cream differ (cream and ointment for the relief of the inflammation and pruritic manifestations of corticosteroid-responsive dermatoses vs. treatment of plaque psoriasis for the lotion), they share the same strength (0.05%), route of administration (topical), and overlapping dose (once or

[1]USAN stem search conducted on July 14, 2015.

twice daily for the cream and ointment vs. twice daily for the lotion). Hence, we find that Ultravate is an acceptable proprietary name for the lotion formulation.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, June 1, 2015 e-mail, the Division of Dermatology and Dental Products (DDDP) did not forward any concerns relating to the proposed proprietary name at the initial phase of the review. However, they did comment that "there are two approved NDAs for Ultravate (which are owned by Ranbaxy) and that this lotion NDA is owned by Ferndale. Ferndale is manufacturing the lotion for Ranbaxy."

2.2.4 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 1 (see Appendix A for a description of FAERS database).

Table 1: FAERS Search Strategy	
Date search	July 14, 2015
Drug Names	Ultravate [product name]
MedDRA Search Strategy	Product name confusion (PT) Medication error (PT) Intercepted medication error (PT) Drug dispensing error (PT) Intercepted drug dispensing error (PT) Circumstance or information capable of leading to a medication error (PT)
Time/Date Limits	No date limitation

The FAERS database search retrieved one case that was not relevant to drug name confusion.

2.2.5 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Dermatology and Dental Products (DDDP) via e-mail on July 20, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DDDP on July 20, 2015, they stated no additional concerns with the proposed proprietary name Aczone.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

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

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Ultravate, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your May 8, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

2. ***FDA Adverse Event Reporting System (FAERS)***

   The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at:
   http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name.

1. **Promotional Assessment**: For prescription drug products, the promotional review of the proposed name is conducted by OPDP. For over-the-counter (OTC) drug products, the promotional review of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP or DNCE provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. 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. [1]

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Affirmative answers to these questions indicate a potential area of concern.
Y/N	Does the name have obvious Similarities in Spelling and Pronunciation to other Names?
Y/N	Are there Manufacturing Characteristics in the Proprietary Name?
Y/N	Are there Medical and/or Coined Abbreviations in the Proprietary Name?
Y/N	Are there Inert or Inactive Ingredients referenced in the Proprietary Name?
Y/N	Does the Proprietary Name include combinations of Active Ingredients
Y/N	Is there a United States Adopted Name (USAN) Stem in the Proprietary Name?
Y/N	Is this the same Proprietary Name for Products containing Different Active Ingredients?
Y/N	Is this a Proprietary Name of a discontinued product?

b. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

[1] National Coordinating Council for Medication Error Reporting and Prevention. http://www.nccmerp.org/aboutMedErrors.html. Last accessed 10/11/2007.

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/s/

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