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APPLICATION NUMBER:

207154Orig1s000

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)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	July 8, 2015
Application Type and Number:	NDA 207154
Product Name and Strength:	Aczone (Dapsone) Gel, 7.5%
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Allergan Inc.
Submission Date:	April 28, 2015
Panorama #:	2015-411667
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, RPh
DMEPA Team Leader:	Kendra Worthy, PharmD
DMEPA Associate Director:	Lubna Merchant, MS, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Aczone, 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

Aczone (Dapsone) Gel, 5% (NDA 021794) was approved on July 7, 2005. The proposed proprietary name, Aczone, was found conditionally acceptable in the IND for the 7.5% gel formulation[1].

The applicant submitted the name, Aczone, for review during the NDA on April 28, 2015.

1.2 PRODUCT INFORMATION

The following product information is provided in the April 18, 2014 proprietary name submission.

- Intended Pronunciation: ak-zōn
- Active Ingredient: dapsone
- Indication of Use: Topical treatment of acne vulgaris
- Route of Administration: Topical
- Dosage Form: Gel
- ***Proposed Strength***: 7.5%
  Currently Marketed: 5%
- ***Proposed Dose and Frequency (7.5% strength):*** Apply approximately a pea-sized amount of ACZONE Gel, 7.5%, in a thin layer to the acne affected areas ***once daily.***
  Current Dose and Frequency (5% strength): Apply approximately a pea-sized amount of ACZONE Gel, 5%, in a thin layer to the acne affected areas ***twice daily.***
- How Supplied:
  Currently: 3 g laminate tube sample; 30 g, 60 g, 90 g laminate tube
  Proposed: 3 g laminate tube sample; 30 g, 60 g, 90 g airless pumps
- Storage: 20 - 25° C (68 - 76° F), excursions permitted to 15 - 30° C (59 - 86° F)
- Container and Closure Systems: n/a

[1] Mena-Grillasca, C. Proprietary Review for Aczone (IND 054440). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); Insert Date As 2014AUG08. RCM No.: 2014-17244.

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 the proposed name, Aczone, is derived from the existing product, Aczone (dapsone) Gel, 5%. This proprietary name is comprised of a single word that contains the letters 'ac', which are used as a pharmaceutical abbreviation for oral products that are meant to be taken "before meals". However, since this is a topical product the letters 'ac' in the name are not misleading and cannot contribute to medication errors. Additionally, as noted above we did not retrieve any medication errors associated with name confusion with the name Aczone.

The Applicant is proposing a new 7.5% strength for their product line. The proposed 7.5% and the currently marketed 5% strengths share the same indication and dose; however, the frequency of administration differs (5% is applied twice daily vs. 7.5% is applied once daily). It is a common and accepted practice to have a product line with multiple formulations/dosage forms and strengths managed under one proprietary name. Therefore, given the precedent for using this naming convention, Aczone is an acceptable proprietary name for the 7.5% strength.

[1]USAN stem search conducted on June 25, 2015.

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