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APPLICATION NUMBER:

203567Orig1s000

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: March 26, 2014
Application Type and Number: NDA 203567
Product Name and Strength: Jublia (Efinaconazole) Topical Solution, 10%
Product Type: Single-ingredient Product
Rx or OTC: Rx
Applicant/Sponsor Name: Dow Pharmaceutical Sciences
Submission Date: February 4, 2014
Panorama #: 2014-16885
DMEPA Primary Reviewer: Carlos M Mena-Grillasca, RPh
DMEPA Team Leader: Lubna Merchant, MS, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Jublia, 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 for this proposed proprietary name.

1.1 REGULATORY HISTORY

The proposed proprietary name Jublia was found conditionally acceptable during first review cycle of the NDA in OSE review 2013-240, dated April 12, 2013.

1.2 PRODUCT INFORMATION

The following product information is provided in the 2/4/2014 proprietary name submission.

- Intended Pronunciation: Joob lee' ah
- Active Ingredient: Efinaconazole
- Indication of Use: Onychomycosis
- Route of Administration: Topical
- Dosage Form: Solution
- Strength: 10%
- Dose and Frequency: Apply to the affected toenail(s) once daily
- How Supplied: 4 ml and 8 mL bottles
- Storage: 25°C (77°F); excursions permitted to 15-30 (59-86°F)
- Container and Closure Systems: HDPE bottles containing (b) (4) inside plug with (b) (4) brush and (b) (4) cap

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 name¹.

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Jublia in their submission. 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.

2.2.3 FDA Name Simulation Studies

One hundred fifty-seven practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. Thirty-six participants interpreted the name correctly (outpatient n=4, voice n=6, inpatient n=26). A total of 103 participants misinterpreted the capital letter 'J'; 27 for an 'L' (outpatient n=21, inpatient n=6), 23 for an 'S' (outpatient n=21, voice n=2), 21 for a 'Ch' (voice n=21), 14 for a 'T' (outpatient n=1, inpatient n=13), 12 for a 'F' (outpatient n=7, inpatient n=5), and 6 for a 'G' (voice n=6). (Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, February, 18, 2014 e-mail, the Division of Dermatology and Dental Products (DDDP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of $\geq 50\%$ retrieved from our POCA search organized as highly similar, moderately similar or low similarity for further evaluation.

¹USAN stem search conducted on March 14, 2014.

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