

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**203567Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**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\*\*\***

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<b>Date of This Review:</b>	March 26, 2014
<b>Application Type and Number:</b>	NDA 203567
<b>Product Name and Strength:</b>	Jublia (Efinaconazole) Topical Solution, 10%
<b>Product Type:</b>	Single-ingredient Product
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	Dow Pharmaceutical Sciences
<b>Submission Date:</b>	February 4, 2014
<b>Panorama #:</b>	2014-16885
<b>DMEPA Primary Reviewer:</b>	Carlos M Mena-Grillasca, RPh
<b>DMEPA Team Leader:</b>	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 name<sup>1</sup>.

### **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.

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<sup>1</sup>USAN stem search conducted on March 14, 2014.

<b>Table 1. POCA Search Results</b>	<b>Number of Names</b>
Highly similar name pair: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	37
Low similarity name pair: combined match percentage score $\leq 49\%$	0

### ***2.2.6 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities***

We note that none of the product characteristics other than the package size changed from our previous review. However, we considered the worst case scenario by assuming a quantity of #1. Therefore, three names previously evaluated in OSE review 2013-240, dated April 12, 2013 will not be re-evaluated (Januvia, <sup>(b) (4)</sup>\*\*\*, and Jetrea).

Our analysis of the remaining 35 names contained in Table 1 determined that none of the names will pose a risk for confusion as described in Appendices C through E.

### ***2.2.7 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 March 19, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DDDP on March 25, 2014, they stated no additional concerns with the proposed proprietary name, Jublia.

## **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 Teena Thomas, OSE project manager, at 301-796-0549.

### **3.1 COMMENTS TO THE APPLICANT**

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

If any of the proposed product characteristics as stated in your February 4, 2014 submission are altered, 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. Phonetic and Orthographic Computer Analysis (POCA)**

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

#### **Drugs@FDA**

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States 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* and *generic drugs; therapeutic biological products, prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at [http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther\\_biological](http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological)).

(b) (4)

(b) (4) contains the names of prescription and many OTC drugs available in the United States. (b) (4) includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for (b) (4) (<http://www.nlm.nih.gov/research/umls/overview.html#>).

#### **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.

## 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.<sup>2</sup>

**\*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?

<sup>2</sup> National Coordinating Council for Medication Error Reporting and Prevention.  
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

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. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, (b) (4) and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score  $\geq 70\%$ .
- Moderately similar pair: combined match percentage score  $\geq 50\%$  to  $\leq 69\%$ .
- Low similarity: combined match percentage score  $\leq 49\%$ .

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. Based on our root cause analysis of post marketing experience errors, we find the expression of strength and dose, which is often located in close proximity to the drug name itself on prescriptions and medication orders, is an important factor in mitigating or potentiating confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion is limited (e.g., route, frequency, dosage form, etc.).

- For highly similar names, there is little that can mitigate a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of  $\geq 70$  percent are likely to be rejected by FDA. (See Table 3)
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics (e.g., route, frequency, dosage form, etc.) to

mitigate confusion may be limited when the strength or dose overlaps. FDA will review these names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4)

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist (See Table 5).

- c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name 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. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are 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 record their interpretations of the orders which are recorded electronically.

- d. 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.

**Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is  $\geq$  70%).**

Answer the questions in the checklist below. Affirmative answers to these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair do not share a common strength or dose (see Step 1 of the Moderately Similar Checklist).			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
<b>Y/N</b>	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	<b>Y/N</b>	Do the names have different number of syllables?
<b>Y/N</b>	Are the lengths of the names dissimilar* when scripted?  <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	<b>Y/N</b>	Do the names have different syllabic stresses?
<b>Y/N</b>	Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?	<b>Y/N</b>	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
<b>Y/N</b>	Is there different number or placement of cross-stroke or dotted letters present in the names?	<b>Y/N</b>	Across a range of dialects, are the names consistently pronounced differently?

Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

**Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is  $\geq 50\%$  to  $\leq 69\%$ ).**

Step 1	<p>Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths have a higher potential for confusion and should be evaluated further (see Step 2).</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>For any combination drug products, consider whether the strength or dose may be expressed using only one of the components.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> <li>○ Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa.</li> <li>○ Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with</li> </ul>
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	<p>moderate similarity.</p> <ul style="list-style-type: none"> <li>○ Similar sounding doses: 15 mg is similar in sound to 50 mg</li> </ul>	
<p>Step 2</p>	<p>Answer the questions in the checklist below. Affirmative answers to these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion between moderately similar names <b>with</b> overlapping or similar strengths or doses.</p>	
	<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names begin with different first letters?</li> </ul> <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> <li>• Are the lengths of the names dissimilar* when scripted?</li> </ul> <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> <li>• Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?</li> <li>• Is there different number or placement of cross-stroke or dotted letters present in the names?</li> </ul>	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names have different number of syllables?</li> <li>• Do the names have different syllabic stresses?</li> <li>• Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?</li> <li>• Across a range of dialects, are the names consistently pronounced differently?</li> </ul>

	<ul style="list-style-type: none"> <li>• Do the infixes of the name appear dissimilar when scripted?</li> <li>• Do the suffixes of the names appear dissimilar when scripted?</li> </ul>	
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**Table 5: Low Similarity Name Pair Checklist (i.e., combined score is  $\leq 49\%$ ).**

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where there are data that suggest a name with low similarity might be vulnerable to confusion with your proposed name (for example, misinterpretation of the proposed name as a marketed product in a prescription simulation study). In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

**Appendix B:** Prescription Simulation Samples and Results

**Figure 1. Jublia Study (Conducted on February 14, 2014)**

Handwritten Requisition Medication Order	Verbal Prescription
<p>Medication <span style="float: right;">Order:</span> <i>Jublia apply to affected area once daily</i></p>	<p>Jublia UAD</p>
<p><u>Outpatient Prescription:</u>  <i>Jublia #1 UAD</i></p>	<p>Qty. 1</p>

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

As of Date 3/17/2014

275 People Received Study

157 People Responded

**Study Name: Jublia**

Total	56	50	51	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
CHABLIA	0	6	0	6
CHABLIYA	0	1	0	1
CHEBLEA	0	1	0	1
CHEBLIA	0	1	0	1
CHIBLEA	0	6	0	6
CHIBLEAH	0	1	0	1
CHIBLIA	0	4	0	4
CHIPLEA	0	1	0	1
DON'T KNOW	1	0	0	1
FABBIA	1	0	0	1
FABLIA	4	0	0	4
FABLIA #1	1	0	0	1
FEIBLIA	0	0	1	1
FUBLIA	1	0	3	4
FUBLIN	0	0	1	1
GIBLEA	0	1	0	1
GIBLEEA	0	1	0	1
GIBLIA	0	3	0	3
GYBLIA	0	1	0	1

JABBIA	1	0	0	1
JABELIA	0	1	0	1
JABLEA	0	1	0	1
JABLIA	0	3	0	3
JEBLIA	0	2	0	2
JIBLEYA	0	1	0	1
JIBLIA	0	3	0	3
JUBLIA	4	6	26	36
JULBIA	0	0	1	1
JUVLIA	0	1	0	1
LABLIA	6	0	0	6
LUBBIA	1	0	0	1
LUBLIA	14	0	6	20
SABBIA	1	0	0	1
SABLIA	9	0	0	9
SHEBLIA	0	1	0	1
SUBLEA	0	1	0	1
SUBLIA	11	0	0	11
TABLIA	1	0	1	2
TIBLIA	0	0	1	1
TUBLIA	0	0	11	11
UNKNOWN	0	1	0	1
XUBLIA	0	1	0	1
ZUBLIA	0	1	0	1

**Appendix C:** Moderately Similar Names (i.e., combined POCA score is  $\geq 50\%$  to  $\leq 69\%$ ) with no overlap or numerical similarity in Strength and/or Dose

No.	Proposed Name	POCA Score (%)
1.	Enjuvia	52

**Appendix D:** Moderately Similar Names (i.e., combined POCA score is  $\geq 50\%$  to  $\leq 69\%$ ) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Jublia Strength(s): 10% Usual Dose: Apply to affected toenail(s) once daily	POCA Score (%)	Prevention of Failure Mode
			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
2.	Cimzia	50	<b>Dose:</b> xx mg vs. apply to affected toenail(s) or UAD <b>Orthographic:</b> The capital letters and the infix of this name pair have sufficient orthographic differences
3.	Dulera	50	<b>Orthographic:</b> The infixes of this name pair have sufficient orthographic differences.
4.	Gynol II (otc)	50	<b>Dose:</b> 1 applicatorful intravaginally vs. apply to affected toenail(s) or UAD <b>Orthographic:</b> The infixes and suffixes of this name pair have sufficient orthographic differences. <b>Phonetic:</b> The names have different number of syllables (3 vs. 2). The second and third syllables in Jublia sound different than the second syllable in Gynol.
5.	Jenloga	58	<b>Dose:</b> 1 tablet or xx mg vs. apply to affected toenail(s) or UAD <b>Orthographic:</b> The infixes and suffixes of this name pair have sufficient orthographic differences. <b>Phonetic:</b> The second and third syllables in Jublia sound different than the second syllable in Jenloga.

No.	Proposed name: Jublia Strength(s): 10% Usual Dose: Apply to affected toenail(s) once daily	POCA Score (%)	Prevention of Failure Mode  In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
6.	Junel 1/20 Junel 1.5/30	52	<b>Strength:</b> Jublia is a single strength product vs. Junel is available in two strength with no overlapping strengths between the products  <b>Orthographic:</b> The infixes and suffixes of this name pair have sufficient orthographic differences.
7.	Quflora	52	<b>Dose:</b> 1 tablet or xx mg vs. apply to affected toenail(s) or UAD  <b>Orthographic:</b> The capital letters and the suffixes of this name pair have sufficient orthographic differences.
8.	(b) (4) ***	54	<b>Orthographic:</b> The suffixes of this name pair have sufficient orthographic differences.
9.	Sublimaze	52	<b>Dose:</b> xx mg or xx mcg or xx mL vs. apply to affected toenail(s) or UAD  <b>Orthographic:</b> The suffixes of this name pair have sufficient orthographic differences.
10.	Suclear	54	<b>Orthographic:</b> The infixes of this name pair have sufficient orthographic differences.
11.	Tabloid	53	<b>Dose:</b> xx mg or xx mcg or xx mL vs. apply to affected toenail(s) or UAD  <b>Orthographic:</b> The suffixes of this name pair have sufficient orthographic differences.
12.	Uro Blue	50	<b>Dose:</b> xx tablets vs. apply to affected toenail(s) or UAD  <b>Orthographic:</b> The suffixes of this name pair have sufficient orthographic differences.

**Appendix E:** Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
13.	(b) (4) ***	50	This is a secondary proposed proprietary name for IND (b) (4). The proposed name (b) (4) was found conditionally acceptable in OSE review (b) (4), dated (b) (4).
14.	(b) (4) ***	65	This is a secondary proposed proprietary name for NDA (b) (4) and the product was approved under the proprietary name (b) (4).
15.	(b) (4) ***	52	Proposed name for NDA (b) (4) withdrawn by the applicant on (b) (4). The product was approved under the proprietary name (b) (4).
16.	(b) (4) ***	56	This is a secondary proposed proprietary name for IND (b) (4). The product was approved under the proprietary name (b) (4) (NDA (b) (4)).
17.	(b) (4) ***	60	Proposed name for IND (b) (4) withdrawn by the applicant. The secondary name (b) (4) was found conditionally acceptable in OSE review (b) (4), dated (b) (4). IND (b) (4) is inactive as of (b) (4).
18.	(b) (4) ***	51	Proposed name for ANDA (b) (4) withdrawn by the applicant on (b) (4). The product was approved under the proprietary name (b) (4).
19.	(b) (4) ***	56	Proposed name for IND (b) (4) withdrawn by the applicant. The secondary name (b) (4)k was found conditionally acceptable in OSE review (b) (4), dated (b) (4).
20.	(b) (4) ***	66	Proposed name for NDA (b) (4) withdrawn by the applicant on (b) (4). The product was approved under the proprietary name (b) (4).
21.	(b) (4) ***	52	Proposed name found unacceptable for ANDA (b) (4). The product was approved under the generic name.

No.	Name	POCA Score (%)	Failure preventions
22.	(b) (4) ***	54	This is a secondary proposed proprietary name for NDA (b) (4). The product was approved under the proprietary name (b) (4).
23.	(b) (4) ***	60	Proposed proprietary name found unacceptable for NDA (b) (4) by OPDP in OSE review (b) (4), dated (b) (4). The product was approved under the proprietary name (b) (4).
24.	Jublia	100	Proposed proprietary name subject of this review.
25.	(b) (4) **	50	Proposed proprietary name found unacceptable for IND (b) (4). The secondary name (b) (4) was found conditionally acceptable in OSE review (b) (4), dated (b) (4).
26.	(b) (4) ***	64	Proposed proprietary name found unacceptable for IND (b) (4) by OPDP in OSE review (b) (4), dated (b) (4).
27.	(b) (4) ***	54	Name identified in 'Name entered by safety evaluator' database. Unable to find this name in any internal database.
28.	(b) (4) ***	52	Proposed proprietary name for IND (b) (4) withdrawn by the applicant.
29.	(b) (4)	55	Name identified in (b) (4) database. Unable to find product characteristics in commonly used drug databases.
30.	Vagilia	52	Name identified in Drugs@FDA database. Unable to find product characteristics in commonly used drug databases.
31.	(b) (4) ***	58	This is a secondary proposed proprietary name for NDA (b) (4) and the product was approved under the proprietary name (b) (4).
32.	(b) (4) ***	50	Proposed proprietary name found unacceptable for NDA (b) (4) by OPDP in OSE review (b) (4), dated (b) (4). The product was approved under the proprietary name (b) (4).

No.	Name	POCA Score (%)	Failure preventions
33.	(b) (4) ***	51	Proposed proprietary name found unacceptable for NDA (b) (4) in OSE review (b) (4), dated (b) (4). The product was approved under the proprietary name (b) (4)
34.	(b) (4) ***	56	This is a secondary proposed proprietary name for NDA (b) (4) and the product was approved under the proprietary name (b) (4)

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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CARLOS M MENA-GRILLASCA  
03/26/2014

LUBNA A MERCHANT  
03/26/2014

**Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Surveillance and Epidemiology  
Office of Medication Error Prevention and Risk Management**

**Proprietary Name Review**

Date: April 12, 2013

Reviewer: Carlos M Mena-Grillasca, RPh, Safety Evaluator  
Division of Medication Error Prevention and Analysis

Team Leader: Lubna Merchant, MS, PharmD  
Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, RPh  
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Jublia (Efinaconazole)  
Topical Solution, 10%

Application Type/Number: NDA 203567

Applicant/Sponsor: Dow Pharmaceutical Sciences, Inc.

OSE RCM #: 2013-240

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

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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.

### 1.1 REGULATORY HISTORY

The Sponsor had originally submitted the proposed name (b) (4) to IND 077732. The proposed name was found to be misleading by the Office of Prescription Drug Promotion (OPDP). Thus, DMEPA found the name unacceptable under RCM # 2012-576, dated April 12, 2012. Subsequently, the Applicant submitted the proposed name (b) (4) to NDA 203567, which was found unacceptable under RCM # 2012-1966, dated November 8, 2012. Finally, the Applicant submitted the proposed name Jublia to NDA 203567 for evaluation.

### 1.2 PRODUCT INFORMATION

The following product information is provided in the January 17, 2013 proprietary name submission.

- Active Ingredient: Efinaconazole
- Indication of Use: Treatment of onychomycosis
- Route of Administration: Topical
- Dosage Form: Solution
- Strength: 10 %
- Dose and frequency: Apply to the affected area once daily
- How Supplied: Trade size is a (b) (4) in a 10 mL HDPE bottle with brush/cap assembly. (b) (4)
- Storage: 25°C (77°F); excursions permitted to 15°-30°C (59°-86 °F)
- Intended pronunciation: Joob lee' ah

## 2 RESULTS

The following sections provide the 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 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

The January 30, 2013 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

### 2.2.2 Components of the Proposed Proprietary Name

The Applicant indicates in their submission that the name was derived from a blank canvas.

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

Eighty-one practitioners participated in DMEPA’s prescription studies. The interpretations did not overlap with any currently marketed products nor did they look or sound similar to any marketed products or products pending approval. Fifty-nine interpreted the name correctly (inpatient n=25; outpatient n=18; voice n=16). Seven participants in the outpatient study misinterpreted the ‘li’ for an ‘i’, omitting the letter ‘l’. Five participants in the inpatient study misinterpreted the ‘a’ for an ‘o’. Three participants in the voice study misinterpreted the letter ‘a’ for an ‘o’. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

### 2.2.4 Comments from Other Review Disciplines at Initial Stage of Review

In response to the OSE, January 30, 2013 e-mail, the Division of Dermatology and Dental Products (DDDP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

### 2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Jublia. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Jublia, identified by the primary reviewer, the Expert Panel Discussion (EPD), and External Study.

**Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, and External Study)**

<b>Look Similar</b>					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Atelvia	FDA	(b) (4)***	FDA	Jetrea	FDA
Folbee	FDA	Jablee	FDA	Jinteli	FDA
Folbic	FDA	Jakafi	FDA	Juxtapid	FDA
Gildess	FDA	Jalyn	FDA	Lialda	FDA
<b>Look and Sound Similar</b>					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Januvia	FDA, External Study	(b) (4)***	FDA	Jublia***	FDA

Our analysis of the 15 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined none of the names will pose a risk of confusion as described in Appendices D and E.

### ***2.2.6 Communication of DMEPA's Final Decision to Other Disciplines***

DMEPA communicated our findings to the Division of Dermatology and Dental Products via e-mail on March 15, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Dermatology and Dental Products on March 22, 2013, they stated no additional concerns with the proposed proprietary name, Jublia.

## **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, Jublia, and have concluded that this name is acceptable.

The proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. The results are subject to change. If any of the proposed product characteristics as stated in your January 17, 2013 submission are altered, the name must be resubmitted for review.

## 4 REFERENCES

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

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

### 2. *Phonetic and Orthographic Computer Analysis (POCA)*

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

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

Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

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

USPTO provides information regarding patent and trademarks.

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

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

### 9. *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.

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

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

**11. *Access Medicine* ([www.accessmedicine.com](http://www.accessmedicine.com))**

Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

**12. *USAN Stems* (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)**

USAN Stems List contains all the recognized USAN stems.

**13. *Red Book* ([www.thomsonhc.com/home/dispatch](http://www.thomsonhc.com/home/dispatch))**

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

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

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

**15. *Medical Abbreviations* ([www.medilexicon.com](http://www.medilexicon.com))**

Medical Abbreviations dictionary contains commonly used medical abbreviations and their definitions.

**16. *CVS/Pharmacy* ([www.CVS.com](http://www.CVS.com))**

This database contains commonly used over the counter products not usually identified in other databases.

**17. *Walgreens* ([www.walgreens.com](http://www.walgreens.com))**

This database contains commonly used over the counter products not usually identified in other databases.

**18. *Rx List* ([www.rxlist.com](http://www.rxlist.com))**

RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

**19. *Dogpile* ([www.dogpile.com](http://www.dogpile.com))**

Dogpile is a [Metasearch](#) engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

**20. *Natural Standard* (<http://www.naturalstandard.com>)**

Natural Standard is a resource that aggregates and synthesizes data on complementary and alternative medicine.

## APPENDICES

### Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP 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 provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, 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.). 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>1</sup>

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. 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. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

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. DMEPA considers the product characteristics associated with the proposed product 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. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.<sup>2</sup>

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

<sup>2</sup> Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA 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. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor’s intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing 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).

**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/Similar shape 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>
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>

Lastly, DMEPA 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 searches 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. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses 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, DMEPA reviews 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. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

### **2. Expert Panel Discussion**

DMEPA gathers CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). 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 database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional 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. FDA Prescription Simulation Studies**

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name 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. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are 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 record their interpretations of the orders which are recorded electronically.

#### 4. 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.

#### 5. 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, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their 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>3</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 1.2 of this review. 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? And are there any components of the name that may function as a source of error beyond sound/look-alike?”***

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 or because of some other component of the name. 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:

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<sup>3</sup> Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

***“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.

Moreover, 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 Overall Risk Assessment:

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’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)].
- 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 but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

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 generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for 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 Sponsor 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/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading 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 preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

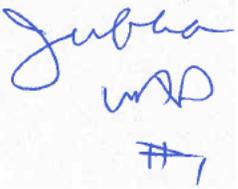
Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Sponsor 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 Sponsors’ 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.

**Appendix B:** Letters with Possible Orthographic or Phonetic Misinterpretation

<b>Letters in Name, Jublia</b>	<b>Scripted May Appear as</b>	<b>Spoken May Be Interpreted as</b>
Capital ‘J’	D, F, G, I, L, S, T, Z	--
Lower case ‘j’	f, g, p, q	--
Lower case ‘u’	a, n, y, v, w, Any Vowel	Any vowel
Lower case ‘b’	l, h, k, li	p
Lower case ‘l’	f, t	--
Lower case ‘i’	e, l	Any vowel, y
Lower case ‘a’	e, o, u, n, v	Any vowel
<b>Letter Strings</b>		
bl	ld	--

**Appendix C: Prescription Simulation Samples and Results**

**Figure 1. Jublia Study (Conducted on February 4, 2013)**

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> 	<p>Jublia Use as Directed Disp. #1</p>
<p><u>Outpatient Prescription:</u></p> 	

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

As of Date 3/11/2013

192 People Received Study  
81 People Responded

Study Name: Jublia

INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
JUBBIA	1	0	0	1
JUBIA	0	0	7	7
JUBILA	0	1	0	1
JUBLEA	0	1	0	1
JUBLIA	25	16	18	59
JUBLIEA	0	1	0	1
JUBLIO	5	0	0	5
JUBLIS	1	0	0	1
JUBRIA	0	0	1	1
JUPLEA	0	1	0	1
JUPLIA	0	2	0	2
TUBLIA	0	1	0	1

**Appendix D:** Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Proprietary Name	Active Ingredient	Similarity to Jublia	Failure preventions
1.	<b>Gildess</b>	Norethindrone and Ethinyl Estradiol	Look	Family name for a product line of oral contraceptive products (i.e. Gildess 1/20, Gildess 1.5/30, Gildess Fe 1/20, Gildess Fe 1.5/30). A prescription would need to include specific information to identify the product. (b) (4)
2.				
3.	<b>Jablee</b>	n/a	Look	Name found in USPTO database for pharmaceutical preparations. However, this name is not available in any major drug reference and specific product information is not available. (b) (4)
4.				
5.	<b>Jublia</b>	Efinaconazole	Look and Sound	Proposed proprietary name under review.
6.	<b>Juxtapid</b>	Lomitapide mesylate	Look	Name lack significant orthographic similarities.

**Appendix E:** Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

No.	<p><b>Proposed name:</b> Jublia  <b>Dosage Form:</b>                      Topical Solution  <b>Strength:</b> 10%  <b>Usual Dose:</b>                      Apply topically to affected area once daily.</p>	<p><b>Failure Mode:</b>  <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>   <b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b>   <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
7.	<p><b>Atelvia</b>                      (Risedronate Sodium)                      Delayed-release Tablets, 35 mg   <u>Dosage:</u>                      Take one tablet in the morning immediately following breakfast with at least 4 ounces of plain water. Do not lie down for 30 minutes after taking Atelvia.</p>	<p><u>Orthographic:</u>                      Both names have a similar number of letters (7 vs. 6). The capital letter 'A' may look like the capital letter 'J' when scripted. Both names have two up stroke letters ('t' and 'l' vs. 'b' and 'l') and end in the same letter string 'ia'.   <u>Strength:</u>                      Both are single strength products and thus no strength is required on a prescription.   <u>Frequency of administration:</u>                      Both products are dosed once daily.</p>	<p><u>Orthographic:</u>                      The middle portions of the names look different when scripted ('te' vs. 'ub').   <u>Dose:</u>                      Apply to affected area or UAD vs. 1 tablet</p>

No.	<b>Proposed name:</b> Jublia <b>Dosage Form:</b> Topical Solution <b>Strength:</b> 10% <b>Usual Dose:</b> Apply topically to affected area once daily.	<b>Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
8.	<b>Folbee</b> (Cyanocobalamin, Folic Acid, and Pyridoxine) Tablets, 1 mg/2.5 mg/25 mg  <u>Dosage:</u> 1 tablet orally daily	<u>Orthographic:</u> Both names have the same number of letters. The capital letter 'F' may look like the capital letter 'J' when scripted. Both names have two up stroke letters ('l' and 'b' vs. 'b' and 'l'). The ending letter strings 'ee' vs. 'ia' may look similar when scripted.  <u>Strength:</u> Both are single strength products and thus no strength is required on a prescription.  <u>Frequency of administration:</u> Both products are dosed once daily.	<u>Orthographic:</u> Although both names share the same up stroke letters, the inverted positioning help differentiate the names.  <u>Dose:</u> Apply to affected area or UAD vs. 1 tablet

No.	<b>Proposed name:</b> Jublia <b>Dosage Form:</b> Topical Solution <b>Strength:</b> 10% <b>Usual Dose:</b> Apply topically to affected area once daily.	<b>Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
9.	<b>Folbic</b> (Cyanocobalamin, Folic Acid, and Pyridoxine) Tablets, 2 mg/2.5 mg/25 mg  <u>Dosage:</u> 1 tablet orally daily	<u>Orthographic:</u> Both names have the same number of letters. The capital letter 'F' may look like the capital letter 'J' when scripted. Both names have two up stroke letters ('l' and 'b' vs. 'b' and 'l'). The ending letter strings 'ic' vs. 'ia' may look similar when scripted.  <u>Strength:</u> Both are single strength products and thus no strength is required on a prescription.  <u>Frequency of administration:</u> Both products are dosed once daily.	<u>Orthographic:</u> Although both names share the same up stroke letters, the inverted positioning help differentiate the names.  <u>Dose:</u> Apply to affected area or UAD vs. 1 tablet

No.	<b>Proposed name:</b> Jublia <b>Dosage Form:</b> Topical Solution <b>Strength:</b> 10% <b>Usual Dose:</b> Apply topically to affected area once daily.	<b>Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
10.	<p><b>Jakafi</b> (Ruxolitinib) Tablets, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg</p> <p><u>Dosage:</u></p> <p>The starting dose of Jakafi is 20 mg given orally twice daily for patients with a platelet count greater than 200 X 10<sup>9</sup>/L, and 15 mg twice daily for patients with a platelet count between 100 X 10<sup>9</sup>/L and 200 X 10<sup>9</sup>/L.</p> <p>Perform a complete blood count before initiating therapy with Jakafi. Monitor complete blood counts every 2 to 4 weeks until doses are stabilized, and then as clinically indicated. Modify dose for thrombocytopenia.</p> <p>Increase dose based on response and as recommended to a maximum of 25 mg twice daily. Discontinue after 6 months if no spleen reduction or symptom improvement.</p>	<p><u>Orthographic:</u></p> <p>Both names have the same number of letters and begin with the capital letter 'J'. The letter 'a' may look like the corresponding letter 'u' when scripted. Both names have two up stroke letters in similar positions.</p> <p><u>Strength:</u></p> <p>Although Jublia is a single strength product, which may be omitted in a prescription, both products have an overlapping strength (10 mg vs. 10%).</p>	<p><u>Orthographic:</u></p> <p>The letter string 'afi' may look different than the letter string 'lia' and help differentiate the names when scripted.</p> <p><u>Strength, dose and units:</u></p> <p>Jublia is a single strength product vs. Jakafi is available in multiple strengths, which would be required on a prescription. Although there is an overlap with the 10 mg Jakafi and Jublia 10% the dose and units would differentiate the products (Apply to affected areas or UAD vs. 10 mg or 1 tab).</p>

No.	<b>Proposed name:</b> Jublia <b>Dosage Form:</b> Topical Solution <b>Strength:</b> 10% <b>Usual Dose:</b> Apply topically to affected area once daily.	<b>Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
11.	<b>Jalyn</b> (Dutasteride and Tamsulosin Hydrochloride) Capsules, 0.5 mg/0.4 mg  <u>Dosage:</u> One capsule orally daily approximately 30 minutes after the same meal each day	<u>Orthographic:</u> Both names have similar number of letters (5 vs. 6). Both names begin with the capital letter 'J'. The letter 'a' may look like the corresponding letter 'u' when scripted. Both names have an up stroke letters 'l' in a similar position.  <u>Strength:</u> Both are single strength products and thus no strength is required on a prescription.  <u>Frequency of administration:</u> Both products are dosed once daily.	<u>Orthographic:</u> Jublia has an additional up stroke letter 'b' that is not present in Jalyn. Jalyn contains a down stroke letter 'y' that is not present in Jublia. These differences give the names a different shape and may help differentiate them when scripted.  <u>Dose:</u> Apply to affected areas or UAD vs. xx mg or 1 cap

No.	<b>Proposed name:</b> Jublia <b>Dosage Form:</b> Topical Solution <b>Strength:</b> 10% <b>Usual Dose:</b> Apply topically to affected area once daily.	<b>Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
12.	<b>Januvia</b> (Sitagliptin) Tablets, 25 mg, 50 mg, 100 mg  <b>Dosage:</b> 100 mg orally once daily. Dosage adjustment for renally impaired patients to 25 mg or 50 mg orally once daily.	<u>Orthographic:</u> Both names have similar number of letters (7 vs. 6). Both names begin with the capital letter 'J'. The letter 'a' may look like the corresponding letter 'u' when scripted. Both names end with the letter string 'ia'.  <u>Phonetic:</u> First syllable: Both names begin with a 'j' sound.  Last two syllables in the names are similar or the same ('vee-ah' in Januvia vs. 'lee-ah' in Jublia).  <u>Strength:</u> Although Jublia is a single strength product, which may be omitted in a prescription, both products have numerical similarity in strength (100 mg vs. 10%).  <u>Frequency of administration:</u> Both products are dosed once daily.	<u>Orthographic:</u> Jublia contains two upstroke letters 'bl' that are not present in Januvia, which gives the names a different shape when scripted.  <u>Phonetic:</u> Januvia has four syllables vs. three syllables in Jublia. The additional syllable in Januvia (sounding 'new'), provides phonetic differentiation between the names  <u>Strength, dose and units:</u> Jublia is a single strength product vs. Januvia is available in multiple strengths, which would be required on a prescription. Although there is numerical similarity with one strength the dose and units would further differentiate the products (Apply to affected areas or UAD vs. 100 mg or 1 tab).

No.	<b>Proposed name:</b> Jublia <b>Dosage Form:</b> Topical Solution <b>Strength:</b> 10% <b>Usual Dose:</b> Apply topically to affected area once daily.	<b>Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
13.	<b>Jetrea</b> (Ocriplasmin) Injection, 2.5 mg/mL  <u>Dosage:</u> The recommended dose is 0.125 mg (0.1 mL of the diluted solution) administered by intravitreal injection to the affected eye once as a single dose.	<u>Orthographic:</u> Both names have the same number of letters. Both names begin with the capital letter 'J', have an upstroke in the same position ('t' vs. 'l'), and share the ending letter 'a'.  <u>Strength:</u> Both are single strength products and thus no strength is required on a prescription.	<u>Orthographic:</u> Jublia contains an additional upstroke letter that are not present in Jetrea, which gives the names a different shape when scripted.  <u>Dose:</u> Apply to affected areas or UAD vs. xx mg or xx mL  <u>Frequency and route of administration:</u> Once daily topical application vs. single dose by intravitreal injection

No.	<b>Proposed name:</b> Jublia <b>Dosage Form:</b> Topical Solution <b>Strength:</b> 10% <b>Usual Dose:</b> Apply topically to affected area once daily.	<b>Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
14.	<b>Jinteli</b> (Norethindrone Acetate and Ethinyl Estradiol) Tablets, 1 mg/5 mcg  <b>Dosage:</b> One tablet orally daily	<u>Orthographic:</u> Both names have similar number of letters (7 vs. 6). Both names begin with the capital letter 'J'. The letter string 'in' may look like the corresponding letter 'u' when scripted. Both names contain two up strokes  <u>Strength:</u> Both are single strength products and thus no strength is required on a prescription.  <u>Frequency of administration:</u> Both products are dosed once daily.	<u>Orthographic:</u> The position of the upstrokes letters ('Jinteli' vs. 'Jublia') give the names a different shape when scripted. The up stroke letters in Jinteli are separated by the letter 'e' vs. no separation between the up strokes letters in Jublia.  <u>Dose:</u> Apply to affected areas or UAD vs. xx mg

No.	<b>Proposed name:</b> Jublia <b>Dosage Form:</b> Topical Solution <b>Strength:</b> 10% <b>Usual Dose:</b> Apply topically to affected area once daily.	<b>Failure Mode:</b> <b>Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
15.	<b>Lialda</b> (Mesalamine) Delayed-release Tablets, 1.2 grams  <b>Dosage:</b> Two to four 1.2 g tablets taken once daily with food.	<u>Orthographic:</u> Both names have the same number of letters. The capital letter 'L' may look like the capital letter 'J' when scripted. Both names have two up strokes letters next to each other ('ld' vs. 'bl') and end with the letter 'a'.  <u>Strength:</u> Both are single strength products and thus no strength is required on a prescription.  <u>Frequency of administration:</u> Both products are dosed once daily.	<u>Orthographic:</u> Lialda has two letters preceding the upstrokes ('ia') vs. Jublia only has one letter preceding the upstrokes ('u').  <u>Dose:</u> Apply to affected areas or UAD vs. 2 to 4 tablets

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LUBNA A MERCHANT on behalf of CARLOS M MENA-GRILLASCA  
04/12/2013

LUBNA A MERCHANT  
04/12/2013

CAROL A HOLQUIST  
04/12/2013

**Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Surveillance and Epidemiology  
Office of Medication Error Prevention and Risk Management**

**Proprietary Name Review**

Date: November 8, 2012

Reviewer: Carlos M Mena-Grillasca, RPh, Safety Evaluator  
Division of Medication Error Prevention and Analysis

Team Leader: Lubna Merchant, MS, PharmD  
Division of Medication Error Prevention and Analysis

Division Deputy Director: Kellie Taylor, PharmD, MPH  
Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, RPh  
Division of Medication Error Prevention and Analysis

Drug Name and Strength: (b) (4) (Efinaconazole)  
Topical Solution, 10%

Application Type/Number: NDA 203567

Applicant/Sponsor: Dow Pharmaceutical Sciences, Inc.

OSE RCM #: 2012-1996

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