CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208144Orig1s000

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:	December 20, 2017
Application Type and Number:	NDA 208144
Product Name and Strength:	Lumify (Brimonidine Tartrate) Ophthalmic Solution, 0.025%
Product Type:	Single-Ingredient Product
Rx or OTC:	OTC
Applicant/Sponsor Name:	Bausch & Lomb Inc.
Panorama #:	2017-19772214
DMEPA Safety Evaluator:	Grace P. Jones, PharmD, BCPS
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS
DMEPA Deputy Director (Acting):	Danielle Harris, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Lumify, from a safety and misbranding 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

DMEPA previously found the proposed proprietary name, Luminesse***, acceptable under IND 108524 on February 9, 2015 and NDA 208144 on May 8, 2015.[a,b] NDA 208144 received a Refuse to File on May 29, 2015.

After NDA 208144 resubmission, the Applicant submitted the proposed proprietary name, Luminesse***, for our review. DMEPA found the proposed proprietary name Luminesse*** conditionally acceptable on May 3, 2017.[c] However, the review team later on identified safety concerns with the proposed proprietary name, Luminesse***, and communicated these concerns to the Applicant via teleconference on November 7, 2017. The Applicant subsequently withdrew the proposed proprietary name, Luminesse***, on November 14, 2017 and submitted a new proposed proprietary name, (b) (4) ***, for review on November 16, 2017.

Upon review of the proposed proprietary name, (b) (4) ***, we determined that the proposed proprietary name is similar in spelling and pronunciation, and has orthographic and phonetic similarities to the proprietary name, (b) (4). Thus, we communicated these findings to the Applicant via teleconference on December 18, 2017.[d]

The Applicant withdrew (b) (4) *** and submitted the name, Lumify, for review on December 19, 2017.

1.2 PRODUCT INFORMATION

The following product information is provided in the December 19, 2017 proprietary name submission.

- Intended Pronunciation: Loom-i-fy
- Active Ingredient: Brimonidine tartrate

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[a] Taylor, K. Proprietary Name Review for Luminesse (IND 108524). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 February 9. Panorama No: 2014-26139.

[b] Bridges, T. Proprietary Name Review for Luminesse (NDA 208144). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 MAY 8. Panorama No: 2014-215952.

[c] Harris, D. and Bridges, T. Proprietary Name Review for Luminesse (NDA 208144). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 MAY 3. Panorama No: 2017-13451512.

[d] Harris, S. General Advice Letter/Teleconference meeting minutes for (b) (4) (NDA 208144) Bridgewater (NJ): Bausch & Lomb Inc.; 2017 DEC 19.

- Indication of Use: Relieves redness of the eye due to minor eye irritations
- Route of Administration: Ophthalmic
- Dosage Form: Solution
- Strength: 0.025%
- Dose and Frequency: Adults and children 5 years and older: instill 1 drop in the affected eye(s) every 6-8 hours, no more than four times daily.
- How Supplied: Trade and sample bottles in 2.5 ml and 7.5 ml (in 10 ml bottles)
- Storage: Store at 15°-25°C (59°-77°F); (b) (4) (b) (4); discard remaining product 120 days after opening

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

Based on email communication dated November 30, 2017, the Division of Nonprescription Drug Products (DNDP) had no concerns regarding the proposed proprietary name Lumify. DMEPA concurs with DNDP's assessment and concludes that the proposed proprietary name does not misbrand the proposed product.

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[e].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Lumify, 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 and thirty practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

[e] USAN stem search conducted on December 1, 2017.

2.2.4 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[f] identified 25 names with a combined phonetic and orthographic score of **≥**55% or an individual phonetic or orthographic score **≥**70%**.** These names are included in Table 1 below.

2.2.5 Names with Strength Overlap and Potential Orthographic, Spelling, and Phonetic Similarities

The proposed product, Lumify will be available in 0.025% strength. Since this is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify names with strength overlap. Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic, and phonetic differences are listed in Appendix I.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and eDRLS search. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	25
Low similarity name pair: combined match percentage score ≤54%	0

2.2.7 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 25 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Nonprescription Drug Products (DNDP) via e-mail on December 18, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNDP on

[f] POCA search conducted on November 16, 2017 in version 4.2.

December 19, 2017, they stated no additional concerns with the proposed proprietary name, Lumify.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Abiola Olagundoye-Alawode, OSE project manager, at 301-796-3982.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 19, 2017 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. ***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).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm 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 RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/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.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP 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. [g]

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).

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

Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

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, CernerRxNorm, and names in the review pipeline using a 55% 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 ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

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. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[h]. We evaluate all moderately similar names retrieved from POCA to

[h] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary

identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.

- Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information 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 to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such 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 (See Table 5) 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.

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 ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of 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 does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	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?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?

Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	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 ≥55% to ≤69%).

Step 1	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 or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • 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. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

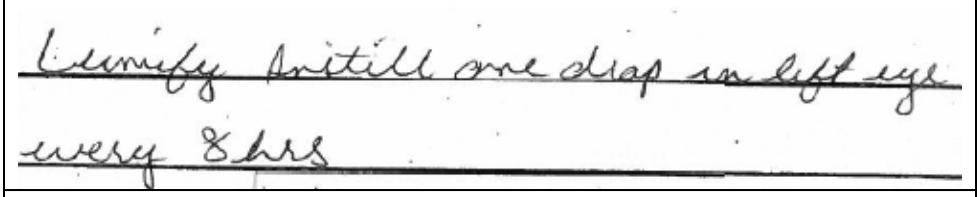
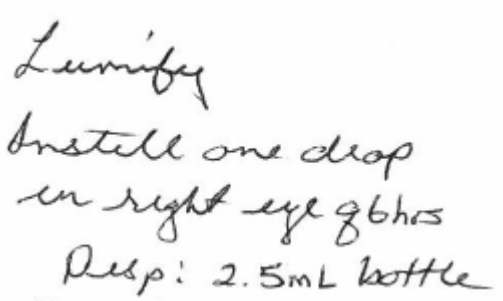
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • 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? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity 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.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Lumify Study (Conducted on November 17, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Lumify Instill one drop in right eye every 6 hours Dispense: 2.5 mL bottle
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

295 People Received Study
130 People Responded

Study Name: Lumify

Total	**47**	**45**	**38**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
LEIMIFY	0	0	1	1
LERNIFY	0	0	1	1
LUMAFI	0	4	0	4
LUMAFY	0	4	0	4
LUMASAI	0	1	0	1
LUMAZIE	0	1	0	1
LUMICIDE	0	1	0	1
LUMIFI	0	1	0	1
LUMIFY	47	22	28	97
LUMIFY INSTILL	0	0	1	1
LUMISAI	0	1	0	1
LUMIS-EYE	0	1	0	1
LUMISI	0	2	0	2
LUMISIE	0	1	0	1
LUMISIGH	0	1	0	1
LUMITHY	0	2	0	2
LUMIZEYE	0	1	0	1
LUMIZI	0	1	0	1
LUMIZIDE	0	1	0	1
LUNIEFY	0	0	1	1
LUNIFY	0	0	6	6

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	Proposed name: Lumify Established name: Brimonidine Tartrate Dosage form: Ophthalmic Solution Strength(s): 0.025% Usual Dose: 1 drop in the affected eye(s), every 6-8 hours	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
	N/A		

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Lamisil	60
2.	(b) (4)***	67
3.	Lunesta	56

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name: Lumify** **Established name: Brimonidine Tartrate** **Dosage form: Ophthalmic Solution** **Strength(s): 0.025%** **Usual Dose: 1 drop in the affected eye(s), every 6-8 hours**	**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**
4.	Ilumya***	63	This name pair has sufficient orthographic and phonetic differences.
5.	Lomotil	56	The suffixes of this name pair have sufficient orthographic differences and the name pair has sufficient phonetic differences.
6.	lumason	62	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
7.	lumicain	56	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
8.	lumigan	60	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
9.	luminal	60	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
10.	lumizyme	66	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different. The products also have differing product characteristics that minimize the risk for medication errors: Dosage form: ophthalmic solution vs. for injection Route: ophthalmic vs. intravenous infusion Strength: 0.025% vs. 50 mg Dose: 1 drop in affected eye Q6-8H or UAD vs. 20 mg/kg every 2 weeks Indication: relieves redness of the eye due to minor eye irritations vs. Pompe (acid α-glucosidase enzyme deficiency)

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
	N/A	

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

No.	Name	POCA Score (%)	Failure preventions
11.	(b) (4) ***	57	Name found unacceptable under OSE RCM # (b) (4). Sponsor has yet to submit a new name.
12.	Flumist 2015-2016	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	Lidifen	56	International product formerly marketed in the United Kingdom
14.	L-Mycin	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	Lomifylline	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
16.	Lozi-Flu	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
17.	Lufyllin	54	Name identified in RxNorm database. Per Drugs At FDA and Red Book, product is discontinued and no generic alternatives are available.
18.	Lufyllin-400	54	Name identified in RxNorm database. Per Red Book, product is discontinued and no generic alternatives are available.
19.	lumen C	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
20.	(b) (4) ***	66	Name found unacceptable under OSE RCM # (b) (4) - (b) (4). Subsequent name also found unacceptable under OSE RCM # (b) (4). Sponsor has yet to submit a new name.
21.	(b) (4) ***	64	Name found unacceptable under OSE RCM (b) (4). Application was withdrawn on 9/11/2013.
22.	Lunelle	57	Name identified in RxNorm database. Per Drugs At FDA and Red Book, product is discontinued and no generic alternatives are available.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[i].

No.	Name	POCA Score (%)
23.	Flunisin	56
24.	Ruby-Fill	55
25.	Uniphyl	56

[i] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
1.	2-Count HEAT PATCHES
2.	A Breath of Fresh Air
3.	AC CLEAR TREATMENT MASK
4.	Acne Face and Body Scrub
5.	ALOE SOOTHING RENEWAL MASK
6.	Alora
7.	Alternaria alternata
8.	AMARANTHUS PALMERI POLLEN
9.	AMARANTHUS TUBERCULATUS POLLEN
10.	ANTI AGING TREATMENT MASK
11.	Aromafields Jasmine Scented Antibacterial Hand Wash
12.	Aromafields Lavender Scented Antibacterial Hand Wash
13.	Aromafields Plumeria Scented Antibacterial Hand Wash
14.	Aromafields Tiger Lily Scented Antibacterial Hand Wash
15.	ATRIPLEX WRIGHTII POLLEN
16.	Australian Dream Carpal Tunnel Pain
17.	Australian Dream Pain Relieving Arthritis
18.	Breakup with your ex skin cells
19.	Budpak Muscle Rub
20.	BurnX
21.	Bye Bye to Dry
22.	Cephalosporium
23.	Clean ems Hand Cleaner Towels
24.	Climara
25.	COLLAGEN BOOSTING RENEWAL MASK
26.	Cover Fx Blemish Treatment Concealer G Light
27.	Cover Fx Blemish Treatment Concealer G Medium
28.	Cover Fx Blemish Treatment Concealer N Deep
29.	Cover Fx Blemish Treatment Concealer N Light
30.	Cover Fx Blemish Treatment Concealer N Med-Deep
31.	Cover Fx Blemish Treatment Concealer N Medium
32.	Cover Fx Blemish Treatment Concealer N X-Deep
33.	Cover Fx Blemish Treatment Concealer N X-Light
34.	Cover Fx Blemish Treatment Concealer P Light
35.	Cover Fx Blemish Treatment Concealer P Medium
36.	CVS Arthritis Pain Relief
37.	CVS Medicated Heat 1 ct
38.	CVS Sore Muscle Rub
39.	DHT X
40.	DRH T STEM CELL Bio Cellulose Mask
41.	ElishaCoy Skin Repairing Snail Eye Balm
42.	EPICOCCUM NIGRUM
43.	Estradiol

No.	Name
44.	Estradiol Transdermal System
45.	Helminthosporium
46.	HemoTreat
47.	Hormodendrum
48.	Hurt Blocker Pro
49.	Icy Hot Vanishing Scent
50.	ILLUMINATING Treatment Mask
51.	KLAVUU GREEN PEARLSATION TEATREE CARE SPOT CORRECTOR
52.	Levothyroxine Sodium
53.	Minivelle
54.	Muscle Rub
55.	Omega 3
56.	Pain Relieving Arthritis
57.	Pelo Baum Lash Lash
58.	Personal CARE Acne Control
59.	Pharmaskincare Acnecare Cream
60.	Pharmaskincare Brightening Dermarelief Cream
61.	Pharmaskincare Multi-Gly Skin Relief Cream
62.	Pore Gone For Good
63.	Proactiv
64.	Pullularia
65.	RENOKIN LASH LASH
66.	REZIL
67.	Rugby Capsaicin
68.	Selsun Oro
69.	Silver Nitrate
70.	Stop the Clock
71.	Sure Relief SR Relief
72.	Sure Result SR Relief
73.	TEATREE RELAXING RENEWAL MASK
74.	Tobacco Leaf
75.	TOO MUCH FUN IN THE SUN
76.	TREEANNSEA DESERT ROSE
77.	TREEANNSEA ESKIMO MELLA TIME RELEASE AGE DEFINE
78.	Tretinoin
79.	Triamcinolone Acetonide
80.	UNITHROID
81.	VITA BRIGHTENING RENEWAL MASK
82.	Vivelle-Dot
83.	Volumex
84.	What Happened Last Night

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

/s/

GRACE JONES
12/20/2017

CHI-MING TU
12/20/2017

DANIELLE M HARRIS
12/21/2017

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:	May 3, 2017
Application Type and Number:	NDA 208144
Product Name and Strength:	Luminesse (Brimonidine Tartrate) Ophthalmic Solution, 0.025%
Product Type:	Single-ingredient Product
Rx or OTC:	OTC
Applicant/Sponsor Name:	Bausch & Lomb
Panorama #:	2017-13451512
DMEPA Deputy Director (Acting):	Danielle Harris, PharmD, BCPS
DMEPA Division Director:	Todd Bridges, RPh

1. INTRODUCTION

The memorandum is written to summarize the acceptability of the proposed proprietary name, Luminesse, for NDA 208144, from a safety and misbranding perspective.

2. MATERIALS REVIEWED

We reviewed the following materials:

- The current safety and misbranding analysis for Luminesse, conducted under NDA 208144, attached to this memorandum authored by Dr. Grace Jones,
- The previous safety and misbranding analysis, conducted under IND 108524, dated January 29, 2015, authored by Dr. Grace Jones, and
- The previous DMEPA proprietary name memorandum, dated February 9, 2015, authored by Dr. Kellie Taylor which is appended to the analysis conducted by Dr. Jones, under IND 108524

3. DISCUSSION AND CONCLUSIONS

On January 29, 2015, Dr. Kellie Taylor consulted OCC to review the arguments outlined in the proprietary name review, conducted by Dr. Grace Jones, under IND 108524, dated January 29, 2015.[a] The review recommends that the proposed name Luminesse, for IND 108524 be found unacceptable because the proposed proprietary name evokes the word "luminescence," which Dr. Jones concluded overstates the efficacy of the drug product because the name implies a unique effectiveness. Based on the guidance provided by OCC, the DMEPA decision to accept the name was documented in a memorandum authored by Dr. Kellie Taylor dated February 9, 2015.[b] The guidance provided by OCC is summarized in Dr. Taylor's memorandum.

In the current evaluation of the proprietary name, Luminesse, under NDA 208144, Dr. Jones, recommends that the proposed name be found unacceptable based on the same misbranding concerns as those raised during the aforementioned proprietary name review under the IND. After careful consideration of Dr. Jones' position, and the previous advice obtained from OCC summarized in Dr. Taylor's memorandum, DMEPA maintains the conclusion that the name, Luminesse, is conditionally acceptable.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Luminesse, and have concluded that this name is conditionally acceptable.
If any of the proposed product characteristics as stated in your February 28, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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[a] Jones, G. Proprietary Name Review for Luminesse (IND 108524). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 JAN 29. Panorama No: 2014-26139.

[b] Taylor, K. Proprietary Name Review Memorandum for Luminesse (IND 108524). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 FEB 09. RCM No.: 2014-26139.

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

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Rx or OTC:	OTC
Applicant/Sponsor Name:	Bausch & Lomb
Panorama #:	2017-13451512
DMEPA Primary Reviewer:	Grace P. Jones, PharmD, BCPS
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Luminesse, from a safety and misbranding 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 Applicant previously submitted the proposed proprietary name, Luminesse, on August 18, 2014 under IND 108524. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Luminesse, conditionally acceptable in a memorandum dated February 9, 2015[c] under IND 108524.

The Applicant filed NDA 208144 on March 31, 2015, and submitted the proposed proprietary name, Luminesse, on April 23, 2015 under NDA 208144. DMEPA found the name, Luminesse, conditionally acceptable on May 8, 2015[d] under NDA 208144. However, the Agency found the application incomplete to allow for a substantive review. Thus on May 29, 2015, the application received a Refuse to File (RFT) letter.

The Applicant resubmitted NDA 208144 on February 27, 2017, and submitted the proposed proprietary name, Luminesse, on February 28, 2017 for review.

1.2 PRODUCT INFORMATION

The following product information is provided in the February 28, 2017 proprietary name submission.

- Active Ingredient: Brimonidine tartrate
- Indication of Use: Relieves redness of the eye due to minor eye irritations
- Route of Administration: Ophthalmic
- Dosage Form: Ophthalmic Solution
- Strength: 0.025%
- Dose and Frequency: Adults and children 5 years and older: instill 1 drop in the affected eye(s) every 6-8 hours, no more than four times daily.
- How Supplied: Trade and sample bottles in 2.5 ml and 7.5 ml (in 10 ml bottles)

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[c] Taylor, K. Proprietary Name Review for Luminesse. IND 108524. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 FEB 09. RCM No.: 2014-26139.

[d] Bridges, T. Proprietary Name Memorandum for Luminesse. NDA 208144. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 MAY 08. RCM No.: 2015-215952.

- Storage: Store at 15°-25°C (59°-77°F); (b) (4) (b) (4); discard remaining product 120 days after opening

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT AND COMMENTS AT INITIAL REVIEW

At the initial phase of the review, in response to our initial OSE, March 9, 2017 email, the Division of Nonprescription Drug Products (DNDP) provided the following comments relating to the proposed proprietary name:

- *There is potential confusion with Luminesse and Latisse (bimatoprost)*.
- *Luminesse sounds and looks alike to Luminess*, *which is an airbrush make-up brand.*
- *Luminesse sounds similar to the word "luminesce," which means to glow but does not appear to be a safety issue.*
- *Luminesse sounds and looks alike to Luminesce, which is an anti-aging skin care brand but does not appear to be a safety issue.*

We note that Latisse*,* which is used to treat hypotrichosis of the eyelashes, was included in our previous evaluation of the proposed proprietary name[e] and we maintain our previous determination that the proposed name has sufficient orthographic and phonetic differences from Latisse to minimize the risk of confusion between the two names.

In addition, we note that Luminess, which is a cosmetics company that markets the airbrush cosmetic Luminess Air, was included in our previous evaluation of the proposed proprietary name. We maintain our previous determination that there is sufficient prevention of failure mode to minimize risk of confusion between the two names.[e]

We note that Luminesce is a skin care product available in several formulations. Luminesce is included in our evaluation in Appendix C.

We concur with DNDP's initial comments at the initial phase of the review that Luminesse sounds similar to the word "luminesce." We determined that the proposed proprietary name would misbrand the proposed product. We find the proposed name suggests "luminous" and "luminescence," which overstates the efficacy of the drug product. Therefore, we conclude that the proposed name is misbranded because it implies a unique effectiveness. Our rationale for denial is provided in Section 3.1 below.

2.2 SAFETY ASSESSMENT

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

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[e] Jones, G. Proprietary Name Review for Luminesse (IND 108524). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 JAN 29. Panorama No: 2014-26139.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Luminesse 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

Seventy-eight practitioners participated in DMEPA's prescription name simulation studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Forty-eight practitioners correctly interpreted the name Luminesse. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[g] identified 118 names with the combined phonetic and orthographic score of ≥55% or individual orthographic or phonetic score of ≥70%.

We had identified and evaluated 194 names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed name. We note that the product characteristics have changed. Specifically, the recommended dosage/instructions for use, changed (b) (4) (b) (4), under the IND, to instill 1 drop in the affected eye(s) every 6-8 hours under the NDA. We considered this change during our re-evaluation of the previous names of concern, and we agree with the findings from our previous reviews for the names evaluated previously.

Therefore, our March 24, 2017 POCA search identified 27 names that were not previously analyzed. These names are included in Table 1 below.

2.2.5 Names with Strength Overlap and Potential Orthographic, Spelling, and Phonetic Similarities

The proposed product, Luminesse, will be available in 0.025% strength. Since this is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify names with strength overlap. Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences are listed in Appendix I.

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[f] USAN stem search conducted on March 13, 2017.

[g] POCA search conducted on March 24, 2017 in version 4.0.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and eDRLS search. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	24
Low similarity name pair: combined match percentage score ≤54%	0

2.2.7 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 27 names contained in Table 1 determined 27 names will not pose a risk for confusion as described in Appendices C through H.

3 REVIEWER'S CONCLUSIONS

The proposed proprietary name is not acceptable. The proposed name is misleading and misbrands the proposed product.

If you have further questions or need clarifications, please contact Abiola Olagundoye-Alawode, OSE project manager, at 301-796-3982.

3.1 REVIEWER'S COMMENTS REGARDING LUMINESSE

We have completed our review of the proposed proprietary name, Luminesse, and have concluded that this name is unacceptable for the following reasons:

The proposed proprietary name, Luminesse, is misleading and misbrands the proposed product because it implies a unique effectiveness that overstates the efficacy of the proposed product and potentially broadens the indication of the proposed product. The proposed proprietary name, Luminesse, evokes the words 'luminesce', 'luminescent', or 'luminescence' which are synonymous with the words radiance, illumination, and glow. Given the proposed product is indicated for the nonprescription relief of ocular redness due to minor eye irritations, the proposed proprietary name, Luminesse, implies a unique effectiveness that the proposed product could lead to improved vision when in fact it consists of a common substance (brimonidine) that has not demonstrated improvement in vision.

Furthermore, along with evoking 'luminescence,' the proposed name, Luminesse, can be associated with the words 'luminous,' further associating the proposed product to fanciful connotations suggesting enlightening, brightness, and beauty. In the context of relief of ocular

redness, the proposed proprietary name, Luminesse, can imply that the eyes can become luminous or luminescent, thus, potentially broadening the indication.

Therefore, we object to Luminesse based on the Federal Food, Drug, and Cosmetic Act (FD&C Act) which provides that labeling or advertising can misbrand a product if misleading representations are made (See 21 U.S.C. 321(n)). The FD&C Act also provides that a drug is misbranded if its labeling is false or misleading in any particular (21 USC 352(a)). A proprietary name, which appears in labeling, could result in such misbranding if it is false or misleading, such as by making misrepresentations with respect to safety or efficacy.

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).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm 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 RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/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.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP 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. [h]

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

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

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, CernerRxNorm, and names in the review pipeline using a 55% 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 ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

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. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-

alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[i]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information 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 to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such 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 (See Table 5) 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.

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

[i] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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 ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of 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 does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?

Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	Y/N	Do the names have different syllabic stresses?
Y/N	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?	Y/N	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	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 ≥55% to ≤69%).

Step 1	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 or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • 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. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.

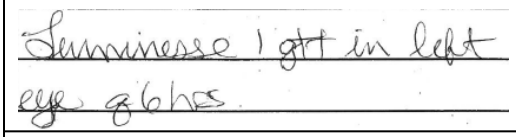
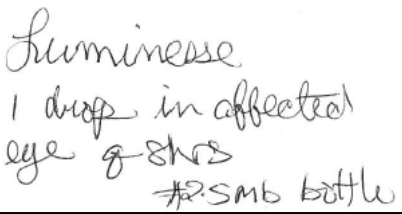
<table>
<tr><td></td><td colspan="2">• Similar sounding doses: 15 mg is similar in sound to 50 mg</td></tr>
<tr><td rowspan="2">Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><td>Orthographic Checklist (Y/N to each question)
• Do the names begin with different first letters?
Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.
• Are the lengths of the names dissimilar* when scripted?
*FDA considers the length of names different if the names differ by two or more letters.
• 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?
• Is there different number or placement of cross-stroke or dotted letters present in the names?
• Do the infixes of the name appear dissimilar when scripted?
• Do the suffixes of the names appear dissimilar when scripted?</td><td>Phonetic Checklist (Y/N to each question)
• Do the names have different number of syllables?
• Do the names have different syllabic stresses?
• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
• Across a range of dialects, are the names consistently pronounced differently?</td></tr>
</table>

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity 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.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Luminesse Study (Conducted on March 13, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Luminesse instill 1 drop in affected eye every 8 hours Dispense 2.5 ml bottle
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

299 People Received Study

78 People Responded

Study Name: Luminesse

Total	**24**	**21**	**33**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
LEMINESSE	0	0	1	1
LEMMINESSE	0	0	1	1
LERMINESSE	0	0	1	1
LEUMINESSE	0	0	2	2
LEUNINESE	0	0	1	1
LEVMINESSE	0	0	1	1
LIMINESSE	0	0	1	1
LUMANESE	0	2	0	2
LUMANISE	0	1	0	1
LUMENID	0	1	0	1
LUMENY	0	1	0	1
LUMINE	0	1	0	1
LUMINEE	0	1	0	1
LUMINEESE	1	0	0	1
LUMINESE	1	7	0	8
LUMINESE 1 DROP IN AFFECTED EYE	0	1	0	1
LUMINESSE	22	2	24	48
LUMINESSE EYE DROPS	0	0	1	1
LUMINIQ	0	1	0	1
LUMINISE	0	1	0	1
LUMINY	0	1	0	1
MONIN	0	1	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name: Luminesse** **Established name: Brimonidine tartrate** **Dosage form: Ophthalmic Solution** **Strength(s): 0.025%** **Usual Dose: 1 drop in the affected eye(s), every 6-8 hours**	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Albumins	70	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	Glibenese	73	International product marketed in France, Belgium, Denmark, Poland, and Russia.
3.	Luminesce	96	Luminesce is a cosmetic product that is marketed as an anti-aging skin care line of products and is marketed in various different formulations. The Luminesce anti-aging skin care product line includes products that are marketed as a serum, skin brightener, cleanser, moisturizer, night repair, masque, and body renewal. The Luminesce formulations do not overlap with that of the proposed product. Thus, based on the differences in product characteristics, it is unlikely that these products will be confused.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	(b) (4)***	56
2.	(b) (4)***	60
3.	Sinemet	60

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Luminesse Established name: Brimonidine tartrate Dosage form: Ophthalmic Solution Strength(s): 0.025% Usual Dose: 1 drop in the affected eye(s), every 6-8 hours	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
1.	Elinest	56	This name pair has sufficient orthographic and phonetic differences.
2.	Jaimiess***	58	This name pair has sufficient orthographic and phonetic differences.
3.	Linseed Oil	59	This name pair has sufficient orthographic and phonetic differences.
4.	Luesinum	58	This name pair has sufficient orthographic and phonetic differences.
5.	(b) (4) ***	60	This name pair has sufficient orthographic and phonetic differences.
6.	Lysine Plus	56	This name pair has sufficient orthographic and phonetic differences.
7.	Saline Mist	58	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
1.	N/A	N/A

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

No.	Name	POCA Score (%)	Failure preventions
1.	Flumist 2015-2016	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	Genesis	55	Veterinary product.
3.	(b) (4) ***	58	Proposed proprietary name for IND (b) (4) found to be unacceptable (OSE # (b) (4) dated 04/26/2016). Sponsor withdrew name and submitted a new proprietary name, (b) (4) ***, for review.
4.	Little Noses	55	Name identified in RxNorm database. Brand discontinued with no generic equivalent available.
5.	(b) (4) ***	58	Proposed proprietary name for IND (b) (4) found to be unacceptable (OSE # (b) (4) dated 12/20/2016). Sponsor withdrew name and submitted a new proprietary name, (b) (4) ***, for review.
6.	mintuss Ex	56	Name identified in RxNorm database. Brand discontinued with no generic equivalent available.
7.	Plum Seed Oil	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
8.	Sinumist	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[j].

No.	Name	POCA Score (%)
1.	Clindets	58
2.	Bemisiose	56
3.	Flunisin	56
4.	Insulase	56
5.	Somnite	56
6.	Somnote	56

[j] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
1.	A Breath of Fresh Air
2.	AC CLEAR TREATMENT MASK
3.	Acne Face and Body Scrub
4.	ALOE SOOTHING RENEWAL MASK
5.	Alora
6.	Alternaria alternata
7.	AMARANTHUS PALMERI POLLEN
8.	AMARANTHUS TUBERCULATUS POLLEN
9.	ANTI AGING TREATMENT MASK
10.	Aromafields Jasmine Scented Antibacterial Hand Wash
11.	Aromafields Lavender Scented Antibacterial Hand Wash
12.	Aromafields Plumeria Scented Antibacterial Hand Wash
13.	Aromafields Tiger Lily Scented Antibacterial Hand Wash
14.	ATRIPLEX WRIGHTII POLLEN
15.	Australian Dream Carpal Tunnel Pain
16.	Australian Dream Pain Relieving Arthritis
17.	Breakup with your ex skin cells
18.	Budpak Muscle Rub
19.	BurnX
20.	Bye Bye to Dry
21.	Cephalosporium
22.	Clean ems Hand Cleaner Towels
23.	Climara
24.	COLLAGEN BOOSTING RENEWAL MASK
25.	Cover Fx Blemish Treatment Concealer G Light
26.	Cover Fx Blemish Treatment Concealer G Medium
27.	Cover Fx Blemish Treatment Concealer N Deep
28.	Cover Fx Blemish Treatment Concealer N Light
29.	Cover Fx Blemish Treatment Concealer N Med-Deep
30.	Cover Fx Blemish Treatment Concealer N Medium
31.	Cover Fx Blemish Treatment Concealer N X-Deep
32.	Cover Fx Blemish Treatment Concealer N X-Light
33.	Cover Fx Blemish Treatment Concealer P L ght
34.	Cover Fx Blemish Treatment Concealer P Medium
35.	CVS Arthritis Pain Relief
36.	CVS Medicated Heat 1 ct
37.	CVS Sore Muscle Rub
38.	DHT X
39.	DRH T STEM CELL Bio Cellulose Mask

No.	Name
40.	EPICOCCUM NIGRUM
41.	Estradiol
42.	Estradiol Transdermal System
43.	Helminthosporium
44.	HemoTreat
45.	Hormodendrum
46.	Icy Hot Vanishing Scent
47.	ILluminATING Treatment Mask
48.	Levothyroxine Sodium
49.	minivelle
50.	Muscle Rub
51.	Pain Relieving Arthritis
52.	Personal CARE Acne Control
53.	Pore Gone For Good
54.	Proactiv
55.	Pullularia
56.	RENOKIN LASH LASH
57.	REZIL
58.	Rugby Capsaicin
59.	Selsun Oro
60.	Silver Nitrate
61.	Stop the Clock
62.	Sure Relief SR Relief
63.	TEATREE RELAXING RENEWAL MASK
64.	Tobacco Leaf
65.	TOO MUCH FUN IN THE SUN
66.	TREEANNSEA DESERT ROSE
67.	TREEANNSEA ESKIMO MELLA TIME RELEASE AGE DEFine
68.	Tretinoin
69.	Triamcinolone Acetonide
70.	UNITHROID
71.	VITA BRIGHTENING RENEWAL MASK
72.	Vivelle-Dot
73.	Volumex
74.	What Happened Last Night

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

/s/

GRACE JONES
05/04/2017

DANIELLE M HARRIS on behalf of CHI-MING TU
05/04/2017

DANIELLE M HARRIS
05/04/2017

DANIELLE M HARRIS on behalf of TODD D BRIDGES
05/04/2017