CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

218424Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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Date of This Review:	July 11, 2023
Application Type and Number:	NDA 218424
Product Name and Strength:	Lumify Preservative Free (brimonidine tartrate) ophthalmic solution, 0.025%
Product Type:	Single Ingredient Product
Rx or OTC:	Over-the-counter (OTC)
Applicant/Sponsor Name:	Bausch & Lomb Inc (B&L)
PNR ID #:	2023-1044725127
DMEPA 2 Safety Evaluator:	Grace P. Jones, PharmD
DMEPA 2 Team Leader:	Ashleigh Lowery, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Lumify Preservative Free, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A, respectively. B&L did not submit an external name study for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on May 2, 2023.

- Intended Pronunciation: Loom-i-fy Preservative Free
- Active Ingredient: brimonidine tartrate
- Indication of Use: Drug Facts labeling (DFL) *Uses*:
    - relieves redness of the eye due to minor eye irritations
- Route of Administration: ophthalmic
- Dosage Form: ophthalmic solution
- Strength: 0.025%
- Dose and Frequency: DFL *Directions*:
    - adults and children 5 years of age and over:
        - twist tab completely off to open vial
        - instill 1 drop in the affected eye(s)
        - discard vial immediately after use; do not re-use
        - store unused single-use vials in the child-resistant carton
        - do not use more than 4 times daily
        - remove contact lenses before use
        - wait at least 10 minutes before re-inserting contact lenses after use
        - if using other ophthalmic products while using this product, wait at least 5 minutes between each product
        - to avoid contamination, do not touch tip of container to any surface
    - children under 5 years of age: consult a doctor
- How Supplied:
    - 0.4 mL single-use vial
    - Foil pouch containing 5 single-use vials in a block – for sale and as sample
    - Child-resistant carton containing 20 single-use vials (4 foil pouches)
- Storage: store at 15-25 °C (59-77 °F)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT & COMMENTS FROM THE REVIEW DISCIPLINE AT INITIAL REVIEW

At the initial phase of the review, the Division of Nonprescription Drugs II (DNPD II) commented that adding "Preservative Free" to the name implies added benefit and that lacking preservative, i.e., benzalkonium chloride, in an ophthalmic product does not confer a benefit in safety or efficacy. The DNPD II also noted that "Preservative Free" as part of the proprietary name is already used in the nonprescription marketplace for a preservative free ophthalmic product. We acknowledge the DNPD II's comments and further discuss the proposed name in Section 2.2.6 and find that the proposed proprietary name Lumify Preservative Free would not misbrand the proposed product.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Lumify Preservative Free.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

B&L did not provide a derivation or intended meaning for the proposed proprietary name, Lumify Preservative Free, in their submission. This proprietary name is comprised of multiple words, the root name Lumify and the modifier, Preservative Free. The modifier Preservative Free contains the letters 'iv,' which is a medical abbreviation for the intravenous route of administration. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the location of this abbreviation in the middle of the name and the lack of prominence of this abbreviation makes it unlikely that the letters 'iv' within the proposed proprietary name, Lumify Preservative Free, could lead to confusion in this case. Additionally, we have no expectation that the word "Preservative" would be spelled differently to avoid containing an abbreviation.

2.2.3 FDA Name Simulation Studies

Seventy-eight practitioners participated in DMEPA's prescription studies for Lumify Preservative Free. Three practitioners from the inpatient (n=2) and voice (n=1) name simulation studies omitted the proposed modifier "Preservative Free" in their responses. We further evaluate the use of a modifier in Section 2.2.5.

The remaining 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 prescription simulation studies.

[a] USAN stem search conducted on May 18, 2023.

2.2.4 Evaluation of the roto name, Lumify

The root name, Lumify, has been the proprietary name for brimonidine tartrate ophthalmic solution, 0.025%, since its approval on December 22, 2017, for the nonprescription use to relieve redness of the eye due to minor eye irritations. The proposed product contains the same active ingredient, brimonidine tartarte. Our routine post-marketing surveillance has not identified name confusion medication error concerns associated with Lumify. Thus, we find the use of the root name, Lumify, in the proposed proprietary name, Lumify Preservative Free, acceptable.

2.2.5 Whether the use of a modifier is sufficient to distinguish the products

The use of a modifier to differentiate products within an OTC product line is a common naming practice within a family brand. Modifiers can assist in differentiating products and may help to prevent potential selection errors when used; however, omission and oversight of modifiers is cited in literature as a common cause of medication errors.[b] Postmarket experience shows that family branding may result in medication errors if the modifier is omitted and the product characteristics are similar or overlap.

As observed in the FDA Name Simulation Studies where 3 practitioners from the inpatient (n=2) and voice (n=1) name simulation studies omitted the proposed modifier "Preservative Free" in their responses. In this instance, if the modifier is omitted, users would receive the Lumify (preservative containing product) with the same active ingredient, brimonidine tartrate. This would result in the consumer receiving a 7.5 mL bottle of Lumify that contains preservatives and multiple doses instead of the preservative free proposed product that should be discarded after a single one-time use. Consumers allergic to preservatives may experience adverse events.

An alternative to using a modifier to distinguish this product from the currently marketed products is to use a different root name. However, marketing the new product under a unique proprietary name also carries a risk of medication errors, such as therapeutic duplication and overdoses.

Although the proposed naming strategy is not devoid of risk because modifiers may be omitted, in this case, we agree that using a modifier may assist in differentiating the current and proposed products.

2.2.6 Evaluation of the Proposed Proprietary Name, Lumify Preservative Free

While we generally discourage proprietary names with product-specific attributes such as the modifier "Preservative Free" that reflects the product's single-use characteristic, the use of the modifier "Preservative Free" in this instance helps to differentiate the proposed product that should be discarded immediately after a single one time use from the currently marketed preservative (i.e., benzalkonium chloride) containing Lumify product where the 7.5 mL bottle contains multiple doses. Moreover, the inclusion of the modifier "Preservative Free" provides

[b] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. J Gen Intern Med. 2002; 17(8): 579-587.

an additional mitigation to prevent potential prescribing and selection errors between the preservative free and preservative containing products.

Additionally, the modifier "Preservative Free" is used in OTC nomenclature for application products (e.g., Alaway Preservative Free) and the words "preservative free" are used in nonprescription labeling to communicate that a product does not contain preservatives.

Thus, we do not object to the use of the modifier "Preservative Free" in the proposed proprietary name.

2.2.7 Communication of DMEPA's Determination

On July 11, 2023, DMEPA 2 communicated our determination to the Division of Nonprescription Drugs II (DNPD II).

3 CONCLUSION

The proposed proprietary name, Lumify Preservative Free, is conditionally 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 BAUSCH & LOMB INC

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

If any of the proposed product characteristics as stated in your submission, received on May 2, 2023, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

USAN Stems List contains all the recognized USAN stems.

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 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.[c]

*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.

[c] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors Last accessed 10/05/2020.

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

   Four 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, verbal pronunciation of the drug name or during computerized provider order entry. 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 vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

c. 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.

   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.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Lumify Preservative Free Study (Conducted on May 5, 2023)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Lumify Preservative Free 1 drop each eye q 8 hrs	Lumify Preservative Free Place 1 drop in affected eye every 8 hours Dispense 1 carton
Outpatient Prescription: Lumify Preservative Free Place 1 drop in affected eye q 8 hrs # 1 carton	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Lumify Preservative Free	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Lumify Preservative Free - 2023-05-05
People Received Study: 256
People Responded: 78

Total	17	19	23	19	78
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
LUMAFINE PRESERVATIVE FREE	0	0	1	0	1
LUMIFY	2	0	1	0	3
LUMIFY PERSATIVE FREE	0	0	1	0	1
LUMIFY PF	0	0	4	0	4
LUMIFY PRESERVATIV FREE	0	0	1	0	1
LUMIFY PRESERVATIVE FREE	15	19	12	19	65
LUMIFY PRESERVATIVE-FREE	0	0	1	0	1
RHUEMIFY PRESERVATIVE-FREE	0	0	1	0	1
RUMIFY PRESERVATIVE-FREE	0	0	1	0	1

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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