NDA 218424

NDA APPROVAL

Bausch & Lomb Incorporated
Attention: Shaun A. Mbithi
Director, Global Regulatory Affairs
400 Somerset Corporate Blvd
Bridgewater, NJ 08807

Dear Shaun Mbithi:

Please refer to your new drug application (NDA) dated and received May 2, 2023, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lumify Preservative Free (brimonidine tartrate) ophthalmic solution, 0.025%.

We acknowledge receipt of your major amendment dated January 31, 2024, which extended the goal date by three months.

This new drug application provides for the use of Lumify Preservative Free (brimonidine tartrate) ophthalmic solution, 0.025% for relief of redness of the eye due to minor eye irritations.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the enclosed labeling, described in the table below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Draft Labeling	**Date Submitted**
Lumify Preservative Free Foil Pouch – Trade (5 count)	May 2, 2023
Lumify Preservative Free 0.4 mL Vial	May 2, 2023
Lumify Preservative Free Carton (20 count)	December 12, 2023
Lumify Preservative Free Foil Pouch – Sample (5 count)	December 12, 2023

The final printed labeling should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD*

Specifications.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 218424**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As*. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

If you have any questions, contact Michael Boblitz, PharmD, Senior Regulatory Health Project Manager at Michael.Boblitz@fda.hhs.gov or (301) 837-7651.

Sincerely,

{See appended electronic signature page}

Pamela Horn, M.D.
Division Director
Division of Nonprescription Drugs II
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

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/

PAMELA J HORN
04/19/2024 12:17:09 PM