



NDA 208144/S-001

SUPPLEMENT APPROVAL

Bausch + Lomb
Attention: Shaun A. Mbithi
Senior Manager, Regulatory Affairs
400 Somerset Corporate Boulevard
Bridgewater, NJ 08807

Dear Ms. Mbithi:

Please refer to your supplemental New Drug Application (sNDA) dated and received May 18, 2018, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lumify (brimonidine tartrate ophthalmic solution, 0.025%).

We acknowledge receipt of your amendment dated and received November 2, 2018, which constituted a resubmission following our Refusal to File letter dated July 17, 2018.

This “Prior Approval” supplemental new drug application provides for the addition of a 0.4 mL fill size (b)(4) in an aluminum pouch; the addition of a drug product manufacturing, packaging, release testing and stability testing site at (b)(4); and the addition of contract laboratories (b)(4) to perform analytical testing.

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 FPL must be identical to the submitted labeling and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Submitted Draft Labeling	Date Submitted
0.4 mL (single dose) foil pouch (sample) – updated to remove the gray color from the seal area	November 2, 2018
0.4 mL (single dose) carton (sample)	May 18, 2018
0.4 mL (single dose) vial (sample and trade)	May 18, 2018
Coupon (Save \$2.00 on 7.5 mL size)	May 18, 2018
0.4 mL (single dose) foil pouch (trade)	January 22, 2019
0.4 mL (single dose) carton (trade)	January 22, 2019

The FPL should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (April 2017, Revision 4)*. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 208144/S-001.**” Approval of this submission by FDA is not required before the labeling is used.

Remove the “New Product” text from the principal display panel 6 months after introduction into the marketplace.

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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. 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).

If you have any questions, call Jung Lee, Regulatory Project Manager, at (301) 796-3599.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Deputy Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
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/

KAREN M MAHONEY
02/21/2019 12:00:00 AM