NDA 208144/S-011

SUPPLEMENT APPROVAL

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

Dear Ms. Mbithi:

Please refer to your supplemental new drug application (sNDA) dated and received March 25, 2020, and your amendment, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lumify (brimonidine tartrate ophthalmic solution), 0.025%.

This "Prior Approval" supplemental new drug application provides for the following:

1. Alternate carton artwork for the multidose 2.5 mL and 7.5 mL fill size containers which include an additional carton color with the flag 'DIFFERENT LOOK SAME PRODUCT"
2. Addition of bottle opening directions on the bottle image of the carton
3. Addition of 'LARGE SIZE' to the 7.5 mL fill size carton artwork
4. Update to all artwork (bottle label and carton) with company name change

APPROVAL & LABELING

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 enclosed agreed-upon labeling.

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 in the "Drug Facts" format (21 CFR 201.66), where applicable and be identical to the following:

Submitted Labeling	Date Submitted
2.5 mL trade carton – grey and purple	March 25, 2020
2.5 mL sample carton – grey	March 25, 2020

2.5 mL trade container – grey	March 25, 2020
2.5 mL sample container – grey	March 25, 2020
7.5 mL trade carton – grey and purple	March 25, 2020
7.5 mL trade container – grey	March 25, 2020
2 x 7.5 mL multi-pack carton – original grey	March 25, 2020
2 x 7.5 mL blister card multi-pack – original grey	March 25, 2020

The FPL 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 208144/S-011**." 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 and 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

[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

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 Anna Thai, Regulatory Project Manager, at 301-796-6533.

Sincerely,

{See appended electronic signature page}

Karen Minerve Murry, MD, FACE
Acting Deputy Director, Office of Nonprescription Drugs
Acting Director, Division of Nonprescription Drugs I
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
09/23/2020 05:02:03 PM