

NDA 21996/S-017

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 October 14, 2020, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Alaway (ketotifen fumarate ophthalmic solution, 0.035%).

This “Prior Approval” sNDA provides for label rebranding artwork for the following:

- 5 mL Children’s Alaway carton and container
- 10 mL Alaway carton and container
- 10 mL Alaway alternate (allergy aisle) carton
- 2 x 10 mL Alaway twin pack carton
- Coupon insert

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 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 Labeling	Date Submitted
5 mL Children’s Alaway carton	April 14, 2021
5 mL Children’s Alaway container	April 14, 2021

10 mL Alaway carton	April 14, 2021
10 mL Alaway alternate (allergy aisle) carton	April 14, 2021
10 mL Alaway container	April 14, 2021
2 x 10 mL Alaway twin pack carton	April 14, 2021
Coupon insert	April 14, 2021

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 021996/S-017.**” Approval of this submission by FDA is not required before the labeling is used.

We note that you state in the October 14, 2020, cover letter that the (b) (4) fill sizes are currently not manufactured. We remind you that if these fill sizes are to be manufactured in the future with the labeling changes included in this supplement, you will need to submit a new supplement for FDA review.

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.

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>

If you have any questions, call Michael Boblitz, Regulatory Project Manager, at (301) 837-7651.

Sincerely,

{See appended electronic signature page}

Karen Minerve Murry, MD, FACE
Deputy Director
Office of Nonprescription 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/

KAREN M MURRY
04/14/2021 05:43:27 PM