DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021996/S-008

SUPPLEMENT APPROVAL

Bausch & Lomb, Inc.
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 August 15, 2014 submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Alaway (ketotifen fumarate ophthalmic solution), 0.035%.

We acknowledge receipt of your amendments dated January 23 and January 30, 2015.

This "Prior Approval" sNDA provides for the addition of a 10 mL plus 1 mL bonus pack carton and a 2 x 10 mL twin pack carton to the existing stock keeping units (SKUs). In addition, the following changes were incorporated to the existing and newly proposed SKUs:

- Carton Labeling:
  - The Statement of Identity was enlarged proportional to the proprietary name. Also, the strength of the active ingredient (0.035%) was added to the Statement of Identity on the PDP, side, and top panels.
  - The "For external use only" warning was listed as the first warning and a hairline was added preceding "Do not use".
  - The inactive ingredients have been revised to remove the word "and" following "sodium hydroxide" and replaced with a comma. The period is removed after "water for injection".
  - The location of the expiration date and lot number is identified on the carton.

- Container Label:
  - Revised "Read and keep carton for full Drug Facts information" to read "Keep carton for full Drug Facts information".
  - The strength of the active ingredient (0.035%) has been incorporated in the statement of identity.
  - The location of the expiration date and lot number is identified on the container label.

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 following carton and immediate containers (bottles) submitted January 30, 2015, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

- 1 mL (0.03 fl. oz.) carton and bottle
- 10 mL (0.34 fl. oz.) carton and bottle
- 10 mL (0.34 fl. oz.) + 1 mL (0.03 fl. oz.) carton
- 10 mL (0.34 fl. oz.) + 1 mL (0.03 fl. oz.) [allergy aisle] carton
- Twin-pack (2 x 10 mL) carton

The FPL should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021996/S-008."** 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 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, 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(s) 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}

Theresa Michele, MD
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 and this page is the manifestation of the electronic signature.

/s/

DANIEL BRUM
02/11/2015
Signed on behalf of Dr. Theresa Michele