DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-996/S-001

Bausch & Lomb Incorporated
Attention: Teresa Micuda
Regulatory Specialist
8500 Hidden River Parkway
Tampa, FL 33637

Dear Ms. Micuda:

Please refer to your supplemental new drug application dated December 14, 2006, received December 18, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alaway (0.0345% ketotifen fumarate equivalent to 0.025% ketotifen) ophthalmic solution.

We acknowledge receipt of your submission dated April 16 and 18, 2007.

This supplemental new drug application was for a 1 ml product configuration that will be used as a "Professional Sample – Not for Sale" and is packaged in a 3 cc -------- bottle.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (1 ml carton label with Drug Facts and 1 ml bottle label), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-996/S-001.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the flag "New" from the principal display panel six months after introduction into the marketplace.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 LCDR Keith Olin, Regulatory Project Manager, at (301) 796-0962.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Andrea Segal

4/18/2007 12:46:13 PM