DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-065/S-017

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

Dear Ms. Micuda:

Please refer to your supplemental new drug application dated May 12, 2006, received May 15, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Opcon-A Itching and Redness Reliever Eye Drops (0.315% pheniramine & 0.02675% naphazoline hydrochloride) solution.

We acknowledge receipt of your submissions dated March 5, April 25, and June 18, 2007.

Your submission of March 5, 2007 constituted a complete response to our November 14, 2006 action letter.

This supplemental new drug application provides for a new branding initiative of "Opcon-A Allergy" for the 0.5 fl. oz. (15ml) size which includes a revised carton and bottle label.

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 (0.5 fl. oz. carton label with Drug Facts submitted on April 25, 2007 and bottle label submitted on June 18, 2007), 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 20-065/S-017**." Approval of this submission by FDA is not required before the labeling is used.

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 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

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