



NDA 20-065/S-010

Bausch & Lomb
Attn: Joseph B. Hawkins
Director, Regulatory Affairs
8500 Hidden River Parkway
Tampa, FL 33637

Dear Mr. Hawkins:

Please refer to your supplemental new drug application dated November 22, 1995, received November 27, 1995, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Opcon-A Allergy Eye Drops (0.32% pheniramine maleate and 0.03% naphazoline hydrochloride).

We acknowledge receipt of your submissions dated February 21, 1996 and December 23, 2004.

Your submission of December 23, 2004, constituted a complete response to our May 9, 1996, action letter.

This supplemental new drug application provides for a new 30ml package size.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 28, 2004.

We also recommend the following labeling change. This change is not a condition of approval. You may incorporate this change in the labeling at the time of next printing and report the revised labeling in the following annual report.

Revise the following statement “store at room temperature (15-30°C)(59-86°F)” to “store at 20-25°C (68-77°F)” to comply with the current USP definition for controlled room temperature.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call LCDR Keith Olin, Regulatory Project Manager, at (301) 827-2293.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Curtis Rosebraugh
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