



NDA 16-968/S-022

Alcon Laboratories, Inc.
c/o Alcon Research, Ltd.
Attn: Sarah J. Cantrell, Sr. Manager, Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134-2099

Dear Ms. Cantrell:

Please refer to your supplemental new drug application dated May 7, 2004, received May 10, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MIOSTAT (carbachol intraocular solution) 0.01%.

This "Changes Being Effected" supplemental new drug application provides for labeling changes to the drug product.

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 May 7, 2004. We are enclosing the agreed upon text for the package insert and the backing paper.

Please submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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

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 Alison Rodgers, Regulatory Project Manager, at (301) 827-2019.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, MD
Deputy Director
Division of Anti-Inflammatory, Analgesic, and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

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

Wiley Chambers
11/10/04 11:51:40 AM