



NDA 16-968/S-020

Alcon Laboratories, Inc.  
c/o Alcon Research, Ltd.  
Attention: Norma J. Schafer  
Regulatory Affairs Analyst  
6201 South Freeway  
Fort Worth, Texas 76134-2099

Dear Ms. Schafer:

Please refer to your supplemental new drug application dated August 8, 2002, received August 9, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Miostat (carbachol intraocular ophthalmic solution) 0.01% Ophthalmic Solution.

This "Changes Being Effected" supplemental new drug application provides for the addition of the Geriatric Use statement to the Precautions section and additional minor changes to the package insert.

We have completed the review of this supplemental application, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling submitted on August 9, 2002. Accordingly, the supplemental application is approved effective on the date of this letter.

In addition, we recommend that a future labeling supplement include the following changes:

1. In the Description section please identify a target range for pH adjustment.
2. In the How Supplied section please identify the fill volume for the 1.5 mL vial.
3. The Storage statement should be revised to read "Store at 15° -30°C (59°-86°F).

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, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

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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 Lori M. Gorski, Project Manager, at (301) 827-2090.

Sincerely,

*{See appended electronic signature page}*

Wiley A. Chambers, M.D.,  
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

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/s/

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Wiley Chambers  
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