DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-963

OCT 21 1998

Alcon Laboratories
Attention: Scott Krueger
Director, Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Mr. Krueger:

Please refer to your new drug application (NDA) dated February 16, 1998, received February 18, 1998, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Timolol Maleate (timolol maleate ophthalmic gel forming solution) Ophthalmic Gel Forming Solution, 0.25% and 0.5%.

We acknowledge receipt of your submissions dated February 25, March 18 and 25, April 14 (two) and 17, May 28, July 2 and 14, August 18 and 25, September 2 and 29, and October 9 and 13, 1998.

This new drug application provides for the use of Timolol Maleate (timolol maleate ophthalmic gel forming solution) Ophthalmic Gel Forming Solution, 0.25% and 0.5% for the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

We have completed the review of this application, as amended, 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 draft labeling of the submission dated October 13, 1998. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical in content to the October 13, 1998, draft labeling. Marketing the product with FPL that is not identical in content to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL (including package insert, immediate container and carton labels) as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-963." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitment specified in your submission dated September 29, 1998, to

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of this commitment in your annual report to this NDA. The status summary should include the number of patients entered in this study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to this Phase 4 commitment must be clearly designated "Phase 4 Commitment."

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit 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-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

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

Sincerely,

WAC 10/21/98

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