CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-816

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-816

APR 1 1998

Alcon Laboratories, Inc.
Attention: D. Scott Krueger
Director, Regulatory Affairs
P.O. Box 6600
Fort Worth, Texas 76115

Dear Mr. Krueger:

Please refer to your new drug application dated January 26, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AZOPT™ (brinzolamide ophthalmic suspension), 1%. We also refer to the approvable letter dated December 4, 1997.

We acknowledge receipt of your submissions dated November 26, and December 11 and 15, 1997, and January 27 and 28, February 4, March 9, and April 1, 1998.

This new drug application provides for Azopt for the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

We have completed the review of this application, including the submitted draft labeling, 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 in the submission dated April 1, 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 April 1, 1998, draft labeling. Marketing the product with FPL that is not identical may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL 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 "FINAL PRINTED LABELING" for approved NDA 20-816. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

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.

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

Sincerely,

4/4/98

Michael Weintraub, M.D.
Director
Office of Drug Evaluation V
Center for Drug Evaluation and Research