ANDA 75-476 August 20, 1999

Alcon Laboratories, Inc.
Attention: Sarah J. Cantrell
6201 South Freeway, R7-18
Fort Worth, Texas 76134

Dear Madam:

This is in reference to your abbreviated new drug application dated September 30, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Carteolol Hydrochloride Ophthalmic Solution USP, 1%.

Reference is also made to your amendments dated April 20, June 22, and July 27, 1999.

We have completed the review of this abbreviated application and have concluded that based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacture and testing of the drug product), and is subject to change on the basis of new information that may come to our attention. The reference drug product (RLD) upon which you have based this application, Ocupress Ophthalmic Solution 1% of Otsuka America Pharmaceutical, Inc., is subject to a period of patent protection. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until the period has expired, i.e., January 2, 2000.

Because the agency is granting a tentative approval for this application, please submit an amendment at least 60-days (but not more than 90-days) prior to the date your believe your application will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should be submitted even if none of these changes were made.

This submission should be designated clearly in your cover letter as a MINOR AMENDMENT. In addition to this amendment, the Agency may request at any time prior to the final date of approval that you submit an additional amendment containing the information described above.

Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this abbreviated application as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to Agency review before final approval of the application will be made.

The drug product that is the subject of this abbreviated application may not be marketed without final agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act. Also, until the agency issues the final approval letter, your drug product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list, (the "Orange Book"), published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to January 2, 2000, you should amend your application accordingly.

Please contact Joseph Buccine, Project Manager, at (301) 827**B**5848, for further instructions prior to submitting your amendment.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs