ANDA 64-134

October 27, 1999

Bausch & Lomb Pharmaceuticals, Inc.
Attention: David Desris, R.Ph.
8500 Hidden River Parkway
Tampa, FL 33637

Dear Sir:

This is in reference to your abbreviated new drug application dated July 29, 1994, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Tobramycin and Dexamethasone Ophthalmic Suspension USP, 0.3%/0.1%, respectively, packaged in 2.5 mL and 5 mL plastic bottles. We note that this product is subject to the exception provisions of Section 125(d)(2) of Title I of the Food and Drug Administration Modernization Act of 1997.

Reference is also made to your amendments dated August 19 and December 4, 1996; February 14, April 4, April 9, April 15, May 16, June 23, July 1, and October 3, 1997; April 3 and December 10, 1998; and January 14, January 20, April 22, August 10, August 18, September 3, September 9, and October 11, 1999.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Tobramycin and Dexamethasone Ophthalmic Suspension USP, 0.3%/0.1%, respectively, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Tobradex® Ophthalmic Suspension, of Alcon Laboratories Inc.).

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The

Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print.

Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Roger L. Williams, M.D.
Deputy Center Director for
Pharmaceutical Science
Center for Drug Evaluation and Research