DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-231

Food and Drug Administration
Rockville MD 20857

MAY 14 2004

Alcon Research, Ltd.
Attention: Norma J. Schafer
U.S. Agent for: Alcon, Inc.
6201 South Freeway
Forth Worth, Texas 76134-2099

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated August 31, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ofloxacin Ophthalmic Solution USP, 0.3%.

Reference is also made to our Tentative Approval letter dated May 13, 2002, and to your amendments dated February 16, and April 20, 2004.

We have completed the review of this tentatively approved 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 Ofloxacin Ophthalmic Solution USP, 0.3%, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Ocuflox® Ophthalmic Solution, 0.3%, of Allergan, Inc.).

Under Section 506A of the Act, 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 which 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 final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FDA 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 FDA 2253 at the time of their initial use.

Sincerely yours,

(b)(6) [redacted]

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research