DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 1.0 1999

TRANSMITTED VIA FACSIMILE

Scott Krueger
Director, Regulatory Affairs
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099

RE: **NDA 19-992**
Ciloxan (ciprofloxacin HCl) 0.3% as base sterile ophthalmic solution
MACMIS # 7638

Dear Mr. Krueger:

This letter is in reference to Alcon Laboratories, Inc.'s (Alcon) promotion of Ciloxan. Through its surveillance and enforcement activities, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has identified a sales aid (CN99501VS 12/98) that we consider to be false or otherwise misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Promotion of An Unapproved Use

As you know, promotional claims must be supported by adequate evidence. Further, they should not be inconsistent with the product's approved product labeling. In the sales aid, Alcon claims that Ciloxan may be used as a prophylaxis in ophthalmic surgery ("Ciloxan delivers potency to eradicate pathogens in surgery" and "In surgery...don't wait to eradicate"). However, Ciloxan in indicated for the treatment of infections caused by susceptible strains of designated organisms as listed in its approved product labeling—not for prophylaxis in surgery. Thus, your promotion of Ciloxan is inconsistent with its approved product labeling and constitutes an unapproved new use.

Unsupported Clinical Claims

In the sales aid, Alcon presents Ciloxan's eradication rates (kill curves) for staphylococcus epidermidis, and its susceptibility rates for staphylococcus (s.) aureus, s.epidermidis, s. pneumoniae, and pseudomonas aeruginosa. However, Alcon does not provide the context for this information—that this is *in vitro* data and that *in vitro* data is not always indicative of clinical effectiveness. Further, *in vitro* data used in a way that suggests that it has clinical significance when in fact no clinical significance has been demonstrated is false or misleading.

Thus, DDMAC requests that Alcon immediately cease the dissemination of these violative advertisements and any other violative promotional materials that promote Ciloxan for unapproved new uses and imply an unsupported clinical effectiveness. You should respond to DDMAC regarding this violation by April 29, 1999, providing the date Alcon ceased the dissemination of these and other similar promotional materials.

If you have any questions, please contact me by facsimile at (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds Alcon that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 7638 and NDA 19-992.

Sincerely,

Warren F. Rumble
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications