DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 19 1998

TRANSMITTED VIA FACSIMILE

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

RE: **NDA 50-592**
TobraDex (tobramycin 0.3% and dexamethasone 0.1%) Sterile Ophthalmic Suspension and Ointment
MACMIS # 7029

Dear Mr. Krueger:

This letter is in reference to Alcon Laboratories, Inc.'s (Alcon) promotion of TobraDex. The Division of Drug Marketing, Advertising and Communications (DDMAC) has identified, through its surveillance activities, a file card identified as TD98504VS and a journal advertisement that are false and/or misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Promotion of Unapproved Use

The cover of the file card depicts an eye and an ear and has the headline, "The reasons to choose TobraDex are Loud and Clear" which implies both optic and otic use. As you know, TobraDex is not approved for otic use. An advertisement published in the October 1998, issue of *Otolaryngology-Head & Neck Surgery* has similar graphics and text. Further, Alcon distributed the card at the American Association of Otolaryngology convention in San Antonio on September 14-16, 1998, which DDMAC concludes was for the promotion of TobraDex for off-label otic use.

Fair Balance

Neither promotional piece presents information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to the effectiveness of the drug. Both present balancing risk information that is inadequate in content, in a small type that minimizes its importance and readability. Risk information should be presented in both promotional materials with a prominence and readability reasonably comparable with the presentation of information relating to the effectiveness of the drug.

Because of the above violations, DDMAC requests that Alcon immediately cease the dissemination of this violative file card and journal advertisement and any other violative promotional materials that promote TobraDex for otic use. Alcon should respond to DDMAC regarding this violation by December 4, 1998, providing the date it ceased the dissemination of the 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 # 7029 and NDA 50-592.

Sincerely,

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