



DEPARTMENT OF HEALTH & HUMAN SERVICES

FCI

Food and Drug Administration
Rockville MD 20857

APR 16 1999

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 # 7850

Dear Mr. Krueger:

This letter is in reference to Alcon Laboratories, Inc.'s (Alcon) submission, dated March 19, 1999, of promotional materials under cover of Form FDA 2253 for TobraDex. The submission included an advertisement titled, "Go Platinum." The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed this advertisement and has concluded that it is lacking in fair balance or otherwise misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Fair Balance

This advertisement fails to present 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. Although you have presented information regarding the most frequent adverse reactions, ("Hypersensitivity and localized ocular toxicity occur in less than 4% of patients"), the information is presented in a manner that minimizes its importance and readability. Further, we consider that you have minimized the adverse event information by presenting it as yet another claim.

Thus, DDMAC requests that Alcon immediately cease the dissemination of this violative advertisement and any other violative promotional materials that are lacking in fair balance. You should respond to DDMAC regarding this violation by April 30, 1999, providing the date Alcon ceased the dissemination of these and any other violative promotional materials.

Scott Krueger
Alcon Laboratories, Inc.
NDA 50-592

Page 2

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 # 7850 and NDA 50-592.

Sincerely,

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