DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

F.O.I

JAN 5 1999

TRANSMITTED VIA FACSIMILE

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

RE: **NDA 20-816**
Azopt (brinzolamide ophthalmic suspension) 1%
MACMIS # 7440

Dear Mr. Krueger:

This letter is in reference to Alcon Laboratories, Inc.'s (Alcon) submission, dated November 19, 1998, of promotional materials under cover of Form FDA 2253 for Azopt. The submission included a "Dear Doctor" letter and a "formulary approved" sheet. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed these promotional materials and has concluded that they are lacking in fair balance or are otherwise misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Fair Balance

> The letter and formulary sheet fail 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 safety information is presented at the bottom of the promotional materials in small print, the information is presented in a manner 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.

Alcon should immediately cease the dissemination of these violative promotional labeling pieces and all similar promotional materials that are lacking fair balance.

Alcon should respond in writing to DDMAC regarding this issue by January 20, 1999. Alcon's response should include Alcon's intent to comply with the above request should also include the date that it ceased disseminating these and other violative 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 # 7440 and NDA 20-816.

Sincerely,

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