



FEB 23 1999

TRANSMITTED VIA FACSIMILE

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

RE: **NDA 19-845**
Betoptic S (betaxolol HCl) Sterile Ophthalmic Suspension, 0.25%
MACMIS # 7270

Dear Mr. Krueger:

This letter concerns Alcon Laboratories, Inc.'s (Alcon) promotional materials for Betoptic S. The Division of Drug Marketing, Advertising, and Communications (DDMAC), as part of its monitoring and surveillance activities, has identified an advertisement for Betoptic S published in the December 1998, issue of *Review of Ophthalmology* that we consider false and/or misleading and in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow.

Failure to Submit Promotional Materials

We have no record that Alcon submitted this advertisement at the time of initial dissemination under Form FDA 2253. Such submissions are required under 21 CFR 314.81 (b)(3)(i). If this advertisement has not been submitted, Alcon should submit it as well as any other promotional materials that have not been submitted.

Implied Claim for an Unapproved New Use

The advertisement depicts a narrow field view of the Mona Lisa and presents the tagline "More Than Just IOP" below the trade and established names for Betoptic S. DDMAC considers that this presentation implies Betoptic S may protect patients from the visual field-diminishing effects of glaucoma. However, Betoptic S is only indicated for lowering intraocular pressure in patients with chronic open-angle glaucoma and ocular hypertension.

DDMAC is especially concerned about this promotional issue because DDMAC has previously inquired about Alcon's alleged promotion of betaxolol in connection with ocular blood flow and preservation of visual field. On February 15, 1994, Alcon responded to an inquiry from DDMAC regarding this alleged promotion, and stated that in response to DDMAC's request,

Scott Krueger
Alcon Laboratories, Inc.
NDA 19-845

Page 2

Alcon was "taking measures to ensure that there will be no further discussion of the effect of betaxolol on visual field or ocular blood flow...in materials used by Alcon sales representatives." However, it appears from the dissemination of the above advertisement that Alcon is promoting betaxolol in connection with the preservation of visual field.

Thus, DDMAC requests that Alcon immediately cease the distribution of the above advertisement and any other promotional materials that promote unapproved uses for Betoptic and Betoptic S.

Alcon's written response should include Alcon's intent to comply with the above request and should be received by DDMAC by March 9, 1999. Alcon should also include the date that it ceased disseminating these 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 # 7270 and NDA 19-845.

Sincerely,

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