DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

Dave Garbe
Director, Scientific Information and Medical Communications
Allergan, Inc.
2525 Dupont Drive
PO Box 19534
Irvine, CA 92623-9534

RE: **NDA 21-275** Lumigan (bimatoprost ophthalmic solution) 0.03%
MACMIS # 10055

Dear Mr. Garbe:

This letter objects to Allergan, Inc.'s (Allergan), dissemination of violative promotional materials for Lumigan. We specifically refer to a one-page sales aid with the heading, "Superior mean IOP achieved regardless of race." The Division of Drug Marketing, Advertising, and Communications (DDMAC) reviewed the promotional sales aid and concluded that it is false or misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Lack of Fair Balance

Your sales aid is misleading because it fails to present any information relating to the product's side effects and contraindications, or other risk information. Your failure to present any risk information about Lumigan is particularly concerning considering the fact that the approved product labeling (PI) for Lumigan includes a bolded warning. This bolded warning concerns possible permanent changes to pigmented eye tissues such as increased pigmentation of the iris and periorbital tissue (eyelid skin), and increased pigmentation and growth of eyelashes. Further, the PI states that "the long term effects on the melanocytes and the consequences of potential injury to the melanocytes and/or deposition of pigment granules to other areas of the eye are currently unknown." Because of the safety concerns, the PI states that "Lumigan is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open angle glaucoma or ocular hypertension **who are intolerant of other intraocular pressure lowering medications or insufficiently responsive (failed to achieve target IOP determined after multiple measurements over time) to another intraocular pressure reducing medication** (emphasis added). This important information containing the approved indication is also not presented in your sales aid.

Misleading Comparisons

In your sales aid, you claim that Lumigan "[a]chieve[s] low target pressure in more patients," and that Lumigan provides "[s]uperior mean IOP achieves regardless of race." These claims are presented in conjunction with a comparative table that includes Lumigan, latanoprost (Xalatan), and travaprost (Travatan). The table presents IOP values for each drug in black patients, and in non-black patients, and in a manner that suggests that Lumigan is superior to Xalatan and Travatan in both populations. This presentation also suggests that Lumigan has been studied in head-to-head trials with both latanoprost and travoprost when, in fact, it has not. Thus, your sales aid is misleading because it suggests that Lumigan is superior to latanoprost and travoprost when such has not been demonstrated by substantial evidence. We note that you included below the table in very small type the statement, "Data taken from separate comparable studies does not imply head-to-head comparisons." This statement does not negate the misleading message provided in the table.

Overstatement of Efficacy

In your sales aid, you claim that Black patients reached an IOP of 17.1 mm Hg and non-Black patients reached an IOP of 16.9 mm Hg with Lumigan. These claims misleading because imply that Lumigan is more effective than has been shown by substantial evidence. The PI for Lumigan states that patients in the clinical trials had a baseline IOP of 26 mmHg, and that the IOP lowering effect of Lumigan was 7-8 mmHg (thus the mean IOP achieved in controlled clinical trials was 18-19 mmHg). Thus, your claim that patients reached target IOPs of 16.9-17.1 mmHg is misleading and is inconsistent with the approved product labeling.

Requested Actions

In order to address these objections, we request that you immediately cease the dissemination of this violative sales aid and all similar promotional materials that contain the same or similar messages.

You should respond in writing to us regarding this issue by June 22, 2001. Your response should include Allergan's intent to comply with the above request, the date that it ceased disseminating this sales aid and any other violative promotional materials with the same or similar messages, and a list of the discontinued 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-42; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds Allergan that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 10055 and NDA 21-275.

Sincerely,

{See appended electronic signature page}

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Warren Rumble
6/8/01 10:28:28 AM

LUMIGAN™

Achieve low target pressure in more patients

Superior mean IOP achieved <u>regardless</u> of race

Mean IOP achieved from comparable baselines

	LUMIGAN™	travoprost	latanoprost
In a Black population	**17.1 mm Hg**	17.2 mm Hg	18.6 mm Hg
In a non-Black population	**16.9 mm Hg**	18.5 mm Hg	18.6 mm Hg

ALLERGAN

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