DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 15 1999

**TRANSMITTED VIA FACSIMILE**

David Garbe
Director, Scientific Information and Medical Compliance
Allergan, Inc.
2525 DuPont Drive TL-1L
PO Box 19534
Irvine, CA 92623-9534

RE: **NDA 20-613**
Alphagan (brimonidine tartrate ophthalmic solution) 0.2%
MACMIS # 7843

Dear Mr. Garbe:

This letter is in reference to Allergan, Inc.'s (Allergan) submissions (2), dated March 16, 1999, of promotional materials under cover of Form FDA 2253 for Alphagan. The submissions included two journal advertisements titled, "Chart a safe course to long-term efficacy," and four sales aids (RX9262, RX9149, RX9236, and RX9234). The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed these promotional materials and has concluded that they are false or misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Promotion of An Unapproved Use

As you know, promotional claims must be supported by adequate evidence. Further, they should not be inconsistent with the product's approved product labeling. Allergan's advertisements and two of the sales aids for Alphagan claim that visual fields have been unchanged or improved in 95% of patients over 3 years (N=82). Although loss of visual field may be an end-result of uncontrolled glaucoma, your promotion of Alphagan to preserve or improve visual fields is inconsistent with the approved product labeling and constitutes an unapproved new use. Alphagan is indicated for lowering intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension, not for the preservation of visual fields.

The Drop Without the Downside

In its promotional materials, Allergan claims in a tagline "The Drop Without the Downside." We consider this claim to be misleading because it implies that Alphagan

is effective in lowering IOP without side effects. However, Alphagan has numerous Precautions, Adverse Reactions, and Contraindications in its approved product labeling such as the precaution regarding the potential for a decrease in mental alertness for patients who may engage in hazardous activities.

Because of these violative claims, DDMAC requests that Allergan immediately cease the dissemination of these violative promotional materials and any other violative promotional materials that promote Alphagan for unapproved new uses and make misleading claims regarding safety. You should respond to DDMAC regarding this violation by April 29, 1999, providing the date Allergan 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 Allergan that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 7843 and NDA 20-613

Sincerely,

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