**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-770/S-001

Allergan, Inc.
Attention: Lewis Gryziewicz, R.Ph.
Senior Director, Regulatory Affairs
2525 Dupont Drive
P.O. Box 19534
Irvine, California 92623-9534

Dear Mr. Gryziewicz:

Please refer to your supplemental new drug application dated October 14, 2005, received October 17, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alphagan P (brimonidine tartrate ophthalmic solution) 0.1%.

We acknowledge receipt of your submissions dated November 22, 2005, and February 6, 2006.

This "Changes Being Effected in 30 Days" supplemental new drug application provides for a change in the physician's sample bottle and its capacity from 10 mL to 5 mL.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed draft immediate container and carton labeling submitted November 22, 2005.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling is to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces are submitted electronically, labeling does not need to be submitted in paper.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

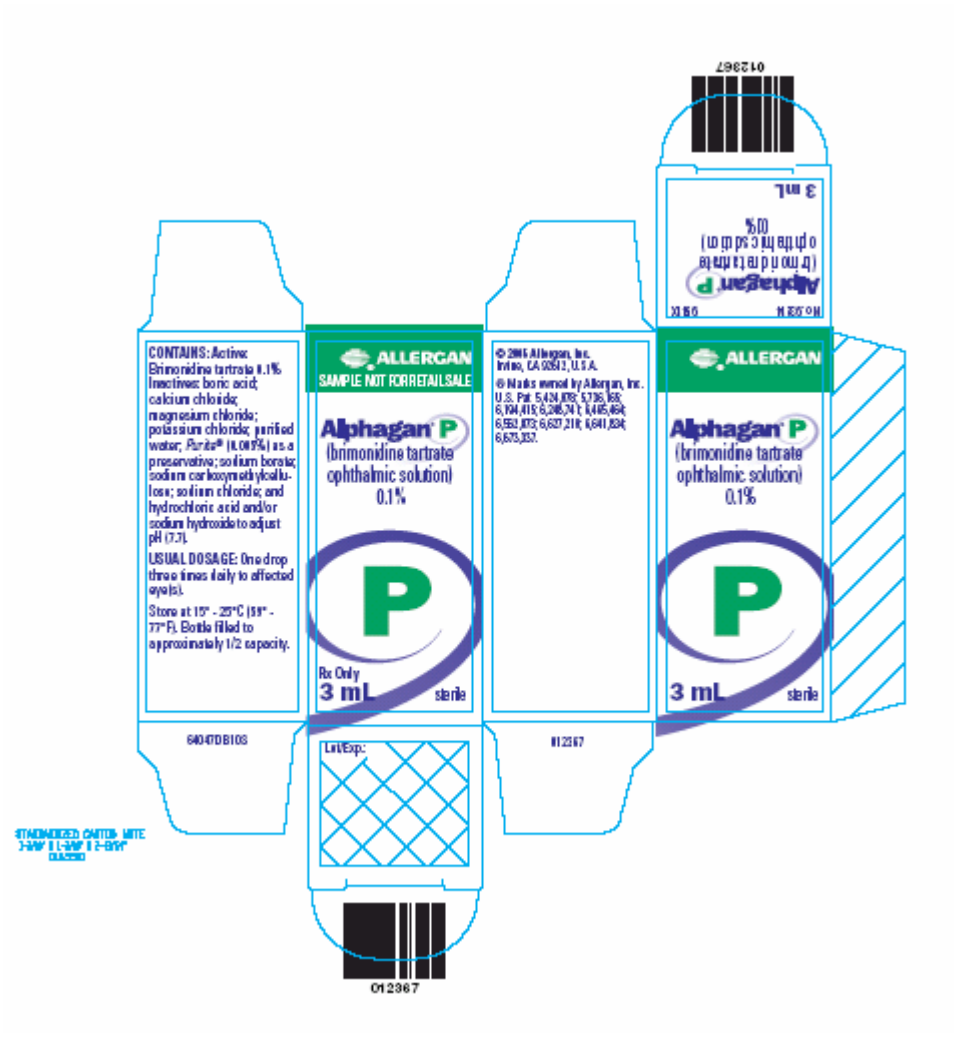
If you have any questions, call Valerie Jimenez, Regulatory Health Project Manager, at (301) 796-1345.

Sincerely,

*{See appended electronic signature page}*

Hasmukh Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure


CONTAINS: Active: Brimonidine tartrate 0.1% Inactives: boric acid; calcium chloride; magnesium chloride; potassium chloride; purified water; Purite® (0.005%) as a preservative; sodium borate; sodium carboxymethylcellulose; sodium chloride; and hydrochloric acid and/or sodium hydroxide to adjust pH (7.3).
USUAL DOSAGE: One drop three times daily to affected eye(s).
Store at 15° - 25°C (59° - 77°F). Bottle filled to approximately 1/2 capacity.
ALLERGAN
SAMPLE NOT FOR RETAIL SALE
Alphagan P
(brimonidine tartrate ophthalmic solution) 0.1%
Rx Only
3 mL
sterile
© 2005 Allergan, Inc.
Irvine, CA 92612, U.S.A.
® Marks owned by Allergan, Inc.
U.S. Pat. 5,424,078; 5,736,155; 6,194,415; 6,296,741; 6,465,464; 6,551,573; 6,627,210; 6,641,834; 6,673,337.
ALLERGAN
Alphagan P
(brimonidine tartrate ophthalmic solution) 0.1%
3 mL
sterile
012367
Lot/Exp:
012367


USUAL DOSAGE: One drop three times daily to affected eye(s). Store at 15° - 25°C (59° - 77°F). Bottle filled to approximately 1/2 capacity.
© 2005 Allergan, Inc.
Irvine, CA 92612, U.S.A.
Lot/Exp:
SAMPLE
Alphagan P
(brimonidine tartrate ophthalmic solution) 0.1%
3 mL
sterile

---

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

---

/s/

---

Hasmukh Patel
4/17/2006 08:08:42 AM