



NDA 21-262/S-010 & S-013

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

Dear Mr. Gryziewicz:

Please refer to your supplemental new drug applications dated June 24, 2002, received June 25, 2002, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Alphagan P (brimonidine tartrate ophthalmic solution) 0.15% .

We acknowledge receipt of your submissions dated August 11 and August 15, 2003. Your submission of August 15, 2003, constituted a complete response to our June 19, 2003, action letter.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for use of the (b)(4)-----container/closure system and changes to the 3 mL carton and container labeling. The ----- is not affected by this supplement since 3mL is designated as the physician sample size.

We completed our review of these applications, as amended. These applications are 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 labeling (text for the immediate container and carton labels) submitted August 15, 2003.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 21-262/S-010 & S-013." Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products, HFD-550, and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Lori Gorski, Regulatory Project Manager, at (301) 817-2090.

Sincerely,

{See appended electronic signature page}

Linda Ng, Ph.D.
Chemistry Team Leader for the
Division of Anti-Inflammatory, Analgesic,
and Ophthalmic Drug Products, HFD-550
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Linda Ng
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