

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-770

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-770

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

Dear Mr. Gryziewicz:

Please refer to your new drug application (NDA) dated May 27, 2004, received June 1, 2004, 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 April 1, June 27, July 20, and August 3, 17, and 18, 2005.

The June 27, 2005, submission constituted a complete response to our April 1, 2005, action letter.

This new drug application provides for the use of Alphagan P (brimonidine tartrate ophthalmic solution) 0.1%, for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

We completed our review of this application, as amended. It 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 labeling submitted August 17, 2005. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 (i.e., package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

NDA 21-770

Page 2

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 this division 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

Please submit one market package of the drug product when it is available.

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 Michael Puglisi, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective and
Ophthalmology Products, HFD-520
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure