CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-262

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-262

Allergan, Inc.
Attention: Lewis Gryziewicz
Director, 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 June 29, 2000, received June 30, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alphagan P (brimonidine tartrate ophthalmic solution) Ophthalmic Solution, 0.15%.

We acknowledge receipt of your submissions dated July 21 and 27, August 2, 8, 11, 16 and 28, September 5 and 26, October 2 (two), 3, 6, 9, 17 and 19, November 2, 9, 21 and 27, and December 8, 12 (two), 13, 19, 20 and 21, 2000, and March 9 and 13, 2001.

This new drug application provides for the use of Alphagan P for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the attached draft package insert submitted December 21, 2000. The immediate container and carton labels must be identical in content to the labeling of the package insert. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submission in Electronic Format – NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 21-262." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have not fulfilled the requirements of 21 CFR 314.55 (or 601.27). We are deferring submission of your pediatric studies until October 1, 2001. We are waiving study requirements for pediatric patients 0 to 2 years for this action on this application.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit 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, Maryland 20857

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

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Lori M. Gorski, Project Manager, at (301) 827-2090.

Sincerely,

(See appended electronic signature page)

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research