

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**20-490/S007**

**20-613/S018**

**21-262/S006**

**APPROVAL LETTER**



NDA 20-490/S-007  
NDA 20-613/S-018  
NDA 21-262/S-006

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 supplemental new drug applications dated August 14, 2001, received August 15, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

Product number	Product Name
20-490/S-007	Alphagan (brimonidine tartrate ophthalmic solution) Ophthalmic Solution 0.5%
20-613/ S-018	Alphagan (brimonidine tartrate ophthalmic solution) Ophthalmic Solution 0.2%
21-262/S-006	Alphagan P (brimonidine tartrate ophthalmic solution) Ophthalmic Solution 0.15%

We acknowledge receipt of your submissions dated September 6 and 12, October 19, November 7 and 16, and December 11, 13, and 17, 2001.

These supplements propose a change in the wording of the pediatric section of the package inserts.

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

The final printed labeling (FPL) must be identical to submitted draft labeling, (package inserts submitted December 13, 2001, for NDA 21-262 and December 17, 2001, for NDAs 20-490 and 20-613).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or

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similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA." Approval of this submission by FDA is not required before the labeling is used.

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 fulfilled the pediatric study requirement at this time.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. 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 inserts directly to:

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

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
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 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

Attachment