These records are from CDER's historical file of information previously disclosed under the Freedom of Information Act (FOIA) for this drug approval and are being posted as is. They have not been previously posted on Drugs@FDA because of the quality (e.g., readability) of some of the records. The documents were redacted before amendments to FOIA required that the volume of redacted information be identified and/or the FOIA exemption be cited. These are the best available copies.

20613

NDA 20-613

Alphagan™

(brimonidine tartrate ophthalmic solution) 0.2% Sterile

Allergan

Volume 1 of 1

Joanne Holmes
phone 7-2527
e-mail HolmesJ

NDA 20-613

Allergan, Inc.
Attention: Adelbert L. Stagg, Ph.D.
Director, Regulatory Affairs
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92713-9534

SEP - 4 1996

Dear Dr. Stagg:

Please refer to your August 31, 1995, new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Alphagan™ (brimonidine tartrate ophthalmic solution) 0.2%.

We acknowledge receipt of your amendments dated October 12 and 23, 1995, and February 26, March 1, 18, 22, and 26, April 5, 11, and 25, May 8, 10 (two), 14, 16, June 4, 12 (two), July 16, and August 28, 1996.

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

We have completed the review of this application, including the submitted draft labeling, 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 draft labeling in the submission dated August 28, 1996 with the following revision: the first sentence of the Clinical Pharmacology section should be revised into the following two sentences, "ALPHAGAN™ is an alpha adrenergic receptor agonist. It has a peak ocular hypotensive effect occurring at two hours post-dosing." Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on August 28, 1996, as revised above. Marketing the product with FPL that is not identical to this revised draft labeling may render the product misbranded and an unapproved new drug.

Please submit sixteen 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. For administrative purposes this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-613. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, additional revisions of that labeling may be required.

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