Dear Mr. Gryziewicz:

Please refer to your supplemental new drug application dated October 14, 2005, received October 17, 2005, 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 November 22, 2005, and February 6, 2006.

This “Changes Being Effected in 30 Days” supplemental new drug application provides for a change in the physician’s sample bottle and its capacity from 10 mL to 5 mL.

We completed our review of this application, as amended. This application 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 immediate container and carton labeling submitted November 22, 2005.

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 are submitted electronically, labeling does not need to be submitted in paper.
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  
Food and Drug Administration  
WO 22, Room 4447  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

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 Valerie Jimenez, Regulatory Health Project Manager, at (301) 796-1345.

Sincerely,

(See appended electronic signature page)

Hasmukh Patel, Ph.D.  
Branch Chief  
Branch VIII, Division of Post-Marketing Evaluation  
Office of New Drug Quality Assessment  
Center for Drug Evaluation and Research

Enclosure
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/
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Hasmukh Patel
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