DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021398/S-007

SUPPLEMENT APPROVAL

Allergan, Inc.
Attention: Kathrin Schalper, PhD, RAC
Senior Manager, US Regulatory Affairs
2525 Dupont Drive
Irvine, CA 92612

Dear Dr. Schalper:

Please refer to your Supplemental New Drug Application (sNDA) dated August 30, 2013, received, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for COMBIGAN (brimonidine tartrate/timolol maleate ophthalmic solution) 0.2%/0.5%. We also refer to your March 30, 2015, submission, which constituted a complete response to our January 9, 2015, action letter.

APPROVAL & LABELING

This "Prior Approval" labeling supplemental new drug application proposes revisions to the package insert to be consistent with the Physician's Label Rule and proposes revisions to the Contraindication, Warnings and Precautions, Adverse Reactions, Drug Interactions, Overdosage, and Patient Counseling Information sections of the label.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below/indicated in the enclosed labeling.

1. Removal of the Recent Major Changes section in the HIGHLIGHTS, as no listings should be one year older than the revision date.
2. Addition of "For Topical Administration" to the product information in the HIGHLIGHTS.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide), with the addition of any labeling changes in pending

"Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 Christina Marshall, Regulatory Project Manager, at (301) 796-3099.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, MD
Deputy Director
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

WILEY A CHAMBERS
10/15/2015