DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22184/S-005

SUPPLEMENT APPROVAL

Allergan, Inc.
Attention: Sally K. Wixson, VMD MS
Manager, US Regulatory Affairs
200 Somerset Corp. Blvd.
Bldg. 200, # 620-5
Bridgewater, NJ 08807

Dear Dr. Wixson:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 16, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for LUMIGAN (bimatoprost ophthalmic solution), 0.01%.

We acknowledge receipt of your amendment dated March 31, 2014. This amendment constituted a complete response to our Complete Response letter dated February 14, 2014.

This "Prior Approval" supplemental new drug application provides for a single package insert for LUMIGAN (bimatoprost ophthalmic solution), 0.01%, and the following revisions to 5.3 Intraocular Pressure, 6.1 Clinical Studies Experience and 6.2 Postmarketing experience sections of the package insert (deletions are in ~~strikethrough~~ and additions are in underlined text):

1. Section 5.3 Intraocular Inflammation is revised as follows:

> ~~**LUMIGAN**® 0.01% and 0.03% should be used with caution in patients with active intraocular inflammation (e.g., uveitis) because the inflammation may be exacerbated.~~
>
> Prostaglandin analogs, including bimatoprost, have been reported to cause intraocular inflammation. In addition, because these products may exacerbate inflammation, caution should be use in patients with active intraocular inflammation (e.g., uveitis).

2. Section 6.1 Clinical Studies Experience, second paragraph, is revised as follows:

> In a 12-month clinical study with bimatoprost ophthalmic solutions 0.01%, the most common adverse reaction was conjunctival hyperemia (31%). Approximately 1.6% of patients discontinued therapy due to conjunctival hyperemia. Other adverse drug reactions (reported in 1 to 4% of patients) with **LUMIGAN**® 0.01% in this study

included conjunctival edema, conjunctival hemorrhage, eye irritation, eye pain, eye pruritus, erythema of eyelid, eyelids pruritus, growth of eyelashes, hypertrichosis, instillation site irritation, punctate keratitis, skin hyperpigmentation, vision blurred, and visual acuity reduced.

3. Section 6.2 Postmarketing Experience section is revised as follows:

The following reaction ~~have~~ has been identified during postmarketing use of **LUMIGAN®** 0.01% in clinical practice. Because ~~they are~~ it was reported voluntarily from a population of unknown size, estimates of frequency cannot be made. The reaction~~s~~, which ~~have~~ has been chosen for inclusion due to either ~~their~~ it's seriousness, frequency of reporting, possible causal connection to **LUMIGAN®** 0.01%, or a combination of these factors, include~~s~~ headache, ~~dizziness, eyelid edema, hypertension, nausea and periorbital and lid changes associated with a deepening of the eyelid sulcus~~.

In postmarketing use with prostaglandin analogs, periorbital and lid changes including deepening of the eyelid sulcus have been observed.

In addition, all throughout the labeling, reference to the Lumigan 0.03% has been deleted.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. 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 revision listed below:

In the Highlights, "for topical ophthalmic use" should be added after the established name of the product, to read: **LUMIGAN® (bimatoprost ophthalmic solution) 0.03% for topical ophthalmic use.**

This change can be implemented at the next printing.

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, except with the requested minor revision listed above, and 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 via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications 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 with the revisions listed above 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 Michael Puglisi, Regulatory Project Manager, at (301) 796-0791.

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: Package Insert

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
09/29/2014