CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-369

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-369

NDA APPROVAL

Allergan, Inc.
Attention: Elizabeth Bancroft
Senior Director, Regulatory Affairs
2525 Dupont Drive
P.O. Box 19534
Irvine, California 92623-9534

Dear Ms. Bancroft:

Please refer to your new drug application (NDA) dated June 26, 2008, received June 27, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Latisse (bimatoprost ophthalmic solution), 0.03%.

We acknowledge receipt of your submissions dated August 18 and 21, September 29, October 21, 24, 28, and 31, and December 9 and 18, 2008.

This new drug application provides for the use of Latisse (bimatoprost ophthalmic solution), 0.03% for treatment of hypotrichosis of the eyelashes by increasing their growth including length, thickness and darkness.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the content of labeling (text for package insert and patient package insert) [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on December 18, 2008.

We acknowledge your December 18, 2008, submission containing final printed carton and container labels. Please submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-369.**" Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PEDIATRIC RESEARCH EQUITY ACT (PREA)

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. We are deferring your submission of pediatric studies for ages 0 to 17 years until December 31, 2012.

Your deferred pediatric study required under section 2 of the Pediatric Research Equity Act (PREA) is considered a required postmarketing study commitment. This commitment is listed below.

Deferred pediatric study under PREA for the treatment of hypotrichosis in pediatric patients ages 0 to 17 years.

Protocol Submission:	by November 30, 2009
Study Start:	by June 30, 2010
Final Report Submission:	by December 31, 2012

Please submit the clinical protocol to your IND for this product. Please submit the final study report to this NDA. The status of this postmarketing study must be reported annually according to 21 CFR 314.81. You should include a status summary of the commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, the number of patients entered into the study. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitments.**"

POSTMARKETING COMMITMENT

We remind you of your postmarketing study commitment in your submission dated December 16, 2008. This commitment is listed below.

To perform a four month, randomized, controlled, comparative study of Latisse (bimatoprost ophthalmic solution) 0.03% in at least 50 African American subjects.

Protocol Submission:	by September 30, 2009
Study Start:	by May 31, 2010
Final Report Submission:	by December 31, 2011

Please submit the clinical protocol to your IND for this product. Please submit the study final report to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of the commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, the number of patients entered into the study. All submissions, including supplements, relating to these postmarketing study commitments should be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence.**"

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

Please submit one market package of the drug product when it is available.

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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, Project Manager, at (301) 796-0791.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Acting Director
Division of Anti-Infective
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 Chambers
12/24/2008 12:32:36 PM