



NDA 21-275/S-014

NDA 21-275/S-015

Allergan, Inc.  
Attention: Stephen Buxbaum  
Director, Regulatory Affairs  
2525 Dupont Drive  
P.O. Box 19534  
Irvine, CA 92623-9534

Dear Mr. Buxbaum:

Please refer to your supplemental new drug applications dated July 29, 2003, received August 1, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lumigan (bimatoprost ophthalmic solution) 0.03%.

We acknowledge receipt of your submission dated September 15, 2003.

These supplemental new drug applications provide for a change in the storage temperature range for the drug product and revised labeling.

We completed our review of these applications, as amended. These applications are 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 labeling (package insert and immediate container and carton labels submitted July 29, 2003).

The following revision should be made to the package insert labeling at the time of next printing:

In the DESCRIPTION section, the unit designation mg/mL should read mg.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-275/S-014, S-015." Approval of this submission by FDA is not required before the labeling is used.

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In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

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, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

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

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) 827-2090.

Sincerely,

*{See appended electronic signature page}*

Linda L. Ng, Ph.D.  
Chemistry Team Leader for the  
Division of Anti-Inflammatory, Analgesic  
and Ophthalmic Drug Products, HFD-550  
DNDC III, Office of New Drug Chemistry  
Center for Drug Evaluation and Research

Enclosure

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/s/

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Linda Ng  
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