DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-586/S-025
NDA 50-586/S-026

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

Dear Ms. Bancroft:

Please refer to your supplemental new drug application dated June 24, 2002, received June 25, 2002, submitted under the Federal Food, Drug, and Cosmetic Act for Pred-G (gentamicin and prednisolone acetate ophthalmic suspension, USP) 0.3%/1.0%.

These applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated June 30, and July 7, 2005, which constituted a complete response to our June 19, 2003, approvable letter.

These "Changes Being Effected in 30 days" supplemental new drug applications propose the (b)(4) container/closure system and changes to the 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 consistent with the enclosed labeling (text for the package insert, carton and container labels) submitted on July 7, 2005. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

In addition, we recommend that a future labeling supplement include the following changes:

> Under the DESCRIPTION section of the package insert, a period should be placed at the end of the sentence that reads "May contain sodium hydroxide and/or hydrochloric acid to adjust the pH (5.4 to 6.6)." This may be corrected with the next labeling supplement.

Under the DOSAGE AND ADMINISTRATION the section of the package insert, the letters of the word "precautions" should be capitalized in the final sentence. This may be corrected with the next labeling supplement.

The American Academy of Ophthalmology has assigned Pink Pantone 197C as cap color for anti-inflammatory products. It is recommended that this product conform to that assignment in a future supplement.

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). If formatted copies of all labeling pieces are submitted electronically, labeling does not need to be submitted in paper.

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 the Division of Anti-Infective and Ophthalmology Products and two copies of both the promotional materials and the package insert directly 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

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 Raphael R. Rodriguez, Regulatory Project Manager, at (301) 796-0798.

Sincerely,

{See appended electronic signature page}

Linda L. Ng, Ph.D.
Chemistry Team leader for the
Division of Anti-Infective and
Ophthalmology Products, HFD-520
DNDC III, Office of New Drug Chemistry
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/

Linda Ng

12/20/2005 10:01:13 AM