DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-760/S-009

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 January 15, 2001, received January 17, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FML (fluorometholone ophthalmic ointment) 0.1%.

We acknowledge receipt of your submissions dated June 19 and 29, 2001.

This supplemental new drug application provides for a change in the manufacturing site of the drug product, the addition of an alternate manufacturer of the drug substance, and revised labeling.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

As discussed by telephone on May 30, 2001, between yourself and Ms. Joanne Holmes of this Division, the following revisions will be made:

1. The statement "CAUTION: Federal (U.S.A.) law prohibits dispensing without a prescription" will be revised to "Rx only" on the package insert and the carton label.

2. A Geriatric Use subsection will be added to the Precautions section of the package insert. It will read "**Geriatric Use:** No overall differences in safety or effectiveness have been observed between elderly and younger patients."

3. In the first sentence of the Warnings section of the package insert, the comma after "defects in visual acuity" will be removed.

The final printed labeling (FPL) must be identical, and include the revisions indicated, to the draft labeling of the package insert and immediate container and carton labels submitted January 15, 2001. These revisions are terms of the approval of this application.

In addition, we have the following recommendations:

4. The cap type and color, the tube type and color, and the fill weight should be included in the How Supplied section of the package insert.

5. Pantone color Pink 197C was assigned as the cap color for anti-inflammatory products by the American Academy of Ophthalmology. We request that this product conform to that recommendation.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-760/S-009." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Raphael R. Rodriguez, MSA, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic
Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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
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