DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 16-851/S-051

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 November 24, 1998, received November 25, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FML (fluorometholone ophthalmic solution, USP) 0.1%.

We acknowledge receipt of your submissions dated February 17, 1999, and April 5, 2001. Your submission of April 5, 2001, constituted a complete response to our February 5, 1999, action letter.

This "Changes Being Effected" supplemental new drug application provides for revised labeling of the package insert.

We have completed the review of this supplemental application, as amended, 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 June 6, 2001, between yourself and Ms. Joanne Holmes of this Division, the following revisions will be made:

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

2. Steroids should not be used in the presence of an infection. The following statement will be deleted from the Warnings section: "Since FML ophthalmic suspension 0.1% contains no antimicrobial, if infection is present, appropriate measures must be taken to counteract the organisms involved."

The final printed labeling (FPL) must be identical, and include the revisions indicated, to the submitted draft labeling of the package insert submitted April 5, 2001. These revisions are terms of the approval of this application.

In addition, we have the following recommendations:

4. The pH and osmolality should be specified in the Description section of the package insert.

5. The target fill volume for each container size and the color and type of plastic for the bottle, dropper tip, and cap should be included in the How Supplied section of the package insert.

6. 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 16-851/S-051." 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