DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-760/S-015

Allergan, Inc.
Attention: Linda J. Bland
Regulatory Affairs Specialist
2525 Dupont Drive
Irvine, CA 92612

Dear Ms. Bland:

Please refer to your supplemental new drug application dated May 11, 2007, received May 14, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FML® (fluorometholone) ophthalmic ointment.

We acknowledge receipt of your submission dated August 24, 2007.

This supplemental new drug application proposes an alternate container/closure system for FML® Ointment and a change of the label statement for storage conditions to read: "Store between 15° - 25°C (59° - 77°F). Avoid exposure to temperatures about 40°C (104°F)."

We completed our review of this supplemental new drug application, as amended. This supplement is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Valerie Jimenez, MS, Senior Regulatory Project Manager, at (301) 796-1345.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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/

Hasmukh Patel

9/12/2007 03:30:53 PM