



NDA 19-216/SCP-021  
NDA 19-216/SLR-022

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 FML FORTE (fluorometholone ophthalmic suspension, USP) 0.25%.

We acknowledge receipt of your submission dated July 15, 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 15, 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 change:

(b) (4)

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*

NDA 19-216/SCP-021

NDA 19-216/SLR-022

Page 2

*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  
1/10/2006 01:12:56 PM