DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-996

Alimera Sciences, Inc.
Attention: Barbara H. Bauschka
Manager, Regulatory Affairs
6120 Windward Parkway, Suite 290
Alpharetta, GA 30005

Dear Ms. Bauschka:

Please refer to your new drug application (NDA) dated January 31, 2006, received February 1, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Alaway (ketotifen fumarate ophthalmic solution) 0.025%.

We acknowledge receipt of your submissions dated May 25, June 28, August 18, and 30, September 1, 6, 18, and 20, October 12, 17, 20, 23, and 26, and November 1 (2), 2006.

This new drug application provides for the use of Alaway (ketotifen fumarate ophthalmic solution), 0.025% for the temporary relief of itchy eyes due to ragweed, pollen, grass, animal hair, and dander.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Please be reminded that the flag "NEW" must be deleted from the principal display, right, and top panels, six months after introduction of the product into the OTC marketplace.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the immediate container and carton labels), and must be in the "Drug Facts" format (21 CFR 201.66). Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

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, we request that you submit two copies of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Please send one of the copies to the Division of Anti-Infective and Ophthalmology Products and the other copy, along with the labeling, to Division of Nonprescription Clinical Evaluation, HFD-560.

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

Please submit one market package of the drug product when it is available.

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

Oversight of this application is being transferred to the Division of Nonprescription Clinical Evaluation.

If you have any questions, call Keith Olin, Regulatory Project Manager, at (301) 796-0962.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Andrea Segal
12/1/2006 12:04:56 PM

Janice Soreth
12/1/2006 01:12:35 PM