DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-066/S-011

Novartis Pharmaceuticals Corporation
Attention: Bridget Walton, MS, RAC
Senior Regulatory Manager
Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Walton:

Please refer to your supplemental new drug application dated December 16, 2005, received December 19, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zaditor™ (ketotifen fumarate ophthalmic solution).

We acknowledge receipt of your submissions dated February 23, April 12, August 22, and 25, September 3, and October 2, 2006.

This supplemental new drug application provides for the switch of Zaditor™ (ketotifen fumarate ophthalmic solution) from prescription only to the to over-the-counter indication of the temporary relief of itchy eyes due to pollen, ragweed, grass, animal hair, and dander.

We completed our review of this application, as amended. This application is 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 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.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

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 labeling, to the 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.

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

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 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

Enclosures

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
10/19/2006 11:48:05 AM

Janice Soreth
10/19/2006 11:49:17 AM