DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021066/S-018

SUPPLEMENT APPROVAL

Alcon Research, Ltd.
Attention: C. Bradley Wooldridge, M.S.
Director, Regulatory Affairs
6201 South Freeway, R3-52
Fort Worth, TX 76134-2099

Dear Mr. Wooldridge:

Please refer to your Supplemental New Drug Application (sNDA) dated March 11, 2010, received March 11, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zaditor® (ketotifen fumarate) ophthalmic solution, 0.035% (equivalent to ketotifen, 0.025%).

We acknowledge receipt of your amendments dated November 4, 2011 and April 26, 2012.

The November 4, 2011, submission constituted a complete response to our August 31, 2010, action letter.

This "Prior Approval" supplemental new drug application provides for the following changes to the 5 ml carton (representative of the 5 ml twin pack carton label) and immediate container labels:

Carton Label:

- revision of tamper-resistant statement
- addition of dosage strength to the Principal Display Panel (PDP)
- addition of "For external use only" warning to the "Drug Facts" label
- revision to the "Questions?" section of the "Drug Facts" label
- revision of inactive ingredients in the "Drug Facts" label
- provision for expiration date and control or lot number
- corporate name change

Immediate Container Label:

- addition of dosage strength to the to the statement of identity
- revision of tamper-resistant statement
- corporate name change

We have 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.

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the submitted labeling (5 ml immediate container and carton labels submitted April 26, 2012) and must be in the "Drug Facts" format (21 CFR 201.66), where applicable. As representative labeling is not acceptable for FPL, please include the 5 ml twin pack carton label as part of your FPL submission for S-018.

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021066/S-018**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REPORTING REQUIREMENTS

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

If you have questions, call Jeff Buchanan, Regulatory Project Manager, at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton and Immediate Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOEL SCHIFFENBAUER
05/03/2012