DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-862

Alcon, Inc.
Alcon Research, Ltd.
Attn: Angela C. Kothe, O.D., Ph.D.
Associate Director, Regulatory Affairs
Mail Code R7-18
6201 South Freeway
Fort Worth, TX 76134-2099

Dear Dr. Kothe:

Please refer to your new drug application (NDA) dated February 25, 2005, received February 28, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NEVANAC (nepafenac ophthalmic suspension) 0.1%.

We acknowledge receipt of your submissions dated December 21, 2004, and May 9, June 2, 20, 24, and 27, July 27, and August 5, and 12, 2005.

This new drug application provides for the use of NEVANAC (nepafenac ophthalmic suspension) 0.1% for the treatment of pain and inflammation associated with cataract surgery.

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.

The final printed labeling (FPL) must be consistent with the enclosed draft package insert submitted August 5, 2005, and carton container labeling submitted August 12, 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.

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). The guidances specify that labeling is to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, container labels, and carton labels) 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 are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional and educational 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:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20795-1266

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).

If you have any questions, contact Raphael R. Rodriguez, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Mark J. Goldberger, M.D.
Director
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: Draft Package Insert

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

/s/

Edward Cox
8/19/2005 04:29:21 PM
for Mark J. Goldberger, MD, MPH