DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-862/S-008

SUPPLEMENT APPROVAL

Alcon, Inc.
c/o Alcon Research, Ltd.
Attention: Angela C. Kothe, OD, Ph.D.
Senior Director, Regulatory Affairs
6201 South Freeway R3-52
Fort Worth, TX 76134-2099

Dear Dr. Kothe:

Please refer to your Supplemental New Drug Application (sNDA) dated June 22, 2011, received June 23, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NEVANAC® (nepafenac ophthalmic suspension) 0.1%.

This "Prior Approval" supplemental new drug application proposes revisions to the package insert and the carton labeling. Specifically,

Revisions to the package insert include:

- Clarification of the Dosage and Administration section (in the Highlights and the Full Prescribing Information)
- An additional instruction in Section 2.2 (Use with Other Topical Ophthalmic Medications)
- An additional recommendation to Section 17.2 (Avoiding Contamination of the Product)
- A correction to the Warnings and Precautions section of the Highlights

Revisions to the carton labeling for the trade and professional sample presentations include:

- Removal of the graphic
- Clarification of the instructions under "Usual Dosage" (consistent with the change made in the package insert)

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

In a future labeling supplement, we recommend that the abbreviation for nonsteroidal anti-inflammatory (NSAID) be included with the term the first time nonsteroidal anti-inflammatory is used in the package insert. Currently, the full name first appears under the Indications and Usage heading of the Highlights without the abbreviation (NSAID).

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical except with the revision-listed above, to the enclosed labeling (text for the package insert) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes with the revisions indicated above approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

We acknowledge your June 22, 2011, submission containing final printed carton labels.

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 regarding this supplement application, please call Ms. Leanna Kelly, Consumer Safety Officer, at (301) 796-1600. For all other inquiries regarding this NDA, please call Mr. Raphael Rodriguez, Regulatory Project Manager, at (301) 796-0798.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Carton Labeling

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

/s/

WILEY A CHAMBERS
06/27/2011