CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203491Orig1s000

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203491

NDA APPROVAL

Alcon Research, Ltd.
Attention: Norma J. Schafer, M.S.
Manager, Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Ms. Schafer:

Please refer to your New Drug Application (NDA) dated December 15, 2011, received December 16, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for nepafenac ophthalmic suspension, 0.3%.

We acknowledge receipt of your amendments dated:

February 10, 2012	July 16, 2012	September 7, 2012
February 13, 2012	July 17, 2012	September 10, 2012
March 15, 2012	July 25, 2012	September 12, 2012
April 6, 2012	July 27, 2012	September 17, 2012
May 7, 2012	August 20, 2012	October 12, 2012
June 6, 2012	August 30, 2012	October 15, 2012

We note that your October 15, 2012, submission, received October 16, 2012, includes final printed labeling (FPL) for the package insert and PDF mock-ups of the carton, container, and pouch labels.

This new drug application provides for the use of nepafenac ophthalmic suspension, 0.3% for the treatment of pain and inflammation associated with cataract surgery.

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 enclosed agreed-upon labeling text and with the minor editorial revisions listed below.

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During an October 16, 2012, teleconference between Ms. Norma Schafer of Alcon and Dr. William Boyd and Ms. Diana Willard of the Agency, it was agreed that the following minor editorial changes would be made to correct the inconsistencies within different sections of the labeling, including labels, submitted October 16, 2012:

1. To be consistent with the agreed-upon text in the **FULL PRESCRIBING INFORMATION, 6 ADVERSE REACTIONS** section, the **ADVERSE REACTIONS** wording in the **HIGHLIGHTS OF PRESCRIBING INFORMATION** section will be changed from:

   ADVERSE REACTIONS
   6.1 Ocular Adverse Reactions
   6.2 Non-Ocular Adverse Reactions

   to:

   ADVERSE REACTIONS
   6.1 Serious and Otherwise Important Adverse Reactions
   6.2 Ocular Adverse Reactions
   6.3 Non-Ocular Adverse Reactions

2. To be consistent with the agreed-upon text in the **FULL PRESCRIBING INFORMATION, 17 PATIENT COUNSELING INFORMATION** section, the wording "**SHAKE WELL THEN INVERT CONTAINER AND SHAKE ONCE BEFORE USING**." on the carton and container labels will be changed to "**SHAKE WELL BEFORE USE.**"

CONTENT OF LABELING

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 to the enclosed labeling (text for the package insert) with the editorial correction identified above. 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.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your October 16, 2012, submission containing final printed carton and container labels.

Marketing the product with FPL that is not identical to the labeling text attached to this letter with the editorial corrections identified above may render the product misbranded and an unapproved new drug.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry titled, "Contents of a Complete Submission for the Evaluation of Proprietary Names", at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf and "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012".)

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 any questions, call Diana Willard, Chief, Project Management Staff, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Carton and 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/

RENATA ALBRECHT
10/16/2012