DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-764/S-002

SUPPLEMENT APPROVAL

Alcon, Inc.
Alcon Research, Ltd.
Attention: Michael C. Son, Ph.D., RAC
Manager II, Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134-2099

Dear Dr. Son:

Please refer to your Supplemental New Drug Application (sNDA) dated December 12, 2008, received December 15, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Brimonidine Tartrate Ophthalmic Solution, 0.15%.

The June 17, 2009, submission constituted a complete response to our June 2, 2009, action letter.

This "Prior Approval" supplemental new drug application provides for revision of the current package insert in the Physician's Label Rule (PLR) format.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, labeling text as agreed upon in a communication between you and Maureen Dillon-Parker of this Division on July 29, 2010.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (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 approved in this supplemental application.

If you intend to have a proprietary name for this product, we recommend that you submit a request for a proposed proprietary name review. (See the draft guidance for industry titled "Complete Submission for the Evaluation of Proprietary Names", at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".)

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 Raphael Rodriguez, Regulatory Project Manager, at (301) 796-0798.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, MD
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21764	SUPPL-2	ALCON RESEARCH LTD	BRIMONIDINE TARTRATE OPHTHALMIC SOL 0.15

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
08/03/2010