DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-816/S-012

SUPPLEMENT APPROVAL

Alcon, Inc.
c/o Alcon Research, Ltd.
Attention: Michael C. Son, Ph.D., RAC
Senior Manager, Regulatory Affairs
6201 South Freeway, R3-52
Fort Worth, TX 76134-2099

Dear Dr. Son:

Please refer to your Supplemental New Drug Application (sNDA) dated January 30, 2009, received February 2, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Azopt (brinzolamide ophthalmic suspension) 1%.

We also refer to our approval letter dated March 8, 2011, which contained the following errors:

1. In Section 11 Description, the amount of benzalkonium chloride per mL of Azopt is incorrectly listed as 0.01 mg. The correct amount of benzalkonium chloride per mL of Azopt is 0.1 mg.
2. The prior action letter date for S-012 was incorrectly listed as July 28, 2010. The correct date of the prior action letter is June 28, 2010.

This replacement approval letter incorporates the correction of the errors. The effective approval date will remain March 8, 2011, the date of the original approval letter.

We acknowledge receipt of your amendments dated July 27, and August 31, 2010.

The July 27, 2010, submission constituted a complete response to our June 28, 2010, 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, agreed-upon labeling text.

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 and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements and any 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 from 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 approved in this supplemental application.

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

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE: 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
03/08/2011