DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22428/S-001

**SUPPLEMENT APPROVAL**

Alcon Pharmaceuticals, Ltd.
c/o Alcon Research, Ltd.
Attention: Karen Lankow
Associate Director, Regulatory Affairs
6201 South Freeway Mail Code R3-52
Fort Worth, TX 76134-2099

Dear Ms. Lankow:

Please refer to your Supplemental New Drug Application (sNDA) dated June 7, 2011, received June 8, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Moxeza (moxifloxacin hydrochloride ophthalmic solution) 0.5%.

This "Prior Approval" supplemental new drug application proposes revision to the carton graphics for the Moxeza trade size (3 mL) and professional sample size (1 mL) cartons.

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.

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on June 7, 2011, as soon as they are available, but no more than 30 days after they are printed.

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "Product Correspondence – Final Printed Carton and Container Labels for approved NDA 22-428/S-001." Approval of this submission by FDA is not required before the labeling is used.

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 supplemental application, call Ms. Leanna Kelly, Consumer Safety Officer, at (301) 796-0471. For all other inquiries regarding this NDA, please contact Ms. Judit Milstein, Chief, Project Management Staff, at (301) 796-0763.

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

ENCLOSURE:
Carton and Container Labeling

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

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/s/

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WILEY A CHAMBERS
10/18/2011