



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-796/S-014

Alcon Research Ltd.
Attention: Michael C. Son, Ph.D.
Manager II, Regulatory Affairs
6201 South Freeway, R7-18
Ft. Worth, TX 76134

Dear Dr. Son:

Please refer to your supplemental new drug application dated April 6, 2007, received April 9, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pilopine HS (pilocarpine hydrochloride ophthalmic gel) 4%.

We acknowledge receipt of your submissions dated October 16, 2007, and January 31, 2008. The October 16, 2007, submission constituted a complete response to our approvable letter dated October 4, 2007.

This 'changes be effected' supplemental new drug application provides for the addition of a geriatric statement to the labeling.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on January 31, 2008.

We note that your January 31, 2008, submission includes final printed labeling (FPL) for your package insert. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
10903 New Hampshire Avenue
Building 22, Mail Stop 4447
Silver Spring, MD 20993-0002

If you have any questions, call Lori Gorski, Regulatory Health Project Manager, at (301) 796-0722.

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 Evaluation and Research

Enclosure

**This is a representation of an electronic record that was signed electronically and
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/s/

Wiley Chambers
4/17/2008 08:48:03 AM