DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-545/S-006

Alcon Research, Ltd.
Attention: Richard O. Reese
Manager, Regulatory Affairs
6201 South Freeway, R7-16
Fort Worth, TX 76134-2099

Dear Mr. Reese:

Please refer to your supplemental new drug application dated October 25, 2006, received October 26, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pataday™ (olopatadine hydrochloride ophthalmic solution) 0.2%.

This "Changes Being Effected" supplemental new drug application provides for minor edits to the labeling.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling package insert and immediate carton labels submitted October 25, 2006.

In the next labeling supplement, it is recommended that you place the preservative under "Inactives" on the container cartons consistent with approved package insert.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Alison Rodgers, Regulatory Project Manager, at (301) 796-0797.

Sincerely,

{See appended electronic signature page}

Janice Soreth, MD
Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Janice Soreth

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