



NDA 21-545/S-008

NDA 21-545/S-009

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 applications dated December 12, 2006, received December 13, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pataday™ (olopatadine hydrochloride ophthalmic solution) 0.2%.

We acknowledge receipt of your submission dated May 30, 2007 (S-008).

These “Changes Being Effectuated in 30 days” supplemental new drug applications provide for:

- A new sample size; a 0.5 mL labeled fill in a 4 mL oval bottle configuration.
- Withdrawal of the currently approved sample size; the 0.25 mL labeled fill volume.

The current trade size configuration, 2.5 mL fill in the same 4 mL oval bottle will not change. The 2.5 mL trade size configuration, labeled and approved as a physician’s sample packaging configuration, will not change.

We completed our review of these supplemental new drug applications as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling must be identical to the immediate carton and container labels submitted December 12, 2006.

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

NDA 21-545/S-008

NDA 21-545/S-009

Page 2

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

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

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Janice Soreth  
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