CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 206276/S-001

Trade Name: PAZEO

Generic Name: olopatadine hydrochloride ophthalmic solution

Sponsor: Alcon Research, Ltd.

Approval Date: 11/27/2015

Indication: PAZEO is a mast cell stabilizer indicated for the treatment of ocular itching associated with allergic conjunctivitis.

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 206276/S-001

APPROVAL LETTER

Alcon Research, Ltd.
Attention: Teresa McElvaney, Technical (CMC) Regulatory Affairs, Fort Worth
6201 South Freeway, R3-50
Fort Worth, TX 76134-2099

Dear Ms. McElvaney:

Please refer to your Supplemental New Drug Application (sNDA) dated July 29, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pazeo® (olopatadine hydrochloride) Ophthalmic Solution, 0.7%.

This "Prior Approval" supplemental new drug application provides for addition of an additional fill size (3.5 mL) for the drug product and changes to the package insert and carton label.

We have completed our review of this supplemental new drug application. This supplement is approved.

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 Erin Andrews, Regulatory Business Process Manager, at (240) 402-8578.

Sincerely,

Dorota M. Matecka -S

Digitally signed by Dorota M. Matecka -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300123291, cn=Dorota M. Matecka -S
Date: 2015.11.27 15:02:19 -05'00'

(Signed on behalf of)
Balajee Shanmugam, Ph.D.
Acting Branch Chief, Branch III
Division of New Drug Product I
Office of New Drug Products
Center for Drug Evaluation and Research Branch

Enclosures:
Carton and Container Image
Prescriber Information

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LABELING

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