CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

206276Orig1s000

Trade Name:	Pazeo 0.7%
Generic Name:	olopatadine hydrochloride ophthalmic solution
Sponsor:	Alcon Research, Ltd..
Approval Date:	January 30, 2015
Indication:	For the treatment of ocular itching associated with allergic conjunctivitis.

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 206276

NDA APPROVAL

Alcon Research, Ltd.
Attention: Naj Sharif, PhD
Global Regulatory Project Manager
6201 South Freeway
Mail Stop: TC-45
Fort Worth, TX 76134-2099

Dear Dr. Shariff:

Please refer to your New Drug Application (NDA) dated and received, July 30, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pazeo (olopatadine hydrochloride ophthalmic solution) 0.7%.

We acknowledge receipt of your amendments dated:

August 5, 2014	October 6, 2014	December 4, 2014
August 25, 2014	October 15, 2014	December 17, 2014
August 28, 2014	October 17, 2014	January 22, 2015
September 4, 2014	October 23, 2014	January 29, 2015
October 3, 2014	October 29, 2014	

This new drug application provides for the use of Pazeo (olopatadine hydrochloride ophthalmic solution) 0.7% for the treatment of ocular itching associated with allergic conjunctivitis.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm.

Content of labeling must be identical to the enclosed labeling text for the package insert. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels received January 29, 2015, 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 *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 "**Final Printed Carton and Container Labels for approved NDA 206276**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric studies requirement for ages 0 to < 2 years because studies are impossible or highly impracticable. This is because allergic conjunctivitis cannot be reliably diagnosed below the age of 2 and therefore the number of potential pediatric patients with the condition is very small.

We note that you have fulfilled the pediatric studies requirement for ages 2 to 16 years for this application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the

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