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RESEARCH**

APPLICATION NUMBER:

206276Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW MEMORANDUM

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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Date of This Review:	December 4, 2014
Application Type and Number:	NDA 206276
Product Name and Strength:	Pazeo (Olopatadine hydrochloride) Ophthalmic Solution, 0.77%
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Alcon
Submission Date:	October 15, 2014
Panorama #:	2014-39505
DMEPA Primary Reviewer:	Rachna Kapoor, PharmD
DMEPA Associate Director:	Yelena Maslov, PharmD

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1 INTRODUCTION

The proposed proprietary name, Pazeo, was found acceptable in OSE Review #2013-16781, dated May 19, 2014 under IND 060991. We note that product characteristics are the same for NDA 206276 currently under review as the IND. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Pazeo, is acceptable from both a promotional and safety perspective under the NDA 206276.

If you have further questions or need clarifications, please contact Karen Townsend, OSE project manager, at 301-796-5413.

2 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Pazeo, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your October 15, 2014 submission are altered, the name must be resubmitted for review.

REFERENCES

1. Kapoor R and Maslov Y. Proprietary name review for Pazeo (IND 060991). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); May 19, 2014. OSE RCM No.: 2013-16781.

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/s/

RACHNA KAPOOR
12/04/2014

YELENA L MASLOV
12/09/2014