

**CENTER FOR DRUG EVALUATION AND
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)

***** This document contains proprietary information that cannot be released to the public*****

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

Contents

1 INTRODUCTION **Error! Bookmark not defined.**
1.1 Comments to the Applicant 1
2 REFERENCES..... 2

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.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.