

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**207988Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

**Proprietary Name 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\*\*\***

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**Date of This Review:** March 6, 2015  
**Requesting Office or Division:** Division of Pulmonary, Allergy, and Rheumatology Products (DPARP)  
**Application Type and Number:** NDA 207988  
**Product Name and Strength:** Zurampic (Lesinurad) Tablets, 200 mg  
**Product Type:** Single Ingredient Product  
**Rx or OTC:** Rx  
**Applicant/Sponsor Name:** GlaxoSmithKline  
**Submission Date:** January 12, 2015  
**Panorama #:** 2014-42583  
**DMEPA Primary Reviewer:** Teresa McMillan, PharmD  
**DMEPA Team Leader:** Kendra Worthy, PharmD

## 1 INTRODUCTION

This memorandum is to re-assess the proposed proprietary name, Zurampic under NDA 207988, which was found acceptable under IND 102128<sup>1</sup>. We note that there is the following minor change in product characteristics: [REDACTED] (b) (4)

[REDACTED] All other product characteristics are the same.

## 2 METHODS AND DISCUSSION

For re-assessment of the proposed proprietary name, DMEPA conducted a gap analysis and searched the POCA database (see section 5) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review # 2014-17059. Additionally, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. We also evaluated previously identified names taking into account [REDACTED] (b) (4) [REDACTED]. Our POCA search identified three new names, [REDACTED] (b) (4) and Movantik. None of the new names represent a potential source of drug name confusion. As a result, we maintain that the name is acceptable.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The February 4, 2015 search of USAN stems did not find any USAN stems in the proposed proprietary name.

## 3 CONCLUSIONS

DMEPA maintains the proposed proprietary name, Zurampic, is acceptable from both a promotional and safety perspective under the NDA 207988.

If you have further questions or need clarifications, please contact Sarah Harris, OSE Project Manager, at 240-402-4774.

## 4 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your January 12, 2015 submission are altered, the name must be resubmitted for review.

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<sup>1</sup> McMillan, Teresa S. Proprietary Name Review for Zurampic (IND 102128). 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); 2014 July 17. 24 OSE RCM No.: 2014-17059.

## 5 REFERENCES

1. **USAN Stems** (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?>) USAN Stems List contains all the recognized USAN stems.
2. **Phonetic and Orthographic Computer Analysis (POCA)**  
POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

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/s/  
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TERESA S MCMILLAN  
03/06/2015

KENDRA C WORTHY  
03/06/2015