

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

207695Orig1s000

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)

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Date of This Review: March 9, 2016
Application Type and Number: NDA 207695
Product Name and Strength: Eucrisa (crisaborole) Ointment, 2%
Product Type: Single ingredient product
Rx or OTC: Rx
Applicant/Sponsor Name: Anacor Pharmaceuticals
Panorama #: 2016-2751092
DMEPA Primary Reviewer: Carlos M Mena-Grillasca, RPh
DMEPA Team Leader (Acting): Mishale Mistry, PharmD, MPH

1 INTRODUCTION

The proposed proprietary name, Eucrisa, was reviewed by DMEPA on January 19, 2016¹ under IND 077537 and was found conditionally acceptable. This memorandum is to reassess the proposed proprietary name, Eucrisa, under NDA 207695.

2 METHODS AND DISCUSSION

For re-assessment of the proposed proprietary name, DMEPA searched the POCA databases² to identify new names with orthographic and phonetic similarity that were not identified in the previous OSE proprietary name review. Additionally, we searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN update. We note that none of the product characteristics have changed since our previous review.

Our re-assessment did not identify any new names that represent a potential source of drug name confusion. Finally, the February 24, 2016 search of the USAN stems did not find any USAN stems in the proposed proprietary name.

Therefore, our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name and we maintain that the name is acceptable.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Dermatology and Dental Products (DDDP) concurred with the findings of OPDP's assessment of the proposed name.

3 CONCLUSIONS

DMEPA maintains the proposed proprietary name is acceptable from both a promotional and safety perspective under the NDA 207695.

If you have further questions or need clarifications, please contact Janet Anderson, OSE project manager, at 301-796-0675.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your February 4, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

¹ Mena-Grillasca C. Proprietary Name Review for Eucrisa (IND 077537). 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); 2016 JAN 19. Panorama No. 2015-1120654.

² Date searched: February 24, 2016; Databases searched: Drugs@FDA and Names Entered by Safety Evaluators

4 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.

Drugs@FDA

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Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther biological>).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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/s/

CARLOS M MENA-GRILLASCA
03/09/2016

MISHALE P MISTRY
03/10/2016