

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208079Orig1s000

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*****

Date of This Review: September 3, 2015
Application Type and Number: NDA 208079
Product Name and Strength: Sernivo (betamethasone dipropionate) Topical Spray, 0.05%
Product Type: Single ingredient product
Rx or OTC: Rx
Applicant/Sponsor Name: Promius Pharma LLC
Panorama #: 2015-887002
DMEPA Primary Reviewer: Carlos M Mena-Grillasca, RPh
DMEPA Team Leader: Kendra Worthy, PharmD
DMEPA Associate Director: Lubna Merchant, MS, PharmD

1 INTRODUCTION

The proposed proprietary name, Sernivo, was reviewed by DMEPA on October 23, 2014¹ and was found acceptable. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Sernivo, is acceptable from both a misbranding and safety perspective under the NDA 208079.

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.

Our re-assessment identified 7 new names that represent a potential source of drug name confusion. However, none of the names pose a risk for confusion as described in Appendices A through C. Finally, the August 24, 2015 search of the USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

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, Sernivo, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your June 30, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

¹ Mena-Grillasca C. Proposed Proprietary Name Review for Sernivo (IND 104853). 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 OCT 23. Panorama No. 2014-25534.

² Date searched: August 24, 2015; 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

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present.

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

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A: Moderately Similar Names (e.g., combined POCA score is $\geq 50\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Sernivo Strength(s): 0.05% Usual Dose: Apply twice daily for up to 4 weeks	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	Zenavod***	58	<p>Dose: Apply to the affected area or UAD vs. 40 mg or 1 capsule.</p> <p>Orthographic: The upstroke letter 'd' at the end of Zenavod help differentiate the names when scripted.</p> <p>Phonetic: The first and second syllables of this name pair sound different.</p>
2.	(b) (4) ***	54	<p>Orthographic: The infixes and suffixes of the names have sufficient orthographic differences.</p> <p>Phonetic: The second and third syllables of this name pair sound different.</p>
3.	(b) (4) ***	53	<p>Dose: Apply to the affected area or UAD vs. (b) (4)</p> <p>Orthographic: The length and infixes names have sufficient orthographic differences.</p> <p>Phonetic: Sernivo has an extra syllable.</p>

Appendix B: Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
4.	(b) (4) ***	61	Proposed name for ANDA 202226 found unacceptable by DMEPA in OSE review 2012-332 and 2012-334, dated October 1, 2012. ANDA 202226 was approved under the name Bekyree.
5.	(b) (4) ***	60	Proposed name for IND (b) (4) found unacceptable by DMEPA in OSE review (b) (4), dated (b) (4)
6.	(b) (4) ***	53	Proposed name for IND (b) (4) found unacceptable by DMEPA in OSE review (b) (4), dated (b) (4)

Appendix C: Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
7.	Carnexiv***	52

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CARLOS M MENA-GRILLASCA
09/03/2015

KENDRA C WORTHY
09/04/2015

LUBNA A MERCHANT
09/04/2015