CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210910Orig1s000

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:	October 11, 2018
Application Type and Number:	NDA 210910
Product Name and Strength:	Aemcolo (rifamycin) Tablets, 194 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Cosmo Technologies, Ltd. c/o Conventus BioMedical Solutions, Inc.
Panorama #:	2018-26167247
DMEPA Team Leader:	Otto L. Townsend, PharmD
DMEPA Team Leader (Acting):	Sevan Kolejian, PharmD, MBA

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Aemcolo, based on the revised strength from 200 mg to 194 mg. The proposed proprietary name, Aemcolo, was previously found conditionally acceptable under NDA 210910 on June 22, 2018.[a]

2 METHODS AND DISCUSSION

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 Anti-Infective Products (DAIP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names taking into account the change in product strength from 200 mg to 194 mg. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The September 26, 2018 search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Nicholas Miles, OSE Project Manager, at 301-796-7025.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on September 25, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

[a] Kolejian, S. Proprietary Name Review for Aemcolo (NDA 210910). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 JUN 22. Panorama No. 2018-22405876.

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.

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/s/

OTTO L TOWNSEND
10/11/2018

SEVAN H KOLEJIAN
10/11/2018

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:	June 22, 2018
Application Type and Number:	NDA 210910
Product Name and Strength:	Aemcolo (rifamycin SV-MMX) Tablets, 200 mg
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Cosmo Technologies, Ltd. c/o Conventus BioMedical Solutions, Inc.
Panorama #:	2018- 22405876
DMEPA Safety Evaluator:	Sevan Kolejian, PharmD, MBA
DMEPA Team Leader:	Otto L. Townsend, PharmD

1. INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Aemcolo, which was found conditionally acceptable under IND 104034 on August 3, 2017.[a] We note that all product characteristics remain the same.

2. METHODS AND DISCUSSION

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 Anit-Infective Products (DAIP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA 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. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The April 23, 2018 search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.3 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Anit-Infective Products (DAIP) via e-mail on June 20, 2018. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DAIP on June 22, 2018, they stated no additional concerns with the proposed proprietary name, Aemcolo.

3. CONCLUSIONS

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Ameet Joshi, OSE Project Manager, at 301-796-6345.

3.1 COMMENTS TO THE APPLICANT

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

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[a] Myers, D. Proprietary Name Review for Aemcolo (IND 104034). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 AUG 3]. Panorama No. 2017-13814600.

If any of the proposed product characteristics as stated in your submission, received on April 17, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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.

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/s/

SEVAN H KOLEJIAN
06/22/2018

OTTO L TOWNSEND
06/22/2018