CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

213004Orig1s000

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:	June 28, 2019
Application Type and Number:	NDA 213004
Product Name and Strength:	Talicia (rifabutin, amoxicillin, and omeprazole) Capsules, 12.5 mg/250 mg/ 10 mg (equivalent to 10.3 mg omeprazole magnesium)[a]
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	RedHill Biopharma, Ltd. (RedHill)
Panorama #:	2019-31411864
DMEPA Safety Evaluator:	Deborah Myers, RPh, MBA
DMEPA Team Leader:	Townsend, Otto, PharmD

[a] The established name and strength have not yet been determined for this product.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Talicia, which was found conditionally acceptable under IND 114552 on December 19, 2018.[b]

We note that there are changes in the product characteristics provided by RedHill (See Section 2.2) for NDA 213004. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Talicia would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Anti-Infective Products (DAIP) concurred with the findings of OPDP's assessment for Talicia.

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. The following changes in product characteristics were provided by RedHill:

- A revised indication incorporating the word, "(b) (4)."

  "Talicia is indicated for the treatment of *H. pylori* infection in adults", revised to "Talicia is indicated for the treatment (b) (4) of *H. pylori* infections in adults."

- (b) (4) Talicia once approved, will (b) (4) be marketed in a carton of two bottles (b) (4). Labeling has been revised to include the bottle and carton labels. (b) (4)

- The order of the actives in the labeling has been rearranged and omeprazole as omeprazole magnesium utilized to acknowledge the active molecule from the salt ex. Talicia, a fixed dose combination capsule of rifabutin, amoxicillin, and omeprazole (as omeprazole magnesium).

- "RHB" will be imprinted in black on the capsule cap and "105" imprinted in black on the capsule base.

- Finally, previously draft labeling was unavailable at the time of original submission. This document includes the draft labeling as submitted in the NDA and the special populations have incorporated this language.

[b] Myers, D. Proprietary Name Review for Talicia (IND 114552). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 DEC 19. Panorama No.: 2018-24104198.

We evaluated previously identified names taking into account the above product characteristic changes and our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Talicia.

Additionally, DMEPA searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The May 8, 2019 search of USAN stems did not find any USAN stems in the proposed proprietary name, Talicia.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Anti-Infective Products (DAIP) via e-mail on June 21, 2019. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Anti-Infective Products (DAIP) on June 28, 2019, they stated no additional concerns with the proposed proprietary name, Talicia.

3 CONCLUSION

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, Talicia, 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 REDHILL BIOPHARMA, LTD. (REDHILL)

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

If any of the proposed product characteristics as stated in your submission, received on May 6, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCE

1. **USAN Stems (**https://www.ama-assn.org/about/united-states-adopted-names-approved-stems**)**

   USAN Stems List contains all the recognized USAN stems.

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/s/

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