CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212379Orig1s000

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:	March 12, 2019
Application Type and Number:	NDA 212379
Product Name and Strength:	Amzeeq (minocycline hydrochloride) foam, 4%
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Foamix Pharmaceuticals Inc.
Panorama #:	2018-28178417
DMEPA Safety Evaluator:	Madhuri R. Patel, PharmD
DMEPA Team Leader (acting):	Teresa McMillan, PharmD

Reference ID: 4502281

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Amzeeq, which was found conditionally acceptable under IND 122770 on March 26, 2018.[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 Amzeeq would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Dermatology and Dental Products (DDDP) concurred with the findings of OPDP's assessment for Amzeeq.

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 proposed proprietary name contains any USAN stems as of the last USAN updates. The December 27, 2018 search of USAN stems did not find any USAN stems in the proposed proprietary name, Amzeeq.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Dermatology and Dental Products (DDDP) via e-mail on March 6, 2019. At that time we also requested additional information or concerns that could inform our review. The Division of Dermatology and Dental Products (DDDP) did not state additional concerns with the proposed proprietary name, Amzeeq.

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, Amzeeq, is acceptable.

If you have any questions or need clarifications, please contact Tri Bui-Nguyen, OSE project manager, at 240-402-3726.

3.1 COMMENTS TO FOAMIX PHARMACEUTICALS INC.

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

If any of the proposed product characteristics as stated in your submission, received on December 20, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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[a] Abraham, S. Proprietary Name Review for Amzeeq (IND 122770). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 MAR 26. Panorama No.: 2017-17963877.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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03/12/2019 08:53:22 AM

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03/12/2019 10:19:34 PM