CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

211801Orig1s000

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:	December 6, 2018
Application Type and Number:	NDA 211801
Product Name and Strength:	Ibsrela (tenapanor) tablets, 50 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Ardelyx, Inc.
Panorama #:	2018-26196968
DMEPA Safety Evaluator:	Sherly Abraham, R.Ph.
DMEPA Team Leader:	Sarah K. Vee, Pharm.D.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Ibsrela, which was found conditionally acceptable under NDA 211801 on August 20, 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 Ibsrela would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Gastroenterology and Inborn Errors Products (DGIEP) concurred with the findings of OPDP's assessment for Ibsrela.

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 3, 2018 search of USAN stems did not find any USAN stems in the proposed proprietary name, Ibsrela.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Gastroenterology and Inborn Errors Products (DGIEP) via e-mail on December 4, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Gastroenterology and Inborn Errors Products (DGIEP) on December 6, 2018, they stated no additional concerns with the proposed proprietary name, Ibsrela.

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, Ibsrela, is acceptable.

If you have further questions or need clarifications, please contact Shawnetta Jackson, OSE project manager, at (301) 796-4952.

3.1 COMMENTS TO ARDELYX, INC.

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

---

[a]Barlow, M. Proprietary Name Review for Ibsrela (NDA 211801). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 Aug 20. Panorama No.: 2018-26196968.

If any of the proposed product characteristics as stated in your submission, received on September 26, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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/

SHERLY ABRAHAM
12/06/2018

SARAH K VEE
12/06/2018