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RESEARCH**

APPLICATION NUMBER:

214662Orig1s000

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:	February 4, 2021
Application Type and Number:	NDA 214662
Product Name and Strength:	Livmarli (maralixibat) oral solution, 9.5 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Mirum Pharmaceuticals Inc (Mirum)
Panorama #:	2020-43885167
DMEPA Safety Evaluator:	Sarah K. Vee, PharmD
DMEPA Team Leader:	Idalia E. Rychlik, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Livmarli, which was found conditionally acceptable under IND 119917 on August 5, 2020.^a

Thus, Mirum submitted the name, Livmarli, under NDA 214662 for re-review on November 12, 2020. We note that there is a change in strength (remains single strength) for NDA 214662 due to the application of the salt policy. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Livmarli would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Hepatology and Nutrition (DHN) concurred with the findings of OPDP's assessment for Livmarli. However, DHN expressed concern between, Livmarli and (b) (4)***. We assess this name pair in section 2.2.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we 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. We also evaluated previously identified names taking into account the change in strength (remains single strength). Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Livmarli.

During the initial phase of the name review, DHN expressed concern between the name pair, Livmarli and (b) (4)***, due to (b) (4). DHN recommended a possible modification to the proposed proprietary name Livmarli***; for example, *"adding a letter to the end of "Livmarli"*** to distinguish it from (b) (4).*

In light of DHN's concerns, we evaluated the name pair and note that (b) (4) provide some orthographic differences. Phonetically, we note that the (b) (4) provide sufficient phonetic differences. Therefore, we find this name pair acceptable.

Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The December 22, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Livmarli.

^a Vee, S. Proprietary Name Review for Livmarli (IND 119917). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 AUG 05. Panorama No.: 2020-39036616.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Hepatology and Nutrition (DHN) via e-mail on January 28, 2021. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Hepatology and Nutrition (DHN) on February 3, 2021, they stated no additional concerns with the proposed proprietary name, Livmarli.

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, Livmarli, is acceptable.

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

3.1 COMMENTS TO MIRUM PHARMACEUTICALS INC

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

If any of the proposed product characteristics as stated in your submission, received on November 12, 2020, 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.

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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