CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214324Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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 15, 2022
Application Type and Number:	NDA 214324
Product Name and Strength:	Tyvaso DPI (treprostinil) inhaler, 16 mcg, 32 mcg, 48 mcg, and 64 mcg
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	United Therapeutics Corporation (UTC)
PNR ID #:	2021-1044724359
DMEPA 2 Safety Evaluator:	Maximilian Straka, PharmD, FISMP
DMEPA 2 Team Leader:	Hina Mehta, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming Tu, PharmD, BCPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Tyvaso DPI, which was found conditionally acceptable under IND 134582 on October 15, 2020[a] and under NDA 214324 on June 9, 2021[b]. However, the Application received a Complete Response on October 15, 2021. UTC resubmitted the proposed proprietary name Tyvaso DPI under NDA 214324 for review on December 23, 2021. 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 Tyvaso DPI would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) and the Division of Cardiology and Nephrology (DCN) concurred with the findings of OPDP's assessment for Tyvaso DPI.

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. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The February 2, 2022 search of USAN stems did not find any USAN stems in the proposed proprietary name, Tyvaso DPI.

2.3 COMMUNICATION OF DMEPA'S DETERMINATION

On February 11, 2022 we communicated our determination to the Division of Cardiology and Nephrology (DCN).

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, Tyvaso DPI, is acceptable.

If you have any questions or need clarifications, please contact Wana Manitpisitkul, OSE project manager, at (240) 402-4156.

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[a] Aidoo, M. Proprietary Name Review for Tyvaso DPI (IND 134582). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 OCT 15. Panorama No.: 2020-39356814.

[b] Aidoo, M. Proprietary Name Review Memo for Tyvaso DPI (NDA 214324). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 JUN 9. Panorama No.: 2021-1044723937.

3.1 COMMENTS TO UNITED THERAPEUTICS CORPORATION

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

If any of the proposed product characteristics as stated in your submission, received on December 23, 2021, 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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