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APPLICATION NUMBER:

208276Orig1s000

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:	April 26, 2018
Application Type and Number:	NDA 208276
Product Name and Strength:	Implantable System for Remodulin [for use with Remodulin (Treprostinil) Injection 200 mg/20 mL]
Product Type:	Device
Rx or OTC:	Rx
Applicant/Sponsor Name:	United Therapeutics Corporation
Panorama #:	2018-20666737
DMEPA Safety Evaluator:	Maximilian Straka, PharmD, FISMP
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS, FISMP

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Implantable System for Remodulin, which was found conditionally acceptable under NDA 208276 on April 7, 2017.[a] We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

The appropriateness of the root name, Remodulin, and the modifiers, "Implantable System for" were evaluated and found acceptable in our previous review and we maintain our previous decision.[b] For re-assessment of the proposed proprietary name, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The February 2, 2018, search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.2 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Cardiovascular and Renal Products (DCRP) via e-mail on April 19, 2018. At that time we also requested additional information or concerns that could inform our review. The Division of Cardiovascular and Renal Products did not forward any additional concerns with the proposed proprietary name, Implantable System for Remodulin.

3 CONCLUSIONS

Our re-assessment did not identify any safety concerns. Therefore, we maintain that the proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Darrell Lyons, OSE project manager, at 301-796-4092.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Implantable System for Remodulin, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your submission, received on January 30, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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[a] Thomas, S. Proprietary Name Review for Implantable System for Remodulin (NDA 208276). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US);2017 Apr 7. Panorama No. 2016- 12573862.

[b] Thomas, S. Proprietary Name Review for Implantable System for Remodulin (NDA 208276). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US);2017 Apr 7. Panorama No. 2016- 12573862.

4 REFERENCES

1. **USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)**
   USAN Stems List contains all the recognized USAN stems.

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/s/

MAXIMILIAN STRAKA
04/26/2018

CHI-MING TU
04/26/2018

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