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RESEARCH**

APPLICATION NUMBER:

203496Orig1s000

CHEMISTRY REVIEW(S)



NDA 203496

**Orenitram (treprostinil) Extended Release Tablets
0.125, 0.25, 1 and 2.5 mg**

United Therapeutics, Inc.

Division of Cardiology and Renal Products, HFD 110

**Shastri Bhamidipati, Ph.D.
Division of New Drug Quality Assessment I
Office of New Drug Quality Assessment**

**Submission Date : 16-AUG-2013
PDUFA Goal Date: 16-FEB-2014**

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Chemistry Review Data Sheet

1. NDA 203496
2. REVIEW #: 4
3. REVIEW DATE: 10-DEC-2013
4. REVIEWER: Shastri Bhamidipati, Ph.D.

5. PREVIOUS DOCUMENTS:

<u>Previous Documents</u>	<u>Document Date</u>
NDA 203496 Original Submission	27-DEC-2011
SD#15 Quality Information	10-AUG-2012
SD#18 Quality Information	24-SEPT-2012
SD# 21 Quality Information	19-OCT-2012

6. SUBMISSION(S) BEING REVIEWED:

<u>Submission(s) Reviewed</u>	<u>Document Date</u>
SD#33 Class 2 Resubmission	16-AUG-2013
SD# 36 Labeling	08-OCT-2013
SD#37 Labeling/Container-Carton Draft	29-OCT-2013
SD#38 Labeling/PPI draft	12-NOV-2013
SD# 39 Proprietary Name	27-NOV-2013

7. NAME & ADDRESS OF APPLICANT:

Name: United Therapeutics, LLC
55 TW Alexander Drive
Address: PO Box 14186
Research Triangle Park, NC 27709



CHEMISTRY REVIEW



Chemistry Review Data Sheet

Representative: Dean Bunce,
Executive Vice President,
Regulatory Affairs & Compliance
55 TW Alexander Drive
PO Box 14186
Research Triangle Park, NC 27709
Telephone: 919-485-8350

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: Treprostinil Extended Release Tablets (Trade name not finalized)
- b) Non-Proprietary Name (USAN): Treprostinil Diolamine
- c) Code Name/# (ONDQA only): N/A
- d) Chem. Type/Submission Priority (ONDQA only):
 - Chem. Type: 3
 - Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: 21 CFR 314.50, 505(b)(1)

10. PHARMACOL. CATEGORY: Cardiology, Pulmonary Arterial Hypertension (PAH)

11. DOSAGE FORM: Extended Release Tablets

12. STRENGTH/POTENCY: 0.125, 0.25, 1.0 and 2.5 mg

13. ROUTE OF ADMINISTRATION: Oral

14. Rx/OTC DISPENSED: Rx OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

SPOTS product – Form Completed

Not a SPOTS product

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