CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-272/S-005

Trade Name: Remodulin Injection 1.0, 2.5, 5.0, and 10 mg/ml.

Generic Name: treprostinil sodium

Sponsor: United Therapeutics Corporation

Approval Date: March 20, 2006

Indications: Remodulin is indicated for the treatment of pulmonary arterial hypertension in patients with NYHA Class II-IV symptoms to diminish symptoms associated with exercise.

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APPLICATION NUMBER:

21-272/S-005

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	**X**
Approvable Letter	
Labeling	**X**
Summary Review	
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	**X**
Chemistry Review(s)	
Environmental Assessment	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Other Review(s)	**X**
Administrative/Correspondence Document(s)	**X**

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APPLICATION NUMBER:

21-272/S-005

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-272/S-005

United Therapeutics Corporation
Attention: Dean Bunce
P.O. Box 14186
One Park Drive
Research Triangle Park, NC 27709

Dear Mr. Bunce:

Please refer to your supplemental new drug application dated October 12, 2005, received October 13, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Remodulin Injection (treprostinil sodium) 1.0, 2.5, 5.0, and 10 mg/ml.

We acknowledge receipt of your submissions dated February 1, 7, 8, 21 and March 6, 2006.

This supplemental new drug application provides a final study report for Phase 4 commitments required as a condition of your May 21, 2002 Subpart H approval. Specifically, this supplement provides information to the labeling on the use of Remodulin Injection (treprostinil sodium) 1.0, 2.5, 5.0, and 10 mg/ml for the treatment of patients with pulmonary arterial hypertension (PAH) requiring transition from Flolan®.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and Providing *Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-272/S-005**." Approval of this submission by FDA is not required before the labeling is used.

We approved this NDA under the regulations at 21 CFR 314 Subpart H for accelerated approval of new drugs for serious or life-threatening illnesses. Approval of this supplement fulfills your commitments made under 21 CFR 314.510.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call:

Mr. John David
Regulatory Project Manager
(301) 796-1059

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Agreed upon labeling text

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