DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-272\S-003

United Therapeutics Corporation
Attention: Rex Mauthe
Senior Vice President, Regulatory Affairs
P.O. Box 14186
One Park Drive
Research Triangle Park, NC 27709

Dear Mr. Mauthe:

Please refer to your supplemental new drug application dated August 11, 2005, received August 15, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Remodulin (treprostinil sodium) 1.0, 2.5, 5.0 and 10 mg/ml injection.

We acknowledge receipt of your submission dated August 11, 2005.

This "Changes Being Effected in 30 days" supplemental new drug application provides revised vial and carton labels in response to the Division of Drug Marketing, Advertising and Communications (DDMAC) March 31, 2005 guidance letter.

We completed our review of this supplemental new drug application. It is are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 11, 2005.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call:

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

Sincerely,

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge
1/20/2006 06:07:38 PM