CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-272

CORRESPONDENCE

ORIGINAL

United Therapeutics CORPORATION

68 T.W. Alexander Drive
P.O. Box 14186
Research Triangle Park, NC 27709
tel 919.485.8350
fax 919.485.8352

NEW CORRESPONDENCE
N-60-C

New Drug Application - General Correspondence

April 2, 2002

Douglas Throckmorton, M.D., Acting Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Cardio-Renal Drug Products, HFD-110
1451 Rockville Pike
Rockville, Maryland 20852

Re: NDA 21-272
Remodulin™ Injection

Dear Dr. Throckmorton:

Reference is made to a telephone conversation today with Ed Fromm of your Division concerning our April 1, 2002, complete response letter.

United Therapeutics herewith commits to the timelines in the February 8, 2002, approvable letter for Protocol P01:13 ("From the date of marketing approval, 50% of planned enrollment for the study should be accomplished within 12 months, with full enrollment by 18 months, and a complete study report should be submitted within 24 months").

Should you have any questions concerning this amendment, please do not hesitate to contact me by phone at 919-485-8350, ext. 192, by facsimile at 919-485-8352, or by email at dbunce@unither.com.

Sincerely,

Dean Bunce
Senior Director, Regulatory Affairs

cc: Robert Temple, M.D., ODEI

Electronic Mail Message

Date: 4/13/01 7:44:03 AM
From: Edward Fromm (FROMME)
To: Dariush Farahifar * (FARAHIFARD)
Cc: Natalia Morgenstern (MORGENSTERN)
Subject: NDA 21-272, Remodulin Injection

Dariush,

Per instructions from Dr. Temple, please classify United Therapeutic's submission dated April 12, 2001 as a Major Multi-discipline Amendment (AZ).

This should extend the review clock by 3 months; the new goal date should be July 16, 2001.

Thank you,

Ed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-272

United Therapeutics Corporation
Attention: Mr. Dean Bunce
P.O. Box 14186
68 T.W. Alexander Drive
Research Triangle Park, NC 27709

Dear Mr. Bunce:

We acknowledge receipt of your July 3, 2001 correspondence notifying us that you are withdrawing your October 16, 2000 new drug application (NDA) for Remodulin (treprostinil sodium) Injection.

Therefore, in accordance with 21 CFR 314.65, this application is withdrawn as of the date of our receipt of your notification, July 5, 2001. This withdrawal does not prejudice any future filing of the application. You may request that the information contained in this withdrawn application be considered in conjunction with any future submission.

If you have any questions, please call:

Mr. Edward Fromm
Regulatory Health Project Manager
(301) 594-5313.

Sincerely,

/S/

{See appended electronic signature page}

Natalia A. Morgenstern
Chief, Project Management Staff
Division of Cardio-Renal Drug 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/

Natalia Morgenstern
7/5/01 03:23:03 PM

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