DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

October 29, 2013

Dean Bunce
Executive Vice President
Regulatory Affairs and Compliance
United Therapeutics Corp.
P.O. Box 14186
55 T.W. Alexander Drive
Research Triangle Park, NC 27709

Re: This is a correction to the acknowledgement letter of 10/23/2013

Dear Mr. Bunce:

Your petition to the Food and Drug Administration requesting the Agency to refrain from approving any ANDA for treprostinil that does not contain the safety information found in Remodulin labeling, was received by this office on 10/17/2013. It was assigned docket number FDA-2013-P-1293/CP1, and it was filed on 10/23/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)

FDA-2013-P-1293

Ack