NDA 021272/S-032

SUPPLEMENT APPROVAL

United Therapeutics Corp.
Attention: Nicole Wilkerson
Associate Director, Regulatory Affairs
55 TW Alexander Drive, PO Box 14186
Research Triangle Park, NC 27709

Dear Ms. Wilkerson:

Please refer to your supplemental new drug application (sNDA) dated March 30, 2021, received March 30, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Remodulin (treprostinil) injection.

This Prior Approval sNDA provides for a new dosage strength, 20mg/mL, of Remodulin (treprostinil) with associated revisions to Sections 3, 11, and 16 of the Package Insert. Carton and container labels for the 20 mg/mL strength were also provided.

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to theenclosed carton and container labeling or carton and container labeling submitted on July 12, 2021, as soon as they are available, but no more than 30 days after they are printed.

Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labeling for approved NDA 021272/S-032**." Approval of this submission by FDA is not required before the labeling is used.

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 Brian Cooney, Regulatory Project Manager, at (301) 796-0886.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD
Deputy Director for Safety
Division of Cardiology and Nephrology
Office of Cardiology, Hematology, Endocrinology, and Nephrology
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARY R SOUTHWORTH
07/30/2021 11:58:31 AM