CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-272

ADMINISTRATIVE DOCUMENTS

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Time Sensitive Patent Information

Pursuant to 21 C.F.R. 314.53

for

NDA #21-272

The following is provided in accordance with the Drug Price Competition and Patent Term Restoration Act of 1984:

- Trade Name: Uniprost™
- Active Ingredient(s): treprostinol sodium (Applied for)
- Strength(s): 1.0 mg/mL, 2.5 mg/mL, 5.0 mg/mL, 10.0 mg/mL
- Dosage Form: Injection
- Approval Date: NDA submitted October 16, 2000

A. This information should be provided for each individual patent submitted.

U.S. Patent Number: 5,153,222

Expiration Date: October 6, 2009

Type of Patent--Indicate all that apply:

1. Drug Substance (Active Ingredient) ___Y ✓N
2. Drug Product (Composition/Formulation) ___Y ✓N
3. Method of Use ✓Y ___N

a. If patent claims method(s) of use, please specify approved method(s)of use or method(s) of use for which approval is being sought that are covered by patent: Treatment of pulmonary hypertension with UT-15.

Name of Patent Owner: United Therapeutics Corp.

U.S. Agent (if patent owner or applicant does not reside or have place of business in the US): Not Applicable

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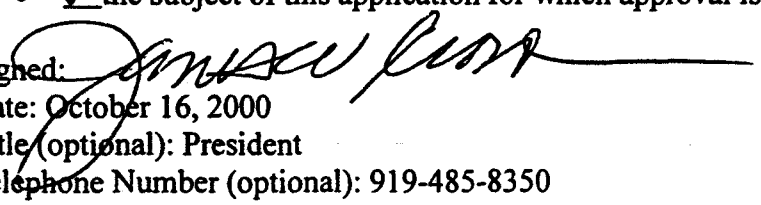
The undersigned declares that the above stated United States Patent Number 5,153,222 covers the composition, formulation and/or method of use of Uniprost. This product is:

- ___currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act)

OR

- ✓ the subject of this application for which approval is being sought.)

Signed: 
Date: October 16, 2000
Title (optional): President
Telephone Number (optional): 919-485-8350

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EXCLUSIVITY SUMMARY FOR NDA # 21-272 SUPPL #_____

Trade Name: Remodulin Generic Name: Treprostinil Sodium Injection

Applicant Name: United Therapeutics Co. HFD # 110

Approval Date If Known:

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following question about the submission.

a) Is it an original NDA?

YES /_X__/ NO /___/

b) Is it an effectiveness supplement?

YES /___/ NO /_X__/

If yes, what type? (SE1, SE2, etc.) _____

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES /_X__/ NO /___/

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

_____

_____

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

_____

_____

d) Did the applicant request exclusivity?

YES /___/ NO /_X__/

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

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e) Has pediatric exclusivity been granted for this Active Moiety?

NO

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule, previously been approved by FDA for the same use? (Rx to OTC switches should be answered NO-please indicate as such)

YES /___/ NO /_X__/

If yes, NDA #_____. Drug Name _____.

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

3. Is this drug product or indication a DESI upgrade?

YES /___/ NO /_X__/

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II ~~FIVE~~SEVEN-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES
(NOTE: Remodulin (treprostinol) has been granted an orphan designation for pulmonary arterial hypertension)
(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES /___/ NO /_X__/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# _____ _____

NDA# _____ _____

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