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RESEARCH**

***APPLICATION NUMBER:***

**21-272**

**MICROBIOLOGY REVIEW**

**REVIEW TO HFD 110**  
**OFFICE OF NEW DRUG CHEMISTRY**  
Microbiology Staff, HFD-805  
Microbiologist's Review #3 of Supplement  
March 28, 2001

- A. 1. NDA: 21-272/N-BI
2. APPLICANT/SPONSOR: United Therapies Corporation  
68 T.W. Alexander Dr.  
Research Triangle Park, NC 27709
- Contact: Dean Bunce  
Associate Director,  
Regulatory Affairs  
919-485-8350
5. MANUFACTURING SITE: \_\_\_\_\_
6. DRUG PRODUCT NAME  
Proprietary: Uniprost (UT-15)  
Nonproprietary: Triprostinol Sodium (applied for)  
Drug Priority Classification: Standard
7. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:
- Subcutaneous injection
  - 1.0, 2.5, 5.0, and 10 mg/mL
8. METHOD(S) OF STERILIZATION: \_\_\_\_\_
9. PHARMACOLOGICAL CATEGORY AND/OR PRINCIPLE INDICATION:  
pulmonary arterial hypertension
- B. 1. DOCUMENT/LETTER DATE: August 11, 2000
2. RECEIPT DATE: August 14, 2000
3. CONSULT DATE: August 16, 2000
4. DATE OF AMMENDMENT: February 19, 2001 (Subject of this review)
5. ASSIGNED FOR REVIEW: March 28, 2001

6. **SUPPORTING/RELATED DOCUMENTS:**

**Review #1 of this supplement was completed on October 26, 2000. A deficiency letter was sent on November 6, 2000. A teleconference was held on February 1, 2000 with Dean Bunce and several representatives of United Therapeutics Corporation to discuss the vials.**

C. **REMARKS: Uniprost (UT-15) has been designated as an orphan drug for the treatment of pulmonary arterial hypertension. The following is a review of the applicant's responses to the microbiology deficiencies listed in the first review.**

D. **CONCLUSIONS: The submission is recommended for approval from the standpoint of microbial product quality.**

**S**

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**Stephen E. Langille, Ph. D.**

cc: **Original NDA-21-272**  
HFD-110/Division File  
HFD-110/Chem./Advani  
HFD 805/Consult File/Langille  
Drafted by S. Langille c:reviews/21-272r3  
Initialed by P. Cooney

2 page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable.

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this page is the manifestation of the electronic signature.**

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/s/

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Stephen Langille  
4/19/01 11:33:10 AM  
MICROBIOLOGIST

Peter Cooney  
4/19/01 01:40:09 PM  
MICROBIOLOGIST

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