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APPLICATION NUMBER:

22-387

CHEMISTRY REVIEW(S)

CMC BRANCH CHIEF MEMORANDUM

To:	NDA 22-387
From:	Ramesh Sood, Ph.D., Branch Chief, ONDQA
Date:	28-Jul-2009
Drug:	Tyvaso (treprostinil) inhalation solution
Route of administration:	Oral Inhalation
Strength:	0.6 mg/mL
Subject:	**"Approval"** recommendation for NDA 22-387

Treprostinil for inhalation (Tyvaso™) is being developed as an alternative to the subcutaneously and intravenously delivered treprostinil solution (Remodulin Injection, NDA 21-272, approved 22-May-2002). Treprostinil is the free acid of a synthetic tricyclic benzindene analogue of prostacyclin. The proposed indication is for the treatment of pulmonary arterial hypertension (WHO Group I) in patients with New York Heart Association (NYHA) Class III symptoms. b(4)

Several pending CMC issues were identified in my previous memo. The company has addressed these issues to the reviewer's satisfaction. The issues related to the drug substance have been resolved.

The facilities related to the manufacturing of the drug product and described in the NDA have been recommended for approval by the Office of Compliance. Categorical exclusion from an environmental assessment requested by the applicant is acceptable.

An acceptable recommendation is made by the microbiology reviewer.

Recommended action: The application is recommended for "APPROVAL" from CMC perspective.

Linked Applications	Submission Type/Number	Sponsor Name	Drug Name / Subject
NDA 22387	ORIG 1	UNITED THERAPEUTICS CORP	TREPROSTINIL FOR INHALATION

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RAMESH K SOOD
07/28/2009

NDA 22-387

Tyvaso (treprostinil) Inhalation Solution

United Therapeutics Corporation

Monica D. Cooper, Ph.D.
ONDQA Pre-Marketing Assessment
Division I/Branch I

Reviewed for the Division of Cardiovascular and Renal Products, HFD-110

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