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*APPLICATION NUMBER:*

**022407Orig1s000**

**PHARMACOLOGY REVIEW(S)**

Memo to the Division File

NDA 22-407

Televancin (Vibativ) for Pneumonia Indications

From: Wendelyn Schmidt, Pharmacology/Toxicology Supervisor

Through: Chris Davi, Project Manager

Date: 9/29/09

Background:

The Pharmacology and Toxicology data applicable to this NDA is cross-referenced to Theravance's previous NDA for Televancin (NDA 22-110). No new pharmacology or toxicology data was submitted to the current NDA. The non-clinical studies are adequate to support the clinical use and sufficient to allow the labeling of this compound.

Recommendation: There are no pharmacology/toxicology objections to the approval of televancin for this indication.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
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NDA-22407	ORIG-1	THERAVANCE INC	VIBATIV

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/s/

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WENDELYN J SCHMIDT  
11/18/2009

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09/29/2009