

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

206473Orig1s000

STATISTICAL REVIEW(S)



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION

NDA # : 206473
Priority or Standard Review: Standard Review
Applicant: Hospira, Inc.
Drug Product: Linezolid Injection (600mg/300mL)
Indication(s): Nosocomial pneumonia; Community-acquired pneumonia;
Complicated skin and skin structure infections, including diabetic
foot infections, without concomitant osteomyelitis; and
Vancomycin-resistant *Enterococcus faecium* infections
Received Date: November 26, 2013
PDUFA Goal Date: September 26, 2014
Reviewer Completion Date: August 19, 2014
Biometrics Division: Division of Biometrics IV
Medical Division: Division of Anti-Infective Products (DAIP)
Documents Reviewed: NDA 206473
Statistical Reviewer: Christopher Kadoorie, Ph.D.
Concurring Reviewer: Thamban Valappil, Ph.D.
Clinical Reviewer: Alma Davidson, M.D.
Acting Clinical Team Leader: Benjamin Lorenz, M.D.
Project Manager: Susmita Samanta

Background

The Applicant, Hospira, Inc., has submitted a 505(b)(2) New Drug Application for Linezolid in 0.9% Sodium Chloride Injection. The reference listed drug (RLD) for this application is ZYVOX® I.V., NDA 21,131 held by Pharmacia & Upjohn Inc. The Applicant is proposing Linezolid Injection in a 0.9% Sodium Chloride vehicle (b) (4). The comparison between the generic drug and the RLD is shown in Table 1.

In this submission, the Applicant has also included the proposed labeling for Linezolid which is based on an outdated Zyvox label. Therefore, the review team has made significant revisions to the proposed label to be in accordance with current Physician’s Labeling Rule (PLR) format and regulatory practices.

Recommendations

This application is relying on the RLD and there are no clinical studies included. From a statistical perspective, there are no issues to report. There are also no recommended edits to the proposed labeling.

Comparison Between Generic Drug and RLD

The generic and RLD have the same active ingredients and concentration. The inactive ingredients of the generic are (b) (4). The generic and RLD also have the same route of administration, dosage form and strength.

Table 1: Comparison between Generic Drug and Reference Listed Drug

	Reference Listed Drug	Generic Equivalent
	Pharmacia and Upjohn Zyvox	Hospira, Inc. Linezolid in 0.9% Sodium Chloride Injection
Conditions of Use	ZYVOX formulations are indicated in the treatment of the following infections caused by susceptible strains of the designated microorganisms: Vancomycin-Resistant <i>Enterococcus faecium</i> infections; Nosocomial pneumonia; Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis; Uncomplicated skin and skin structure infections; Community-acquired pneumonia.	Linezolid Injection is indicated in the treatment of the following infections caused by susceptible strains of the designated microorganisms: Vancomycin-Resistant <i>Enterococcus faecium</i> infections; Nosocomial pneumonia; Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis; (b) (4) Community-acquired pneumonia.
Active Ingredient(s)	Linezolid	Linezolid

Inactive Ingredient(s)	Dextrose Citric acid ¹ Sodium citrate ¹ Sodium hydroxide Hydrochloric acid Water for Injection	Citric acid ¹ Sodium Chloride Sodium hydroxide ¹ Hydrochloric acid Water for Injection
Route of Administration	Injection (Intravenous)	Injection (Intravenous)
Dosage Form	Injectable	Injectable
Strength	200 mg/100 mL 400 mg/200 mL 600 mg/300 mL	600mg/300 mL ²

(b) (4)

2 Hospira is choosing to develop only the 600 mg/300 mL (2 mg/ml) product presentation.

Summary

In the absence of clinical data in this submission, there were no statistical issues to report. The decision on this application is deferred to other disciplines.

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/s/

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08/19/2014

THAMBAN I VALAPPIL
08/20/2014