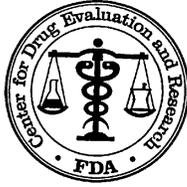


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208744Orig1s000

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

CLINICAL STUDIES

NDA/BLA #: NDA 208744

Drug Name: Tigecycline for injection

Indication(s): Complicated intra-abdominal infections, complicated skin and skin structure infections, community-acquired bacterial pneumonia

Applicant: Accord Healthcare Inc.

Date(s): Stamp date: September 30, 2015

Review Priority: Standard

Biometrics Division: Division of Biometrics IV

Statistical Reviewer: Daniel Rubin, PhD

Concurring Reviewers: Statistical Team Leader: Karen Higgins, ScD

Medical Division: Division of Anti-Infective Products

Clinical Team: Lead Medical Officer: Dmitri Iarikov, MD

Project Manager: Deepak Aggarwal, MS, MSPH

1 SUMMARY

Tigecycline is an intravenously administered antibacterial drug in the tetracycline class that is FDA-approved for the treatment of complicated intra-abdominal infections, complicated skin and skin structure infections, and community-acquired bacterial pneumonia. In this submission the Applicant, Accord Healthcare Inc., seeks to rely on the Agency's previous determination of the safety and efficacy of tigecycline to obtain marketing approval for Tigecycline for Injection, USP 50 mg/vial. This product differs from the reference listed drug (RLD) TYGACIL in that the inactive ingredient maltose monohydrate replaces the inactive ingredient lactose monohydrate. The Applicant's only proposed change to the label of the RLD [REDACTED] (b) (4)

[REDACTED] Because this 505(b)(2) application does not propose other changes to the RLD labeling and there are no clinical data submitted, this reviewer has no statistical comments and defers analysis of this application to the other respective review disciplines.

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/s/

DANIEL B RUBIN
11/04/2015

KAREN M HIGGINS
11/05/2015
I concur.