

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205645Orig1s000

STATISTICAL REVIEW(S)



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: May 15, 2014

TO: Daniel Rubin, PhD
Statistical reviewer
Division of Biometrics IV

FROM: Carmen DeBellas, PharmD, RPh
Regulatory Project Manager
Division of Anti-Infective Products

SUBJECT: Statistical Memo

APPLICATION/DRUG: NDA 205645 tigecycline injection

NDA 205645 is a 505(b)(2) application submitted on August 1, 2013. The submission is referencing the already approved NDA 21-821 for Tygacil. The submission contains no clinical or statistical data; therefore no statistical review is needed.

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/s/

CARMEN L DEBELLAS
05/15/2014

DANIEL B RUBIN
05/15/2014