CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

050823Orig1s000

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 Serial Number:	50-823
Drug Name:	Ceftazidime for Injection USP and Dextrose Injection USP in the Duplex® Container, 1 g and 2 g
Antibiotic Class:	Cephalosporin
Indication(s):	Treatment of the following infections caused by designated susceptible organisms: lower respiratory tract infections, skin and skin-structure infections, bacterial septicemia, bone and joint infections, gynecologic infections, intra-abdominal infections, central nervous system infections (b) (4)
Applicant:	B. Braun Medical Inc.
Submission Type:	505(b)(2)
Stamp Date:	August 13, 2010
PDUFA Goal Date:	June 13, 2011
Review Priority:	Standard
Reference Listed Drug:	Fortaz, NDA 50-578, in the 1g and 2 g strengths
Statistical Reviewer:	Daniel Rubin, Ph.D.
Concurring Reviewers:	Thamban Valappil, Ph.D.
Biometrics Division:	Division of Biometrics IV
Medical Division:	Division of Anti-Infective and Ophthalmology Products
Clinical Reviewer:	Alma Davidson, M.D.
Clinical Team Leader:	Janice Pohlman, M.D., M.P.H.
Project Manager:	Christopher Davi, M.S.

1 SUMMARY

Ceftazidime is a cephalosporin antibiotic that was originally FDA-approved in 1989, and then marketed as Fortaz by GlaxoSmithKline. It is indicated for treatment of the following infections caused by susceptible strains of designated pathogens: lower respiratory tract infections, skin and skin-structure infections, bacterial septicemia, bone and joint infections, gynecologic infections, intra-abdominal infections, central nervous system infections, (b) (4) . The Applicant, B. Braun Medical Inc., proposes to market Ceftazidime for Injection USP and Dextrose Injection USP in the Duplex® Container in 1 g and 2g strengths, which is a new drug delivery system. The Applicant claims bioequivalence to the reference listed drug, Fortaz, approved under NDA 50-578. No new clinical safety or efficacy studies were conducted, and the Applicant's draft label does not contain a Clinical Studies section (i.e., no Section 14). Review was deferred to the medical officer regarding any necessary safety labeling changes stemming from the Applicant's submitted literature or spontaneous reports from the Adverse Event Reporting System. Thus, no statistical issues were identified in this application.

2 CONCLUSION

No statistical issues were identified in this 505(b)(2) application.

SIGNATURES/DISTRIBUTION LIST

Primary Statistical Reviewer: Daniel Rubin, Ph.D.

Concurring Reviewers: Thamban Valappil, Ph.D., Statistical Team Leader

cc:
Division Director, Division of Biometrics IV/Mohammad Huque
Deputy Division Director, Division of Biometrics IV/Daphne Lin
Mathematical Statistician/Lillian Patrician
Project Manager/Christopher Davi

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/s/

DANIEL B RUBIN
01/10/2011

THAMBAN I VALAPPIL
01/11/2011