

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
50-821

STATISTICAL REVIEW(S)



U S Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmacoepidemiology and Statistical Science
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA/Serial Number: 50-821 / 000

Drug Name: Cefipime for Injection

Indication(s): Treatment of pneumonia, empiric therapy for febrile neutropenic patients, uncomplicated and complicated urinary tract infections (including pyelonephritis), uncomplicated skin and skin structure infections and complicated intra-abdominal infections

Applicant: B. Braun Medical Inc.

Date(s): 9/26/08

Review Priority: Standard

Biometrics Division: DBIV

Statistical Reviewer: Scott Komo, Dr.P.H.

Concurring Reviewers: Thamban Valappil, Ph.D.

Medical Division: Division of Anti-Infective and Ophthalmology Drug Products (DAIOP)

Clinical Team: Alma Davidson, M.D.
Janice Pohlman, M.D. M.P.H.

Project Manager: Chris Davi, M.S.

Keywords: Class: Beta-lactam cephalosporin

1 Summary

The Applicant submitted a 505(b)(2) application for cefepime for injection and dextrose injection in the duplex container, 1g. and 2 g. strength using Bristol-Myers-Squibb's Maxipime in the 1g. and 2 g. strengths as the reference listed drug (RLD).

No clinical studies were included in this submission.

2 Conclusion

This 505(b)(2) application included neither clinical studies nor literature references that required review. Thus, no statistical issues were identified for this application.

3 SIGNATURES/DISTRIBUTION LIST (Optional)

Primary Statistical Reviewer: Scott Komo, DrPH
Date: 5/26/09

Concurring Reviewer(s): Thamban Valappil, PhD

Statistical Team Leader: Thamban Valappil, PhD

cc:
DAIOP / Chris Davi
DAIOP / Alma Davidson
DAIOP / Janice Pohlman
DAIOP / Katherine Laessig
DAIOP / Wiley Chambers
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/s/

Scott Komo
5/26/2009 10:56:46 AM
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Thamban Valappil
5/26/2009 11:28:12 AM
BIOMETRICS