

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
50-817

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: 50-817

Drug Name: Cefepime Injection in GALAXY Container

Indication(s): Treatment of Various Infections Caused by Susceptible Strains of Microorganisms (Same Indications Proposed as MAXIPIME NDA 50-679 by Bristol-Myers-Squibb)

Applicant: Baxter Healthcare Corporation

Date(s): Stamp Date: March 2, 2007
PDUFA due date: January 1, 2008

Review Priority: Standard

Biometrics Division: Division of Biometrics IV

Statistical Reviewer: Yan Wang, Ph.D

Statistical Team Leader: Thamban Valappil, Ph.D

Medical Division: Division of Anti-infective and Ophthalmologic Drug Products (HFD-520)

Clinical Team: Alma Davidson, MD

Clinical Team Leader: Sumathi Nambiar, MD, MPH

Project Manager: Kyong Hyon

Background

NDA 50-817 is submitted, under the provisions specified in the Federal Food, Drug and Cosmetic Act, Section 505(b) (2), to seek approval of a new delivery system (Galaxy plastic container) for Cefepime injection for the same indications as MAXIPIME. MAXIPIME is currently approved for the following indications:

1. Pneumonia (moderate to severe) caused by *Streptococcus pneumoniae*, including cases associated with concurrent bacteremia, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, or *Enterobacter* species.
2. Empiric Therapy for Febrile Neutropenic Patients. Cefepime as monotherapy is indicated for empiric treatment of febrile neutropenic patients. In patients at high risk for severe infection (including patients with a history of recent bone marrow transplantation, with hypotension at presentation, with an underlying hematologic malignancy, or with severe or prolonged neutropenia), antimicrobial monotherapy may not be appropriate. Insufficient data exist to support the efficacy of cefepime monotherapy in such patients.
3. Uncomplicated and Complicated Urinary Tract Infections (including pyelonephritis) caused by *Escherichia coli* or *Klebsiella pneumoniae*, when the infection is severe, or caused by *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis*, when the infection is mild to moderate, including cases associated with concurrent bacteremia with these microorganisms.
4. Uncomplicated Skin and Skin Structure Infections caused by *Staphylococcus aureus* (methicillin-susceptible strains only) or *Streptococcus pyogenes*.
5. Complicated Intra-abdominal Infections (used in combination with metronidazole) caused by *Escherichia coli*, *viridans group streptococci*, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Enterobacter* species, or *Bacteroides fragilis*.

Conclusions and Recommendations

There is no clinical trial data included in this NDA submission. There is no statistical issue identified in this NDA. A recently published meta-analysis showed increased mortality in patients treated with cefepime. This meta-analysis and other related data are currently being reviewed by the Division. Until the cause for the observed increased mortality is better understood, it is recommended that this NDA receive an approvable action.

SIGNATURES/DISTRIBUTION LIST

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Date: 12/20/2006

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/s/

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