CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207131Orig1s000

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 # :	207131
Submission Type:	505(b)(2)
Drug Name:	Cefazolin Injection, USP in GALAXY plastic container
Indication(s):	(b) (4) (b) (4)
Applicant:	Celerity Pharmaceuticals, LLC
Stamp Date:	October 16, 2014
PDUFA Goal Date:	August 16, 2015
Reviewer Completion Date:	July 17, 2015
Biometrics Division:	Division of Biometrics IV
Medical Division:	Division of Anti-Infective Products (DAIP)
Statistical Reviewer:	Christopher Kadoorie, Ph.D.
Concurring Reviewer:	Thamban Valappil, Ph.D.
Clinical Reviewer:	Peter Kim, M.D., M.S.
Clinical Team Leader:	Thomas Smith, M.D.
Project Manager:	Fariba Izadi, Pharm.D.

Reference ID: 3794059

Background

The Applicant, Celerity, has submitted a 505(b)(2) New Drug Application (NDA) submission for Cefazolin Injection, USP in GALAXY plastic container and is relying on findings of safety and efficacy for the reference listed drug (RLD). The RLD is B. Braun's 2 g drug product (Cefazolin Injection, USP and Dextrose Injection USP in Duplex® Container) which was approved for the indication of perioperative prophylaxis under NDA 050779. A detailed comparison of Cefazolin Injection, USP vs. the RLD is shown in the Appendix of this review. In this submission, no clinical data or information was submitted and a waiver of bioequivalence studies was granted.

Product Labeling

The Applicant has also submitted the proposed labeling for their product which is mostly based on the labeling for the RLD. (b) (4)

(b) (4)

(b) (4)

Conclusions

There were no clinical data or information submitted on this NDA and a waiver of bioequivalence studies was granted. No statistical issues were identified in this NDA or in the product labeling. According to the clinical reviewer, Dr. Peter Kim, no new safety information was identified that would alter the favorable risk/benefit assessment of cefazolin in the (b) (4)

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Appendix- Comparison of B. Braun (Listed Drug) vs. Celerity (Proposed Drug)

Applicant	B. Braun (Listed Drug)	Celerity (Proposed Drug)
Product	Cefazolin for Injection USP and Dextrose Injection USP in Duplex® Container	Cefazolin Injection, USP in GALAXY plastic container
Active Ingredient	Cefazolin Sodium, USP	Cefazolin, USP[a]
Total Drug Content	2.0 g	2.0 g
Diluent	3% Dextrose, USP	4% Dextrose, USP[b]
Other Inactive Ingredients	none listed	Sodium Bicarbonate, USP
Volume	50 mL in Duplex® Container	100 mL in GALAXY plastic container
Strength	2.0 g (2 g base/vial)	2.0 g (2 g base/100 mL)
Concentration	40 mg/mL (2 g/50 mL)	20 mg/mL (2 g/100 mL)
Osmolality	Iso-osmotic (approx. 290 mOsmol/kg)[c]	Iso-osmotic (approx. 288-301 mOsmol/kg)[d]
Dosage Form	Injectable; sterile lyophilized dry powder packaged with dextrose solution (ready to mix)	Injectable; frozen, pre-mixed iso-osmotic, sterile solution
Container Closure	Duplex® dual-chamber, single-use container for sterile reconstitution of dry powder and diluent for injection	Single-use GALAXY plastic container for frozen, premixed, iso-osmotic, sterile solution
Route of Administration	Injection: IV infusion	Injection: IV infusion
Dosing Regimen	2 g dose infusion over approximately 30 minutes	2 g dose infusion over approximately 30 minutes

(b) (4)

[c] B. Braun Package Insert, Cefazolin for Injection USP And Dextrose Injection USP In Duplex® Container, for intravenous use http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=17f8f038-c204-4dab-80d7-6f7ac41ddbec, retrieved 3/21/2014

[d] Data for proposed Celerity drug product (to be included in NDA submission)

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/s/

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07/17/2015

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07/17/2015