CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208083Orig1s000

STATISTICAL REVIEW(S)

STATISTICAL REVIEW AND EVALUATION

NDA/BLA #:	208083
Drug Name:	Clindamycin in 0.9% Sodium Chloride Injection in GALAXY Container (300 mg/50 mL, 600 mg/50 mL, and 900 mg/50 mL)
Applicant:	Celerity Pharmaceuticals, LLC
Date(s):	Stamp date: 6/30/16 Goal date: 4/30/17
Biometrics Division:	Division of Biometrics IV
Statistical Reviewer:	Karen Higgins, Sc.D.
Concurring Reviewers:	Dionne Price, Ph.D.
Medical Division:	Division of Anti-Infective Products
Clinical Team:	Maria Allende, MD, Medical Officer Thomas Smith, MD, Medical Team Leader
Project Manager:	Naseya Minor, MPH

Summary

This NDA is for Clindamycin in 0.9% sodium chloride injection by Celerity Pharmaceuticals (the Applicant). The Applicant is relying on the previous findings of safety and efficacy demonstrated for CLEOCIN PHOSPHATE IV SOLUTION (Clindamycin phosphate Injection) marketed by Pfizer under NDA 050639 (approved on August 30, 1989 and April 10, 1991 [Pharmacia and Upjohn (now Pfizer)]). The Applicant did not conduct any new clinical studies.

The label is consistent with CLEOCIN prescribing information in that it does not contain a clinical studies section. There is no statistical review needed for this NDA submission.

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/s/

KAREN M HIGGINS
04/18/2017

DIONNE L PRICE
04/18/2017
Concur,