CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209949Orig1s000

CLINICAL MICROBIOLOGY/VIROLOGY REVIEW(S)

Division of Anti-Infective Products
Clinical Microbiology Review

NDA 208385	505(b)(2)
Clinical Microbiology Reviewer:	Avery Goodwin
Date of Submission:	December 20, 2016
PDUFA Date	October 20, 2017
Applicant Name:	Xellia Pharmaceuticals
Drug Name:	Daptomycin for Injection
Dosage Forms (Route of Administration):	350 mg vial (lyophilized) for intravenous use
Indication(s)	Complicated Skin and Skin Structure Infections; *Staphylococcus aureus* Bloodstream Infections (Bacteremia) Including Those with Right-Sided Infective Endocarditis, Caused by Methicillin-Susceptible and Methicillin-Resistant Isolates

Remarks:

Xellia Pharmaceuticals has submitted a 505(b)(2) NDA 209949 requesting the approval to market the Cubist/Merck product, CUBICIN (Daptomycin) 350mg for injection. The Applicant's drug product has the same indication and dosing regimens as CUBICIN and no new clinical microbiology data was submitted. Therefore, this product relies on the previous determination of safety and efficacy of daptomycin that was conducted by Cubist/Merck. The proposed microbiology section of the label submitted by the Applicant aligns with the package insert for CUBIBIN.

From a clinical microbiology perspective, this NDA is approvable.

Clinical Microbiology Reviewer: Avery Goodwin, PhD.

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/s/

AVERY C GOODWIN
08/31/2017