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APPLICATION NUMBER:

210282Orig1s000

CLINICAL MICROBIOLOGY/VIROLOGY
REVIEW(S)

**Division of Anti-Infective Products
Clinical Microbiology Review**

NDA 210282	505(b)(2)
Clinical Microbiology Reviewer:	Avery Goodwin
Date of Submission:	May 19, 2017
PDUFA Date	March 19, 2018
Applicant Name:	Hospira
Drug Name:	Daptomycin for Injection
Dosage Forms (Route of Administration):	350 mg and 500 mg vials for intravenous use
Indication(s)	Complicated Skin and Skin Structure Infections; <i>Staphylococcus aureus</i> Bloodstream Infections (Bacteremia) Including Those with Right-Sided Infective Endocarditis, Caused by Methicillin- Susceptible and Methicillin-Resistant Isolates

Remarks:

Hospira Pharmaceuticals has submitted a 505(b)(2) NDA 210282 requesting the approval to market the Cubist/Merck product, CUBICIN (Daptomycin) 350mg and 500mg 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; however, sections pertaining to breakpoints, Clinical and Laboratory Standards Institute methods and references (b) (4) located on the FDA's breakpoint recognition website (www.fda.gov/STIC).

From a clinical microbiology perspective, this NDA is approvable.

Clinical Microbiology Reviewer: Avery Goodwin, PhD.

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/s/

AVERY C GOODWIN
03/07/2018