

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208385Orig1s000

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 Resubmission:	March 24, 2017
PDUFA Date	September 24, 2017
Applicant Name:	Sagent Pharmaceuticals Inc.
Drug Name:	Daptomycin for Injection
Dosage Forms (Route of Administration):	350 mg lyophilized cake or powder for reconstitution in a single-use vial (Intravenous)
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:

From a clinical microbiology perspective, this sNDA is approvable.

Background:

Sagent Pharmaceuticals has resubmitted a 505(b)(2) NDA 208385 requesting the approval to market the Cubist/Merck product, CUBICIN (Daptomycin) 350mg for injection. The Applicant has addressed product quality issues associated with manufacturing and a safety update related to this submission. The proposed microbiology section of the label submitted by the Applicant aligns with the Cubicin.

Clinical Microbiology Reviewer: Avery Goodwin, PhD.

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/s/

AVERY C GOODWIN
08/17/2017

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

NDA 208385	505(b)(2)
Clinical Microbiology Reviewer:	Avery Goodwin
Clinical Microbiology Team Leader	Kalavati Suvarna
Date Company Submitted:	August 25, 2015
PDUFA Date	June 24, 2016
Applicant Name:	Sagent Pharmaceuticals Inc.
Drug Name:	Daptomycin for Injection
Reference Listed Drug	CUBICIN® (Daptomycin) for Injection
Dosage Forms (Route of Administration):	350 mg lyophilized cake or powder for reconstitution in a single-use vial (Intravenous)
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:

From a clinical microbiology perspective, there are no issues with the approval of this NDA.

Background:

Sagent Pharmaceuticals has submitted a 505(b)(2) NDA 208385 requesting the approval to market Daptomycin 350mg for injection. Daptomycin is indicated for 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.

Clinical Microbiology Reviewer: Avery Goodwin, PhD.

Clinical Microbiology Team Leader: Kalavati Suvarna, PhD.

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/s/

AVERY C GOODWIN
06/03/2016

KALAVATI C SUVARNA
06/03/2016