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APPLICATION NUMBER:

208385Orig1s000

**CLINICAL PHARMACOLOGY AND
BIOPHARMACEUTICS REVIEW(S)**

CLINICAL PHARMACOLOGY REVIEW

NDA 208,385	Submission Date(s): August 25, 2015
Drug	Daptomycin for Injection, 350 mg/mL
Trade Name	Daptomycin
OCP Reviewer	Dakshina M. Chilukuri, PhD
OCP Team Leader	Seong H. Jang, PhD
OCP Division	DCP4
OND Division	DAIP
Sponsor	Sageant pharmaceuticals
Submission Type	505(b)(2)
Formulation	IV Formulation
Indication(s)	Complicated skin and skin structure infections (cSSSI) and <i>Staphylococcus aureus</i> bloodstream infections (bacteremia), including those with right-sided infective endocarditis

1. EXECUTIVE SUMMARY

Sageant Pharmaceuticals submitted a 505(b)(2) application on August 25, 2015. The reference listed drug product (RLD) is Cubicin® (Daptomycin for Injection 500 mg/vial), a sterile lyophilized powder, injectable; approved on 9/21/2003. The proposed drug, Daptomycin for Injection 350 mg/vial is presented as a sterile lyophilized powder, single use injectable.

The active ingredient, indications, route of administration, dosage form and qualitative composition are the same as those of the RLD; however the total strength is different (350 mg/vial) compared to the RLD that has a strength of 500 mg/vial.

The applicant did not submit any new clinical pharmacology information with this NDA. The drug facilities inspection found deficiencies that cannot be resolved during this review cycle. As of now the Office of Pharmaceutical Quality (OPQ) will be recommending a complete response action on this application.

2. RECOMMENDATIONS

No new clinical pharmacology was submitted by the applicant in this NDA and thus, the clinical pharmacology team has no additional comments on this submission.

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/s/

DAKSHINA M CHILUKURI
04/14/2016

SEONG H JANG
04/14/2016