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APPLICATION NUMBER:

209949Orig1s000

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

OFFICE OF CLINICAL PHARMACOLOGY REVIEW

NDA	209949
Submission Date	12/20/2016
Drug	Daptomycin
OCP Reviewer	Sonia Pahwa, Ph.D.
OCP Team Leader	Seong Jang, Ph.D.
OCP Division	DCP4
OND Division	DAIP
Sponsor	Xellia Pharmaceuticals APS
Submission Type	505(b)(2)
Formulation	IV Injection, 350 mg/vial
Indication	• Complicated skin and skin structure infections (cSSSI). • *Staphylococcus aureus* bloodstream infections (bacteremia), including those with right-sided infective endocarditis.
Dosage and Administration	Recommended dosage regimen for adult patients:

Creatinine Clearance (CL_{CR})	Dosage Regimen	
	cSSSI For 7 to 14 days	*S. aureus* Bacteremia For 2 to 6 weeks
≥30 mL/min	4 mg/kg once every 24 hours	6 mg/kg once every 24 hours
<30 mL/min, including hemodialysis and CAPD	4 mg/kg once every 48 hours*	6 mg/kg once every 48 hours*

* Administered following hemodialysis on hemodialysis days.

- Administered intravenously in 0.9% sodium chloride, either by injection over a 2-minute period or by infusion over a 30-minute period.
- Do not use in conjunction with ReadyMED® elastomeric infusion pumps.

Background

Xellia Pharmaceuticals APS submitted a 505(b)(2) New Drug Application (NDA) dated 12/20/2016 for Daptomycin for Injection, 350 mg/vial. The strength, route of administration, dosage regimen of the Applicant's Daptomycin product is identical to those of the reference listed drug (RLD), CUBICIN® (daptomycin) for Injection (NDA 21572) approved on Sept. 12, 2003; manufactured by Merck). The proposed drug product contains the same active and inactive ingredients (b) (4) as the approved RLD.

The approval of this NDA relies on the Agency's findings of safety and efficacy for Daptomycin for Injection (CUBICIN® - NDA 21572). No new clinical pharmacology information was submitted. The Applicant requested a waiver of the requirement for the submission of evidence demonstrating the bioequivalence of the proposed product because Daptomycin for Injection, 350 mg/vial is a parenteral solution intended solely for administration by intravenous injection or infusion; and contains the same active and inactive ingredients as RLD. The Applicant's waiver request was granted.

Recommendation

No new clinical pharmacology information was submitted in this NDA and thus, we have no comments on this application. The label will be filed in DARRTS separately after agreement with the Applicant.

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/s/

SONIA PAHWA
08/24/2017

SEONG H JANG
08/24/2017