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APPLICATION NUMBER: 201023

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

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Clinical Pharmacology Review			
NDA	201023		
Submission Date:	March 31, 2010		
Brand Name:	JEVTANA <sup>®</sup>		
Generic Name:	Cabazitaxel		
Formulation/Strength:	Single Use Vial 60 mg/1.5 mL and Diluent		
<b>OCP Reviewer:</b>	Pengfei Song, Ph.D.		
Pharmacometrics Reviewer:	Nitin Mehrotra, Ph.D.		
OCP Team Leader:	Qi Liu, Ph.D.		
Pharmacometrics Team Leader:	Christine Garnett, Pharm.D.		
OCP Division:	Division of Clinical Pharmacology 5		
ORM Division:	Division of Drug Oncology Products		
Sponsor:	Sanofi-aventis US LLC		
Submission Type; Code:	Original NDA; 000		
Dosing Regimen:	Cabazitaxel 25 mg/m <sup><math>2</math></sup> administered every three weeks as a		
	one-hour IV infusion in combination with oral prednisone		
	10 mg administered daily throughout cabazitaxel treatment		
Indication:	Metastatic hormone refractory prostate cancer previously		
	treated with a docetaxel-containing regimen		

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