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*APPLICATION NUMBER:*  
**201023**

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

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## Clinical Pharmacology Review

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

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