

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**201023s000**

***Trade Name:*** Jevtana

***Generic Name:*** cabazitaxel

***Sponsor:*** Sanofi-aventis U.S., Inc.

***Approval Date:*** June 17, 2010

***Indications:*** In combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

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## 201023s000

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**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**20-1023**

**APPROVAL LETTER**



NDA 201023

**NDA APPROVAL**

sanofi-aventis U.S., LLC  
c/o sanofi-aventis U.S., Inc.  
200 Crossing Boulevard, Mailstop: BX2-712B  
Bridgewater, NJ 08807

Attention: Linda M. Gustavson  
Director, U.S., Associate Therapeutics Head, Oncology

Dear Ms. Gustavson:

Please refer to your New Drug Application (NDA) dated March 31, 2010, received March 31, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Jevtana<sup>®</sup> (cabazitaxel) Injection, 60 mg/1.5 mL.

We acknowledge receipt of your submissions dated April 16 (2), May 5, 7, 10, 18, 21, 24, 25 (2), 28, June 1, 4 (2), 8, 14, 16, and 17, 2010.

This new drug application provides for the use of Jevtana<sup>®</sup> (cabazitaxel) Injection in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert, text for the patient package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

## **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)”. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 201023.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

## **ADVISORY COMMITTEE**

Your application for Jevtana<sup>®</sup> (cabazitaxel) Injection was not referred to an FDA advisory committee because taking this NDA to an advisory committee would result in a several month delay in making this advance in prostate cancer therapy available to patients for whom there is currently no available therapy.

## **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because necessary studies are impossible or highly impracticable since prostate cancer does not occur in children.

## **POSTMARKETING REQUIREMENTS UNDER 505(o)**

Section 505(o) of the FDCA authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute (section 505(o)(3)(A)).

We have determined that an analysis of spontaneous postmarketing adverse events reported under subsection 505(k)(1) of the FDCA will not be sufficient to identify an unexpected serious risk of intravenous infusion of particulate matter into the blood stream.

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