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RESEARCH**

APPLICATION NUMBER:
201023

PHARMACOLOGY REVIEW(S)

MEMORANDUM

Jevtana (Cabazitaxel)

Date: June 14, 2010

To: File for NDA 201023

From: John K. Leighton, PhD, DABT

Associate Director for Pharmacology/Toxicology
Office of Oncology Drug Products

I have examined pharmacology/toxicology supporting review and labeling provided by Drs. Khasar and Helms and supervisory memorandum provided by Dr. Verbois. I concur with their conclusions that Jevtana may be approved for the proposed indication and that no additional pharmacology/toxicology studies are needed.

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-201023

ORIG-1

SANOFI AVENTIS
SPA

CABAZITAXEL (XRP6258)

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/s/

JOHN K LEIGHTON
06/14/2010

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH**

PHARMACOLOGY/TOXICOLOGY NDA REVIEW AND EVALUATION

Application number: 201,023
Supporting document/s: 0000
Applicant's letter date: December 18, 2009
CDER stamp date: 03/31/2010
Product: Cabazitaxel (XRP6258)
Indication: Metastatic prostate cancer
Applicant: Sanofi Aventis SPA
Review Division: Division of Drug Oncology Products
Reviewer: Whitney S. Helms, Ph.D.
Supervisor/Team Leader: Hans Rosenfeldt, Ph.D. acting for
S. Leigh Verbois, Ph.D.
Division Director: Robert L. Justice, M.D., M.S.
Project Manager: Christy L. Cottrell

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6 pages of Pharmacology has been withheld in full immediately following this page as B4 CCI/TS

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-201023	ORIG-1	SANOFI AVENTIS SPA	CABAZITAXEL (XRP6258)

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/s/

WHITNEY S HELMS
06/14/2010

HANS M ROSENFELDT
06/14/2010

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