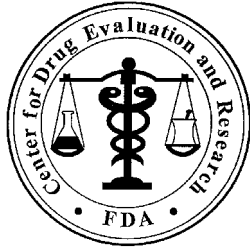


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

20-1023

PROPRIETARY NAME REVIEW(S)



**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology**

Date: May 11, 2010

To: Robert Justice, MD, Division Director
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Subject: Proprietary Name Review

Drug Name(s): Jevtana (Cabazitaxel) Injection
60 mg/1.5 mL Before Initial Dilution

Application Type/Number: NDA 201023

Applicant: Sanofi Aventis

OSE RCM #: 2010-695

***** This document contains proprietary and confidential information that should not be released to the public.*****

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EXECUTIVE SUMMARY

This review summarizes the analysis of the proposed proprietary name, Jevtana, for Cabazitaxel Injection. Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name Jevtana conditionally acceptable for this product. The proposed proprietary name must be re-reviewed 90 days before approval of the NDA.

Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

1. BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from Sanofi Aventis dated April 1, 2010 for an assessment of the proposed proprietary name, Jevtana, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. The Applicant submitted an external study conducted by (b) (4) in support of their proposed proprietary name. The Labels and Labeling included in this submission were reviewed separately in OSE review # 2010-714.

1.2 PRODUCT INFORMATION

Jevtana (Cabazitaxel) is an antineoplastic agent that acts by disrupting the microtubular network in cells. Jevtana in combination with Prednisone is indicated for the treatment of patients with hormone refractory prostate cancer. The recommended dose of Jevtana is 25 mg/m² administered every 3 weeks as a 1- hour infusion. Jevtana is available in 60 mg/1.5 mL Injection Concentrate which requires a two step dilution process prior to administration. The dilution process is as follows:

Step One:

Each Vial of JEVTANA (cabazitaxel) 60 mg/1.5 mL must first be mixed with the entire contents of supplied diluent (b) (4). The resultant solution contains 10 mg/mL of JEVTANA.

Step Two:

Withdraw the required amount of Jevtana from the 10 mg/mL drug solution/diluent mixture prepared in step one and further dilute into either 0.9% sodium chloride solution or 5% dextrose solution for infusion.

The final JEVTANA dilution for infusion should be administered intravenously as a 1-hour infusion at room temperature.

Jevtana will be packaged as a kit containing a Jevtana vial (60 mg/1.5 mL) and a diluent vial (b) (4).

2. METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1, 2.2, and 2.3 identify specific information associated with the methodology for the proposed proprietary name, Jevtana.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter ‘J’ when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.^{1,2}

To identify drug names that may look similar to Jevtana, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (seven letters), upstrokes (two, letters ‘J’ and ‘T’), down strokes (none), cross strokes (one, letter ‘t’), and dotted letters (none). Additionally, several letters in Jevtana may be vulnerable to ambiguity when scripted (See Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Jevtana.

When searching to identify potential names that may sound similar to Jevtana, the DMEPA staff search for names with similar number of syllables (three), stresses (JEV-ta-na or jev-tana or jev-ta-NA), and placement of vowel and consonant sounds. (See Appendix B) The Applicant’s intended pronunciation (Jev-ta-na) was also taken into consideration. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

2.2 PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient medication order and verbal prescription was communicated during the FDA prescription studies.

¹ Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

² Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

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