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 Division of Drug Oncology Products
Through:	Melina Griffis RPh, Team Leader Denise Toyer, PharmD, Deputy Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis
From:	Lubna Najam, MS, PharmD., Safety Evaluator Division of Medication Error Prevention and Analysis
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.*****

CONTENTS

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/m^2 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)

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.