CENTER FOR DRUG EVALUATION AND RESEARCH

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PROPRIETARY NAME REVIEW(S)

Department of Health and Human Services

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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

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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.

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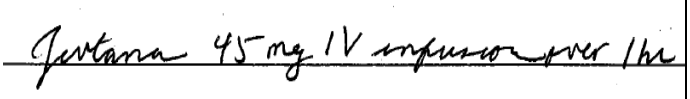
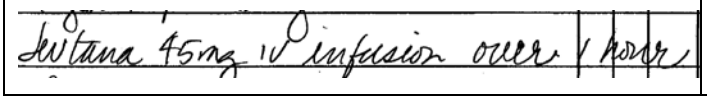
[1] Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at http://www.ismp.org/Tools/confuseddrugnames.pdf

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

Figure 1. Jevtana Study (conducted on April 09, 2010)

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Inpatient prescription- 1: 	Jevtana 45 mg IV infusion over 1 hour
Inpatient prescription-2: 	

2.3 EXTERNAL PROPRIETARY NAME RISK ASSESSMENT

For this product, the Applicant submitted an external evaluation of the proposed proprietary name. The Division of Medication Error Prevention and Analysis conducts an independent analysis and evaluation of the data provided, and responds to the overall findings of the assessment. When the external proprietary name risk assessment identifies potentially confusing names that were not captured in DMEPA's database searches or in the Expert Panel Discussion, these names are included in the Safety Evaluator's Risk Assessment and analyzed independently by the Safety Evaluator to determine if the potentially confusing name could lead to medication errors in usual practice settings. After the Safety Evaluator has determined the overall risk associated with proposed name, the Safety Evaluator compares the findings of their overall risk assessment with the findings of the proprietary name risk assessment submitted by the Applicant. The Safety Evaluator then determines whether the Division's risk assessment concurs or differs with the findings. When the proprietary name risk assessments differ, the Division of Medication Error Prevention and Analysis provides a detailed explanation of these differences.

3. RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of 22 names as having some similarity to the name Jevtana. Twenty of the names were thought to look like Jevtana. These include: Jevtana, Januvia, Janumet, Jenloga, Gentasol, Gentak, Gentran 40, Tekturna, Taxotere, Fentora, Jolessa, Forteo, Jevity, (b) (4) Senatec, Levitra, Lexiva, Sentra AM, Leukine and Extina. The remaining two names were thought to look and sound similar to Jevtana. These include Jantoven and Teveten.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of April 8, 2010.

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

3.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Jevtana.

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

3.3 PRESCRIPTION ANALYSIS STUDIES

A total of 44 practitioners responded, none of the responses overlapped with any existing drug names. Thirteen (n=13) of the participants interpreted the name correctly as "Jevtana," with correct interpretation occurring more frequently in the written studies. The remaining written responses misinterpreted the drug name. The letter 'J' was misinterpreted as the letter 'Z' or 'L', and the letter 'e' was misinterpreted as the letters 'i' and 'u.' In the verbal studies, most of the responses were misspelled phonetic variations of the proposed name.

See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.4 EXTERNAL STUDY

The proprietary name risk assessment submitted by the Sanofi Aventis found the proposed proprietary name acceptable. (b) (4) identified and evaluated eighteen drug names with some potential for confusion with the name Jevtana: Fentanyl, Januvia, Jantoven, Jevity, Extina, Ben-Tann, Daytrana, Detane, Femara, J-Tann, Je-vax, Metanx, Pentasa, Revina, Enjuvia, Opana, Simvastatin, and Ziana. Of the names identified by (b) (4) five were also identified by DMEPA during the database searches: Januvia, Jantoven, Jevity, Extina, and Fentanyl. The remaining 13 names were added to the safety evaluator assessment. It was noted in the evaluation of the (b) (4) study that (b) (4) considered the Jevtana vial concentration as 60 mg/15 mL in their evaluation; however Jevtana is available as 60 mg/1.5 mL. DMEPA considered this inconsistency when evaluating the names identified by (b) (4)

3.5 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator resulted in identification of sixteen additional names which were thought to look or sound similar to Jevtana represent a potential source of drug name confusion. The names identified to have look-alike similarities are (b) (4) Fenobam, Fentanyl, Genatopn, Fertinex, Geritonic, Fareston, Fortaz, Fortamet, (b) (4) Feraheme, Fostimon***, (b) (4) Gantanol, Gentian, and Genelan.

One name "Jevtana" was not evaluated further since it was identified on the U.S. Patent and Trademark Office website registered to the Applicant likely for this product. Thus, we evaluated a total of fifty names: 16 identified by the primary safety evaluator, 13 identified by (b) (4) and 21 identified in section 3.1 above.

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3.6 COMMENTS FROM THE DIVISION OF DRUG ONCOLOGY PRODUCTS (DDOP)

3.6.1 Initial Phase of Review

In response to the OSE, April 12, 2010 e-mail, Division of Drug Oncology Products (DDOP) did not forward any concerns on the proposed name at the initial phase of the name review.

3.6.2 Midpoint of Review

DMEPA notified the Division of Drug Oncology Products via e-mail that we had no concerns with the proposed proprietary name, Jevtana, on April 28, 2010. Per e-mail correspondence from the Division of Drug Oncology Products on May 05, 2010, they indicated the Division had no other issues with the proposed proprietary name, Jevtana.

4. DISCUSSION

Jevtana is the proposed proprietary name for Cabazitaxel Injection. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Sanofi Aventis. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly.

4.1 PROMOTIONAL ASSESSMENT

DDMAC found the proposed proprietary name acceptable from a promotional perspective, and did not offer any additional comments relating to the proposed name. DMEPA and the Division of Drug Oncology Products concurred with the findings of DDMAC's promotional assessment of the proposed name.

4.2 SAFETY ASSESSMENT

Fifty names were identified as having potential similarity to the proposed proprietary name, Jevtana. No other aspects of the name were considered to pose potential confusion with the name. Fifteen of the fifty names did not undergo failure mode and effect analysis (FMEA) for the following reasons: Four names lacked convincing orthographic and/or phonetic similarity to the proposed proprietary name Jevtana (see Appendix D), eleven other names did not undergo failure mode and effect analysis (FMEA) because they were either herbal products or supplements not dispensed pursuant to a prescription, products discontinued or not marketed in the U.S, proposed proprietary names for products later approved under a different proprietary name or withdrawn (see Appendices E, F, and G).

Failure modes and effects analysis (FMEA) was applied to determine if the proposed proprietary name could potentially be confused with the remaining 35 names and lead to medication errors. This analysis determined that the name similarity between Jevtana and all of the identified names was unlikely to result in medication error for the reasons presented in Appendices H and I.

5. CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Jevtana, is not vulnerable to name confusion that could lead to medication errors, nor is it considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Jevtana, for this product at this time. Our analysis is consistent with the external risk assessment conducted by (b) (4) that was provided by the Applicant. The Applicant will be notified via letter.

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.

If you have further questions or need clarifications, please contact Sarah Simon, project manager, at 301-796-5205.

6. COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Jevtana, and have concluded that it is acceptable.

Jevtana will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

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.

7. REFERENCES

1. Micromedex Integrated Index (http://csi.micromedex.com)
Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

2. Phonetic and Orthographic Computer Analysis (POCA)
POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. Drug Facts and Comparisons, online version, St. Louis, MO (http://factsandcomparisons.com)
Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products.

4. FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]
DARRTS is a government database used to organize Applicant and Applicant submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

6. Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

7. Electronic online version of the FDA Orange Book (http://www.fda.gov/cder/ob/default.htm)

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

8. U.S. Patent and Trademark Office (http://www.uspto.gov)

USPTO provides information regarding patent and trademarks.

9. Clinical Pharmacology Online (www.clinicalpharmacology-ip.com)

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

10. Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at (www.thomson-thomson.com)

The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

11. Natural Medicines Comprehensive Databases (www.naturaldatabase.com)

Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

12. Stat!Ref (www.statref.com)

Stat!Ref contains full-text information from approximately 30 texts; it includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology, and Dictionary of Medical Acronyms Abbreviations.

13. USAN Stems (http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml)

USAN Stems List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

15. Lexi-Comp (www.lexi.com)

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

16. Medical Abbreviations Book

Medical Abbreviations Book contains commonly used medical abbreviations and their definitions.

APPENDICES

Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [3]

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate into the overall risk assessment.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail. [4] DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. Accordingly, the DMEPA staff considers the product characteristics

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[3] National Coordinating Council for Medication Error Reporting and Prevention. http://www.nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

[4] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

associated with the proposed drug throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, DMEPA staff considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[5] DMEPA provides the product characteristics considered for this review in section one.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly in spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g.,"T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details). In addition, the DMEPA staff compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. If provided, DMEPA will consider the Applicant's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Applicant has little control over how the name will be spoken in clinical practice.

Table 1. Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name.

Type of similarity	**Considerations when searching the databases**		
	Potential causes of drug name	*Attributes examined to identify similar drug names*	*Potential Effects*

[5] Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

	similarity		
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, the DMEPA staff also considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA staff conducts searches of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database

that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the DMEPA staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel.

2. CDER Expert Panel Discussion

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the DMEPA staff to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Analysis Studies

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of the 123 participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants send their interpretations of the orders via e-mail to DMEPA.

4. Comments from the OND review Division or Generic drugs

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary name and any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND or OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to concur/not concur with DMEPA's final decision.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, conducts a Failure Mode and Effects Analysis, and provides an overall risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.[6] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase. In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section one. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

> ***"Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?"***

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the question is no, the Safety Evaluator is not convinced that the names posses similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

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[6] Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

"Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?"

The answer to this question is a central component of the Safety Evaluator's overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Risk Assessment:

a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.

d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.

e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Applicant with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant. However, the safety concerns set forth in criteria a through e are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or

sound-alike drug names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and a preventable source of medication error that, in many instances, the Agency and/or Applicant can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Applicants have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Applicant and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Applicants' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval. . (See Section 4 for limitations of the process).

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Applicant with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

Appendix B: Letters with possible orthographic or phonetic misinterpretation

Letters in Name, (b) (4)	Scripted may appear as	Spoken may be interpreted as
Capital 'J'	T, I	G
lower case 'j'	f, l, g, y	same as above
lower case 'e'	a, i, e, o	any vowel
lower case 'v'	n, r	f
lower case 't'	l, f, h	d
lower case 'a'	e, o, u	any vowel
lower case 'n'	r, v	en

Appendix C: FDA Prescription Study Responses

Inpatient Medication Order-1	Inpatient Medication Order-2	Voice Prescription
Jivtana	Jevtana	Jeftana
Juvtana	Jevtana	Jevtana
Jevtana	Levtana	Jatana
Lovtana	Tevtana	Jeptana
Juvtana	Jertana	Gatana
Jevtana	Sevtana	Justana
Zevtana,	Levtana	Gentana
Levtana	Jevtana	Jevtana
Jentana	Levtana	Jutana
Justana	Levtana	Jafanna
Jevtana	Jevtana	Justona
Jevtana	Levtana	Jeftana
Jevtana	Levtana	Jotona
Zantana		
Jevtana		
Jurtana		
Jevtana		
Jivtana		

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Appendix D: Proprietary names that lack convincing orthographic and/or phonetic similarities

Proprietary Name	Similarity to Jevtana
Enjuvia	(b) (4)
Opana	(b) (4)
Simvastatin	(b) (4)
Ziana	(b) (4)

Appendix E: OTC, Herbal Product, or Supplement not identified as drug and not dispensed pursuant to a prescription.

Proprietary Name	Similarity to Jevtana	Reason
Gentian	Look	Herbal supplement
Sentra AM	Look	Amino acids and Nutraceutical
Geritonic	Look	Ferrous sulfate/liver and vitamin B complex used as a nutritional supplement with limited information available on product characteristics.
Genelan	Look	OTC Cough syrup with a combination of chlorpheniramine/dextromethorphan/guaifenesina and phenylephrine with limited information available on product characteristics.
Jevity	Look	Tube feeding

Appendix F: Discontinued products with no available generics or products not marketed in the U.S

Proprietary Name	Similarity to Jevtana	Status
Gantanol (Sulfamethoxazole)	Look	Discontinued products with no available generics
Fertinex (Urofollitropin)	Look	Discontinued products with no available generics
Je-Vax (Japanese Encephalitis virus vaccine)	Look	No longer distributed in US under the proprietary name Je-Vax. Now available as Ixiaro.

Appendix G: Proposed proprietary names withdrawn by the applicant.

Proprietary Name	Similarity to Jevtana	Status
(b) (4)		

Appendix H : Products with orthographic, phonetic and/or multiple differentiating product characteristics minimize the risk for medication errors

Product name with potential for confusion	Similarity to Jevtana	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Jevtana (Cabazitaxel) Injection (b) (4)	**N/A**	**60 mg/1.5 mL**	**25 mg/m^2 given as an Intravenous infusion over 1 hour once or every 3 weeks (Dosage range based on average adult is 35 mg-55 mg)**	**N/A**
Teveten (Eprosartan mesylate) Tablets	Look and sound alike	400 mg, 600 mg	400 mg to 600 mg once daily to twice daily	Differences in product characteristics minimize the likelihood of medication error in the usual practice setting. Route of Administration: *Oral vs. intravenous infusion* Dosage Form: *Tablet vs. injection solution* Dose: *25 mg/m^2 (35 mg to 55 mg) vs. 400 mg to 600 mg* Frequency: *Daily to twice daily vs. once or every 3 weeks*

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

Product name with potential for confusion	Similarity to Jevtana	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Jevtana (Cabazitaxel) Injection (b) (4)	**N/A**	**60 mg/1.5 mL**	**25 mg/m^2 given as an Intravenous infusion over 1 hour once or every 3 weeks (Dosage range based on average adult is 35 mg-55 mg)**	**N/A**
Januvia (Sitagliptin phosphate) Tablets	Look alike	25 mg, 50 mg, 100 mg	25 to 100 mg daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *There is no upstroke in Januvia whereas Jevtana contains an upstroke-"t"* Route of Administration: *Oral vs. intravenous infusion* Dosage Form: *Tablet vs. injection solution* Frequency: *Daily vs. once or every 3 weeks*
Janumet (Sitagliptin and metformin) Tablets	Look alike	50/500 mg and 50/1000 mg	50/500 to 100/2000 or 1-2 tablets twice daily with meals	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *The upstroke in Janumet is at the end as opposed to Jevtana where the upstroke-"t" is in the middle of the name* Route of Administration: *Oral vs. intravenous infusion* Dosage Form: *Tablet vs. injection solution* Frequency: *Daily to twice daily vs. once or every 3 weeks* Dose: *25 mg/m^2 (35 mg to 55 mg) vs. 50/500 mg to 100/2000 mg*

Product name with potential for confusion	Similarity to Jevtana	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Jevtana (Cabazitaxel) Injection (b) (4)	**N/A**	**60 mg/1.5 mL**	**25 mg/m^2 given as an Intravenous infusion over 1 hour once or every 3 weeks (Dosage range based on average adult is 35 mg-55 mg)**	**N/A**
Gentak (Gentamycin) Opthalmic Ointment	Look alike	0.3%	Apply ½ inch ointment to the eye 2-3 times daily or every3-4 hours.	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Gentak contains an additional upstroke at the end –"k"* Route of Administration: *Ophthalmic vs. intravenous infusion* Dosage Form: *Ointment vs. injection solution* Frequency: *2-3 times daily vs. once or every 3 weeks*
Jenloga (Clonidine) Modified Release Tablets	Look alike	0.1 mg	0.1 to 0.4 mg or 1-4 tablets daily to twice daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Jenloga contains a downstoke "g" at the end* Route of Administration: *Oral vs. intravenous infusion* Dosage Form: *Tablet vs. injection solution* Frequency: *Daily to twice daily vs. once or every 3 weeks* Dose: *25 mg/m^2 (35 mg to 55 mg) vs. 0.1 mg to 0.4 mg*

Product name with potential for confusion	Similarity to Jevtana	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Jevtana (Cabazitaxel) Injection (b) (4)	**N/A**	**60 mg/1.5 mL**	**25 mg/m^2 given as an Intravenous infusion over 1 hour once or every 3 weeks (Dosage range based on average adult is 35 mg-55 mg)**	**N/A**
Fentora (Fentanyl) Buccal Tablet	Look alike	100 mcg, 200 mcg 400 mcg 600 mg 800 mcg	100 mcg-1200 mcg as needed for pain	Differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Route of Administration: *Oral vs. intravenous infusion* Dosage Form: *Buccal tablet vs. injection solution* Frequency: *As needed vs. once or every 3 weeks* Dose: *25 mg/m^2 (35 mg to 55 mg) vs. 100 mcg, 200 mcg, 400 mcg, 600 mg and 800 mcg*
Forteo (Teriparatide) Subcutaneous Injection	Look alike	250 mcg/mL	20 mcg subcutaneously daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *The suffix "eo" appears shorter than "ana" when scripted* Route of Administration: *Subcutaneous vs. intravenous infusion* Dose: *20 mcg vs. 25 mg/m^2 (35 mg to 55 mg)* Frequency: *Daily vs. once or every 3 weeks*

Product name with potential for confusion	Similarity to Jevtana	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Jevtana (Cabazitaxel) Injection (b) (4)	**N/A**	**60 mg/1.5 mL**	**25 mg/m^2 given as an Intravenous infusion over 1 hour once or every 3 weeks (Dosage range based on average adult is 35 mg-55 mg)**	**N/A**
Tekturna (Aliskeren) Tablets	Look alike	150 mg 300 mg	150 to 300 mg daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Tekturna has an additional upstroke "k" in the name* Route of Administration: *Oral vs. intravenous infusion* Dosage Form: *Tablet vs. injection solution* Frequency: *Daily vs. once or every 3 weeks* Dose: *25 mg/m^2 (35 mg to 55 mg) vs. 150 mg to300 mg*
Jolessa (Ethinyl estradiol amd levonorgesterel) Tabelts	Look alike	0.03 mg/0.15 mg	Take 1 tablet daily	Differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Route of Administration: *Oral vs. intravenous infusion* Dosage Form: *Tablet vs. injection solution* Frequency: *Daily vs. once or every 3 weeks* Dose: *25 mg/m^2 (35 mg to 55 mg) vs. 0.03 mg/0.15 mg or 1 tablet* Patient population: *Females vs. males with prostate cancer*

Product name with potential for confusion	Similarity to Jevtana	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Jevtana (Cabazitaxel) Injection (b) (4)	**N/A**	**60 mg/1.5 mL**	**25 mg/m^2 given as an Intravenous infusion over 1 hour once or every 3 weeks (Dosage range based on average adult is 35 mg-55 mg)**	**N/A**
Gentasol (Gentamycin) Ophthalmic Solution	Look alike	0.3 %	1-2 drops in the eye every 2-4 hours	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Gentasol contains an additional upstroke at the end –"l"* Route of Administration: *Opthalmic vs. intravenous infusion* Dosage Form: *Solution vs. injection solution* Frequency: *Every 2-4 hours vs. once or every 3 weeks* Dose: *25 mg/m^2 (35 mg to 55 mg) vs. 1 to 2 drops*
(b) (4)				

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Product name with potential for confusion	Similarity to Jevtana	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Jevtana (Cabazitaxel) Injection (b) (4)	**N/A**	**60 mg/1.5 mL**	**25 mg/m^2 given as an Intravenous infusion over 1 hour once or every 3 weeks (Dosage range based on average adult is 35 mg-55 mg)**	**N/A**
Senatec (Lidocaine) Lotion	Look alike	3 %	Apply to affected area as needed	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *The upstroke "t" is in different postions in the two names* Route of Administration: *Topical vs. intravenous infusion* Dosage Form: *Lotion vs. injection solution* Frequency: *As needed vs. once or every 3 weeks* Dose: *25 mg/m^2 (35 mg to 55 mg) vs. 1 application*
Levitra (Vardenafil) Tablets	Look alike	2.5 mg, 5 mg, 10 mg, 20 mg	2.5 mg to 20 mg or 1 tablet once or 1 tablet as needed	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *The upstroke "t" is in different positions in the two names* Route of Administration: *Oral vs. intravenous infusion* Dosage Form: *Tablet vs. injection solution* Dose: *25 mg/m^2 (35 mg to 55 mg) vs.* 2.5 mg, 5 mg, 10 mg, 20 mg

Product name with potential for confusion	Similarity to Jevtana	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Jevtana (Cabazitaxel) Injection (b) (4)	**N/A**	**60 mg/1.5 mL**	**25 mg/m^2 given as an Intravenous infusion over 1 hour once or every 3 weeks (Dosage range based on average adult is 35 mg-55 mg)**	**N/A**
Lexiva (Fosamprenavir Tablet and Suspension	Look alike	700 mg tablets and 50 mg/mL suspension	Adults 1-2 tablets daily or twice daily Peds >6yrs 18mg/kg max 700 mg and peds 2-5 yrs 30 mg/kg. max 1400 mg	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *There is only one upstroke in Lexiva whereas Jevtana has an additional upstroke "t".* Route of Administration: *Oral vs. intravenous infusion* Dosage Form: *Tablet or suspension vs. injection solution* Frequency: *Daily or twice daily vs. once or every 3 weeks* Dose: *25 mg/m^2 (35 mg to 55 mg) vs. 700 mg or 1-2 tablets*
Genaton (Aluminium hydroxide and magnesium carbonate) Oral Suspension	Look alike	95 mg/358 mg/15 mL	15-30 mL take 4 times a day or as needed	Differences in product characteristics minimize the likelihood of medication error in the usual practice setting. Route of Administration: *Oral vs. intravenous infusion* Dosage Form: *Suspension vs. injection solution* Frequency: *Four times daily or as needed vs. once or every 3 weeks* Dose: *25 mg/m^2 (35 mg to 55 mg) vs. 15-30 mL (1-2 tablespoons)*

Product name with potential for confusion	Similarity to Jevtana	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Jevtana (Cabazitaxel) Injection (b) (4)	**N/A**	**60 mg/1.5 mL**	**25 mg/m^2 given as an Intravenous infusion over 1 hour once or every 3 weeks (Dosage range based on average adult is 35 mg-55 mg)**	**N/A**
Fareston (Toremifene citrate) Tablets	Look alike	60 mg	60 mg or 1 tablet daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *The upstroke "t" is in different positions in the two names.* Route of Administration: *Oral vs. intravenous infusion* Dosage Form: *Tablet vs. injection solution* Frequency: *Daily vs. once or every 3 weeks* Patient population: *Treatment of breast cancer in women vs. treatment of prostate cancer in men.*
Fortaz (Ceftazidime) Injection powder	Look alike	500 mg, 1 gm and 2 gm	Adults and pediatrics over 12 yrs: 500 mg to 2 gm every 8-12 hours. Pediatrics: 30-50 mg/kg intravenous q8hrs	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *The suffix "az" has a downstroke when scripted and Fortaz appears shorter than Jevtana* Frequency: *Every 8-12 hours vs. once or every 3 weeks* Dose: *25 mg/m^2 (35 mg to 55 mg) vs. 500 mg, 1 gm and 2 gm or above 300 mg for pediatrics..*

Product name with potential for confusion	Similarity to Jevtana	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Jevtana (Cabazitaxel) Injection (b) (4)	**N/A**	**60 mg/1.5 mL**	**25 mg/m^2 given as an Intravenous infusion over 1 hour once or every 3 weeks (Dosage range based on average adult is 35 mg-55 mg)**	**N/A**
Fortamet (Metformin) Tablets extended release	Look alike	500 mg, 1000mg	500 mg to 2000 mg or 1 tablet to 4 tablets taken once daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Orthographic:</u> *Fortamet contains an extra upstroke "t" at the end of the name* <u>Route of Administration:</u> *Oral vs. intravenous infusion* <u>Dosage Form:</u> *Tablet vs. injection solution* <u>Frequency:</u> *Every day vs. once or every 3 weeks* <u>Dose:</u> *25 mg/m^2 (35 mg to 55 mg) vs. 500- 2000 mg*
Garetain*** (Gabapentin) Tablets extended release	(b) (4)	(b) (4)	(b) (4) (b) (4)	(b) (4)

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Product name with potential for confusion	Similarity to Jevtana	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Jevtana (Cabazitaxel) Injection (b) (4)	**N/A**	**60 mg/1.5 mL**	**25 mg/m^2 given as an Intravenous infusion over 1 hour once or every 3 weeks (Dosage range based on average adult is 35 mg-55 mg)**	**N/A**
Benn-Tann (Diphenhydramine tannate) Liquid	Look alike	25 mg/5 mL	25 to 100 mg every 6 hours as needed	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *The prefix "benn" does not look like "Jev" when scripted.* Route of Administration: *Oral vs. intravenous infusion* Dosage Form: *Liquid vs. injection solution* Frequency: *Every 6 hours as needed vs. once or every 3 weeks*
Daytrana (Methylphenidate) transdermal patch	Look alike	10 mg/9 hr 15 mg/8 hr 20 mg/9 hr 30 mg/9 hr	Apply 1 patch daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Daytrana has a downstoke "y" in the name which is absent in Jevtana* Route of Administration: *Transdermal vs. intravenous infusion* Dosage Form: *Patch vs. injection solution* Frequency: *Every day vs. once or every 3 weeks*

Product name with potential for confusion	Similarity to Jevtana	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Jevtana (Cabazitaxel) Injection (b) (4)	**N/A**	**60 mg/1.5 mL**	**25 mg/m^2 given as an Intravenous infusion over 1 hour once or every 3 weeks (Dosage range based on average adult is 35 mg-55 mg)**	**N/A**
Detane (Benzocaine) Topical gel	Look alike	7.5 %	1 application topically as needed for pain or desensitizing	Differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Route of Administration: *Topical vs. intravenous infusion* Dosage Form: *Gel vs. injection solution* Dose: *25 mg/m^2 (35 mg to 55 mg) vs. 1 application*
Extina (Ketoconazole) Topical foam	Look alike	2 %	Apply 1 application topically twice daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Jevtana looks longer than Extina when scripted* Route of Administration: *Topical vs. intravenous infusion* Dosage Form: *Foam vs. injection solution* Dose: *25 mg/m^2 (35 mg to 55 mg) mg vs. 1 application* Frequency: *Twice daily vs. once or every 3 weeks*

Product name with potential for confusion	Similarity to Jevtana	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Jevtana (Cabazitaxel) Injection (b) (4)	**N/A**	**60 mg/1.5 mL**	**25 mg/m^2 given as an Intravenous infusion over 1 hour once or every 3 weeks (Dosage range based on average adult is 35 mg-55 mg)**	**N/A**
Femara (Letrozole) Tablets	Look alike	2.5 mg	2.5 mg or 1 tablet daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Femara dose not have an upstroke "t" which is present in Jevtana* Route of Administration: *Oral vs. intravenous infusion* Dosage Form: *Tablet vs. injection solution* Frequency: *Daily vs. once or every 3 weeks*
J-Tann (Phenylephrine/ brompheniramine) Tablets and Suspension	Look alike	1.58/2.2 mg/ Tablet or 4mg-5mg/5mL	10- 20 ml or 1-4 tablets every 12 hours as needed	Differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Route of Administration: *Oral vs. intravenous infusion* Dosage Form: *Tablet or suspension vs. injection solution* Dose: *25 mg/m^2 (35 mg to 55 mg) vs. 10 to 20 ml or 1 to 4 tablets* Frequency: *Every 12 hours as needed vs. once or every 3 weeks*

Product name with potential for confusion	Similarity to Jevtana	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Jevtana (Cabazitaxel) Injection (b) (4)	**N/A**	**60 mg/1.5 mL**	**25 mg/m^2 given as an Intravenous infusion over 1 hour once or every 3 weeks (Dosage range based on average adult is 35 mg-55 mg)**	**N/A**
Metanx (L-methylfolate with vitamins B6 and B12) Tablets	Look alike	2.8 mg/25 mg/2 mg	1-2 tablets daily to twice daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Orthographic:</u> *The letter "m" does not look like "j" when scripted* <u>Route of Administration:</u> *Oral vs. intravenous infusion* <u>Dosage Form:</u> *Tablet vs. injection solution* <u>Dose:</u> *25 mg/m^2 (35 mg to 55 mg) vs. 1 to 2 tablets* <u>Frequency:</u> *Daily or twice daily vs. once or every 3 weeks*
Pentasa (Mesalamine) Capsules extended release	Look alike	250 mg, 500 mg	2-8 capsules taken 3-4 times daily	Differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Route of Administration:</u> *Oral vs. intravenous infusion* <u>Dosage Form:</u> *Capsules vs. injection solution* <u>Dose:</u> *25 mg/m^2 or 35 mg to 55 mg vs 250 mg to 2 gm or 2 to 8 capsules* <u>Frequency:</u> *3-4 times daily vs. once or every 3 weeks*

Product name with potential for confusion	Similarity to Jevtana	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Jevtana (Cabazitaxel) Injection (b) (4)	**N/A**	**60 mg/1.5 mL**	**25 mg/m^2 given as an Intravenous infusion over 1 hour once or every 3 weeks (Dosage range based on average adult is 35 mg-55 mg)**	**N/A**
Feraheme (Ferumoxytol) Injection	Look alike	30 mg/mL	510 mg given as intravenous injection once repeated in 3-8 days	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Feraheme appears longer than Jevtana when scripted.* Dose: *25 mg/m^2 (35 mg to 55 mg) vs 510 mg* Prescriber: *Jevtana will always be prescribed by an oncologist and Feraheme will be prescribed by nephrologist.*
Fenobam (Fenobam monohydrate) Capsules	Look alike	25 mg	Dose may range from 50 mg to 600 mg given four times daily.	Differences in product characteristics minimize the likelihood of medication error in the usual practice setting. Route of Administration: *Oral vs. intravenous infusion* Dosage Form: *Capsules vs. injection solution* Frequency: *4 times daily vs. once or every 3 weeks*

Product name with potential for confusion	Similarity to Jevtana	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Jevtana (Cabazitaxel) Injection (b) (4)	**N/A**	**60 mg/1.5 mL**	**25 mg/m^2 given as an Intravenous infusion over 1 hour once or every 3 weeks (Dosage range based on average adult is 35 mg-55 mg)**	**N/A**
Revina (Balsam peru/castor oil/trypsin) topical ointment	Look alike	87 mg/788 mg/90units per 1 gm	Apply 1-4 application 2-4 times daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Revina does not have the upstroke"t"* Route of Administration: *Topical vs. intravenous infusion* Dosage Form: *Ointment vs. injection solution* Dose: *25 mg/m^2 (35 mg to 55 mg) vs. 1-4 applications* Frequency: *3-4 times daily vs. once or every 3 weeks*

Appendix I: Potential confusing name with numerical similarity in strength and dose

Proposed name: Jevtana (Cabazitaxel) Injection (b) (4)	**Strength: 60 mg/1.5 mL**	**Usual Dose: 20 mg/m^2 (Dosage range for an average adult is 35 mg to 55 mg) given as an Intravenous infusion over 1 hour once or every 3 weeks**
Failure Mode: Name confusion	**Causes**	**Prevention of Failure (name confusion) Leading to a Medication Error**
Gentran 40 (Dextran 10% in 5% Dextrose solution) How supplied: Available as 500 mL infusion bags. Dose; Ranges from 20-40 mL/minute or 10 mg/kg/day	**Orthographic Similarities:** Both names contain the upstroke "t" in the middle of the name. Both names contain the same number of letters. **Overlap in Route:** Both are given as intravenous infusion **Overlap in Frequency:** Both can be dosed once daily	Differences in product characteristics minimize the likelihood of medication error in the usual practice setting. **Rationale:** Gentran 40 will always be dosed as mL/hr or 1 bag vs. Jevtana which is dosed as 25 mg/m^2 or in the range of 35 mg to 55 mg. The two products do not have any overlapping doses.
Taxotere (Docetaxel) Injection How supplied: 20 mg/0.5 mL injection solution Dose; 60 to 100 mg/m^2	**Orthographic Similarities:** Both names contain an upstroke "t' **Strength:** Taxotere is available as 20 mg/0.5 mL. Jevtana is available as 60 mg/1.5 mL but could be written as 20 mg/0.5 mL **Overlap in Route:** Both drugs are given as intravenous infusion **Overlap in Frequency:** Both drugs can be ordered as once or every 3 weeks. **Overlap in Patient Population:** Both drugs are indicated in patients with prostate cancer **Overlap in Manufacturer:** Both drugs are made by Sanofi Aventis	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. **Rationale:** The upstroke "t' is present at different positions in the two names. The prefix "taxo" dose not look like "jev" when scripted Jevtana is dosed as 25 mg/m^2 (Average adult dose range is 35 mg to 55 mg) whereas Taxotere is dosed as 60 to 100 mg/m^2 and can be increased to 200 mg/m^2. There is no overlap in the recommended doses between these products.

Proposed name: Jevtana (Cabazitaxel) Injection (b) (4)	**Strength: 60 mg/1.5 mL**	**Usual Dose: 20 mg/m^2 (Dosage range for an average adult is 35 mg to 55 mg) given as an Intravenous infusion over 1 hour once or every 3 weeks**
Failure Mode: Name confusion	**Causes**	**Prevention of Failure (name confusion) Leading to a Medication Error**
Leukine (Sargramostin) Injection How supplied/Strength: Injection Powder for Solution: 250 mcg Injection Solution: 500 mcg/mL Intravenous Solution: 500 mcg/mL Dose; 250 mcg/m^2	**Orthographic Similarities:** Both names contain as upstroke in the middle of the name. **Overlap in Frequency:** Both drugs can be given as once. **Overlap in Route:** Both drugs can be given by an intravenous infusion. **Numerical Overlap in Dose:** 250 mcg/m^2 vs. 25 mg/m^2 **Overlap in Patient Population:** Both drugs are used in cancer patients.	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. **Rationale:** Jevtana contains the letter "t" as the upstroke whereas Leukine contains the letter "k" as the upstroke Leukine is indicated in patients with neutrophil counts of less than 1500 cells/mm^3. The use of Jevtana is contraindicated in patients with neutrophil count of less than 1500 cells/mm^3 Leukine is available in multiple dosage forms and strengths (Injection powder 250 mcg or Injection solution and infusion of 500 mcg/mL). The strengths for the two products do not overlap.
Fentanyl How supplied/Strength: Available as 50 mcg/mL injection solution Dose; Varies based on patient and indication , can range from 1-2 mcg/kg or 25-100 mcg/dose; continuous infusion rate ranges from: 1-20 mcg/kg/hour or 25-200 mcg/hour or 50-100 mcg/dose	**Orthographic Similarities:** Both names contain the upstroke "t" in the middle of the name. **Overlap in Route:** Both drugs can be given as intravenous infusion **Overlap in frequency:** Both drugs could be ordered as once. **Overlap in Patient Population:** Both drugs can be used in cancer patients	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. **Rationale:** Fentanyl has a downstroke "y" and an upstroke "l" at the end of the name which is absent in Jevtana. When ordered as an infusion, Fentanyl will always be dosed as 1-20 mcg/kg/hr and Jevtana will be dose as 25 mg/m^2 (35 mg-55 mg for an average adult) as a 1 hour infusion.

Proposed name: Jevtana (Cabazitaxel) Injection (b) (4)	**Strength: 60 mg/1.5 mL**	**Usual Dose: 20 mg/m^2 (Dosage range for an average adult is 35 mg to 55 mg) given as an Intravenous infusion over 1 hour once or every 3 weeks**
Failure Mode: Name confusion	**Causes**	**Prevention of Failure (name confusion) Leading to a Medication Error**
Jantoven (warfarin sodium) Tablets <u>How supplied/Strength:</u> Available in 1 mg, 2 mg, 2.5 mg, 3 mg, 4 mg, 5 mg, 6 mg, 7.5 mg, 10 mg <u>Dose;</u> Ranges from 1 mg to 15 mg	**Orthographic Similarities:** Both names start with the same letter and contain the upstroke "t" in the middle of the name and are of similar length (8 letters vs. 7 letters) **Overlap in frequency:** Both drugs could be dosed once daily.	Differences in product characteristics minimize the likelihood of medication error in the usual practice setting. **Rationale:** Jevtana is available as an injection solution and given by the intravenous route in contrast to Jantoven which is a tablet given orally. Further, the recommended dose of Jevtana is 25 mg/m^2 (35 mg-55 mg for an average adult) which does not overlap with the recommended dose of Jantoven which ranges from 1 mg to 15 mg.

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

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/s/

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