CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206910Orig1s000

PROPRIETARY NAME REVIEW(S)

REQUEST FOR RECONSIDERATION PROPRIETARY NAME REVIEW MEMO

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	December 2, 2014
Application Type and Number:	NDA 206910
Product Name and Strength:	Jadenu (deferasirox) Tablets, 90 mg, 180 mg, 360 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Novartis
Submission Date:	October 22, 2014
Panorama #:	2014-25535
DMEPA Primary Reviewer:	Neil Vora, PharmD, MBA
DMEPA Team Leader:	Yelena Maslov, PharmD
DMEPA Associate Director:	Lubna Merchant, PharmD, MS

Contents

1 INTRODUCTION

This review responds to an October 22, 2014 request from Novartis to reconsider the proposed proprietary name, Jadenu. Novartis initially submitted the proposed proprietary name, Jadenu on June 4, 2014. DMEPA performed a safety assessment of the proposed proprietary name, Jadenu in our previous review and found the name acceptable from a safety perspective[1]. However, OPDP found the name unacceptable based on concerns that the name was misleading[1].

1.1 PRODUCT INFORMATION

The following product information is provided in the June 4, 2014 proprietary name submission.

- Intended Pronunciation: Ja' de nue
- Active Ingredient: deferasirox
- Indication of Use:
    - Chronic iron overload due to blood transfusion (TIO)
    - Chronic iron overload in non-transfusion dependent thalassemia (NTDT)
- Route of Administration: Oral
- Dosage Form: Film coated tablets
- Strength: 90 mg, 180 mg and 360 mg
- Dose and Frequency: Once daily
- How Supplied: Bottles of 30 tablets
- Storage: Store tablets at 25°C (77°F); excursions are permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]. Protect from moisture.

[1] Vora, N. Proprietary Name Review for Jadenu (NDA 206910). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2014 AUG. 28 p. OSE RCM No.: 2014-25535

Reference ID: 3666886

2 METHODS AND MATERIALS

The request for reconsideration submitted on October 22, 2014 includes marketing research data provided by a Novartis sponsored Drug Safety Institute (DSI) study in support of the name Jadenu. These materials were forwarded to OPDP for review.

3 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

3.1 MISBRANDING ASSESSMENT

OPDP reviewed the marketing research data collected by DSI in support of the name Jadenu and made the following assessments and conclusion:

Although, the complete data analysis about the DSI study regarding the name Jadenu was not provided, the information provided appear sufficient to persuade us to withdraw our objection. Specifically, 150 US medical professionals, 45 Canadian medical professionals, and 240 EU medical professionals were asked whether they find anything exaggerated or untrue about the name. In all cases, over 98% of participants did not find anything problematic with the name.

OPDP identified the following issues with the data:

1. *Open-ended questions as presented are appropriate for a first step. However, it is not clear that participants would have understood what "untrue" means and our objection did not cite the "untruth" of the name as a problem in any case.*
2. *As with all DSI studies, participants have an incentive to answer "no" to any open-ended question. If they say "no," they can finish the survey quicker. If they say "yes," then they are required to type out responses.*
3. *The study clearly indicated that 96.7% of participants believed Jadenu to be a "new formulation" (p. 12 of reconsideration request). However, the question of whether they believed it to be a "new product" was not asked.*

OPDP concludes that the information provided for reconsideration by the sponsor is convincing and the above issues regarding the data do not rise to a level which would invalidate the information provided for reconsideration in this case. Therefore, we overturn our objection to the proposed trade name Jadenu.

3.2 SAFETY ASSESSMENT

DMEPA performed a safety assessment of the proposed proprietary name, Jadenu, in our previous review and found the name acceptable from a safety perspective[1]

4 CONCLUSIONS

The proposed proprietary name, Jadenu is acceptable.

If you have further questions or need clarifications, please contact Sarah Harris, OSE project manager, at 240-402-4774.

4.1 COMMENTS TO THE APPLICANT

We have completed our review of the information submitted in support of your Request for Reconsideration of the proposed proprietary name, Jadenu. Although our review of the Drug Safety Institute study identified some methodological weaknesses with respect to the data gathered, our overall interpretation of the data collected from the physician survey indicates that the name is not likely to be misleading. Therefore, since there is no outstanding safety or misbranding concerns regarding Jadenu, we find your proposed proprietary name acceptable.

If any of the proposed product characteristics as stated in your October 22, 2014, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

[1] Vora, N. Proprietary Name Review for Jadenu (NDA 206910). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2014 AUG. 28 p. OSE RCM No.: 2014-25535

Reference ID: 3666886

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

NEIL H VORA
12/02/2014

YELENA L MASLOV
12/03/2014

LUBNA A MERCHANT
12/03/2014

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	August 22, 2014
Application Type and Number:	NDA 206910
Product Name and Strength:	Jadenu (deferasirox) Tablets, 90 mg, 180 mg, 360 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Novartis
Submission Date:	June 4, 2014
Panorama #:	2014-25535
DMEPA Primary Reviewer:	Neil Vora, PharmD, MBA
DMEPA Team Leader:	Yelena Maslov, PharmD
DMEPA Associate Director:	Lubna Merchant, PharmD, MS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Jadenu, from a safety and promotional perspective. Novartis currently markets deferasirox oral tablets for suspension under the proprietary name Exjade. However, for the oral tablets formulation, Novartis is pursuing the proposed proprietary name Jadenu. Please refer to Table 1.

The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the June 4, 2014 proprietary name submission.

- Intended Pronunciation: Ja' de nue
- Active Ingredient: deferasirox
- Indication of Use:
    - Chronic iron overload due to blood transfusion (TIO)
    - Chronic iron overload in non-transfusion dependent thalassemia (NTDT)
- Route of Administration: Oral
- Dosage Form: Film coated tablets
- Strength: 90 mg, 180 mg and 360 mg
- Dose and Frequency: Once daily
- How Supplied: Bottles of 30 tablets
- Storage: Store tablets at 25°C (77°F); excursions are permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]. Protect from moisture.

Reference ID: 3615111

Table 1: Exjade and Jadenu Comparison

Trade Name	Exjade	Jadenu
Active Ingredient	Deferasirox	Deferasirox
Indication	Chronic iron overload in non-transfusion dependent thalassemia (NTDT) syndromes in patients 10 years and older. Chronic iron overload due to blood transfusions in patients 2 years and older.	Chronic iron overload in non-transfusion dependent thalassemia (NTDT) syndromes in patients 10 years and older. Chronic iron overload due to blood transfusions in patients 2 years and older.
Route/Dosage Form/Strength	125 mg, 250 mg and 500 mg tablets ***for oral suspension***	90 mg, 180 mg and 360 mg tablets ***orally***
How Supplied	Bottles of 30 tablets	Bottles of 30 tablets
Usual Dose	10-20 mg/kg/day	7-14 mg/kg/day
Max Dose	20-40 mg/kg/day	14-28 mg/kg/day

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 PROMOTIONAL ASSESSMENT

During the initial steps of the proprietary name review process, the Office of Prescription Drug Promotion (OPDP) did not recommend the use of the proposed proprietary name Jadenu because it is overly fanciful. OPDP provided the following statement:

OPDP objects to the proposed proprietary name "Jadenu" because the use of the suffix "nu" (evoking "new") in the proposed proprietary name would be overly fanciful because the active ingredient, deferasirox, is a common substance for which the limitations are readily recognized when Jadenu is listed by its established name [21 CFR 201.10(c)(3)]. Furthermore, "Jadenu" implies superiority over another drug (Exjade) which has an identical active ingredient (deferasirox). The use of a large part of the name "Exjade" in combination with a word that evokes "new" (i.e., novel) implies that Jadenu (deferasirox) is a new drug; however, Exjade (deferasirox) has been on the market since 2005.

Because the proposed trade name would be overly fanciful and would imply superiority over Exjade, it is misleading.

Please note that the Federal Food Drug and Cosmetic Act (FD&C Act) provides that labeling or advertising can misbrand a product if misleading representations are made (See 21 U.S.C. 321(n)). The FD&C Act also provides that a drug is misbranded if its labeling is false or misleading in any particular (21 USC 352(a)). A proprietary name, which appears in labeling, could result in such misbranding if it is false or misleading , such as by making misrepresentations with respect to safety or efficacy.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[1].

2.2.2 Components of the Proposed Proprietary Name

Novartis did not provide a derivation or intended meaning for the proposed name, Jadenu in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that can contribute to medication error.

2.2.3 FDA Name Simulation Studies

One hundred and thirteen (113) practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. In the voice prescription study, 3 of the 61 participants correctly interpreted the prescription. In the written inpatient study, 34 of the 61 participants correctly interpreted the prescription. In the written outpatient study, 24 of the 61 participants correctly interpreted the prescription. Common misinterpretations in the inpatient include: the addition of the letter "r" at the end of the infix, and misinterpreting the "j" for a "t" in the prefix. Common misinterpretations in the voice study include: "e" for an "a" in the infix, the "d" for a "v" in the infix, the addition of "e" at the end of the name in the suffix, and the addition of "y" in the prefix. Common misinterpretations in the outpatient study include: "u" for "a" and the addition of the letter "m" at the end of the name in the suffix.

Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, June 30, 2014 e-mail, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

[1]USAN stem search conducted on July 9, 2014.

Reference ID: 3615111

2.2.5 *Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	123
Low similarity name pair: combined match percentage score ≤49%	0

2.2.6 *Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities*

Our analysis of the 123 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through G.

2.2.6.1 *Marketing Under a Dual Proprietary Name*

Novartis is proposing the proprietary name, Jadenu, a dual proprietary name for their alternate dosage form of deferasirox. Both products, Jadenu (proposed product), and Exjade (existing product) share the same active ingredient. However, while Exjade is only available as a tablet for oral suspension, Jadenu would be supplied as an oral tablet. Additionally, there are also dosing differences between Exjade and Jadenu. Please refer to Table 1 for comparison.

Typically, the greatest risk of introducing a dual proprietary name is inadvertent concomitant therapy of both products resulting in an overdose if practitioners and/or patients fail to recognize that both products contain the same active ingredient. However, it is an unlikely and improbable scenario for Exjade and Jadenu that the same patient would be seen by two different physicians for transfusion dependent chronic iron overload and/or non-transfusion dependent thalassemia (NTDT) syndromes. Typically these patients would be followed by a hematologist and not a general family practitioner or internal medicine.

We also considered different naming approaches such as whether the product could be safely managed using a dual proprietary name, Jadenu, current name Exjade, or Exjade plus a modifier, and considered different medication risks with each approach. Using the existing name, Exjade, will not be optimal since the Applicant is planning to market deferasirox in two different dosage forms (as indicated in Table 1) with different

[2] POCA search conducted on July 9, 2014.

methods of administration. Thus this approach can result in the wrong product being dispensed and subsequently lead to the wrong administration and cause dosing errors.

The naming strategy involving Exjade plus a modifier would also carry a risk of wrong product and wrong dose errors. For example, prescribers can potentially omit the modifier when prescribing the product as omission of the modifier is one of the common errors that can occur. Additionally, the prescriber can overlook the modifier and mistakenly select the wrong product on electronic computer menus when prescribing medications electronically. Essentially the same type of error, in terms of modifier omission, can occur during the computer entry in a pharmacy.[3] As a result, wrong product for deferasirox can be prescribed and dispensed.

Based on aforementioned information, marketing the proposed product under a dual proprietary name seems to pose minimal risk of patient harm. Thus, we find the use of dual proprietary name, Jadenu acceptable for this product from a safety perspective.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on August 20, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DHP on August 22, 2014, they stated no additional concerns with the proposed proprietary name, Jadenu.

3 CONCLUSIONS

The proposed proprietary name, Jadenu, is acceptable from the safety perspective, but unacceptable from a promotional perspective. The Novartis will be notified of FDA's decision to object to the name based on promotional concerns via letter.

If you have further questions or need clarifications, please contact Kevin Wright, OSE project manager, at 301-796-3621.

---

[3] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. *J Gen Intern Med.* 2002; 17(8): 579-587.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Jadenu, and have concluded that this name is unacceptable for the following reason:

The use of the suffix “nu” (evoking “new”) in the proposed proprietary name, Jadenu, would be overly fanciful because the active ingredient, deferasirox, is a common substance for which the limitations are readily recognized when Jadenu is listed by its established name [21 CFR 201.10(c)(3)]. Furthermore, “Jadenu” implies superiority over another drug (Exjade) which has an identical active ingredient (deferasirox). The use of a large part of the name “Exjade” in combination with a word that evokes “new” (i.e., novel) implies that Jadenu (deferasirox) is a new drug; however, Exjade (deferasirox) has been on the market since 2005. Because the proposed trade name would be overly fanciful and would imply superiority over Exjade, it is misleading.

Please note that the Federal Food Drug and Cosmetic Act (FD&C Act) provides that labeling or advertising can misbrand a product if misleading representations are made (See 21 U.S.C. 321(n)). The FD&C Act also provides that a drug is misbranded if its labeling is false or misleading in any particular (21 USC 352(a)). A proprietary name, which appears in labeling, could result in such misbranding if it is false or misleading , such as by making misrepresentations with respect to safety or efficacy.

4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States 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* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

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.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name.

1. **Promotional Assessment**: For prescription drug products, the promotional review of the proposed name is conducted by OPDP. For over-the-counter (OTC) drug products, the promotional review of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP or DNCE provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. 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. [4]

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Affirmative answers to these questions indicate a potential area of concern.
Y/N	Does the name have obvious Similarities in Spelling and Pronunciation to other Names?
Y/N	Are there Manufacturing Characteristics in the Proprietary Name?
Y/N	Are there Medical and/or Coined Abbreviations in the Proprietary Name?
Y/N	Are there Inert or Inactive Ingredients referenced in the Proprietary Name?
Y/N	Does the Proprietary Name include combinations of Active Ingredients
Y/N	Is there a United States Adopted Name (USAN) Stem in the Proprietary Name?
Y/N	Is this the same Proprietary Name for Products containing Different Active Ingredients?
Y/N	Is this a Proprietary Name of a discontinued product?

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

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. Based on our root cause analysis of post marketing experience errors, we find the expression of strength and dose, which is often located in close proximity to the drug name itself on prescriptions and medication orders, is an important factor in mitigating or potentiating confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion is limited (e.g., route, frequency, dosage form, etc.).

- For highly similar names, there is little that can mitigate a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are likely to be rejected by FDA. (See Table 3)
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics (e.g., route, frequency, dosage form, etc.) to mitigate confusion may be limited when the strength or dose overlaps. FDA will review these names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4)
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist (See Table 5).

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   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 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 record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for 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 OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/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 provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair do not share a common strength or dose (see Step 1 of the Moderately Similar Checklist).			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		

Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥50% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths have a higher potential for confusion and should be evaluated further (see Step 2). For single strength products, also consider circumstances where the strength may not be expressed. For any combination drug products, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: o Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o Similar sounding doses: 15 mg is similar in sound to 50 mg

Step 2	Answer the questions in the checklist below. Affirmative answers to these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion between moderately similar names **with** overlapping or similar strengths or doses.

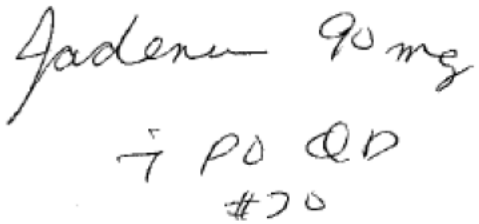
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where there are data that suggest a name with low similarity might be vulnerable to confusion with your proposed name (for example, misinterpretation of the proposed name as a marketed product in a prescription simulation study). In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Jadenu Study (Conducted on June 20, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: 	Jadenu 90 mg by mouth daily
Outpatient Prescription: 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study name: Jadenu

266 people received the study

113 people responded

	38	38	37	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
GENENEW	0	1	0	1
JABENUBE	0	1	0	1
JADANEU	0	2	0	2
JADANEW	0	2	0	2
JADANU	0	3	0	3
JADENA	10	0	0	10
JADENE	1	0	0	1
JADENIA	1	0	0	1
JADENU	24	3	34	61
JADENUM	2	0	0	2
JADERNU	0	0	1	1
JAJESNU	0	1	0	1
JAMANU	0	1	0	1
JANANU	0	2	0	2
JANAVU	0	1	0	1

JASONOU	0	1	0	1
JAVANEU	0	1	0	1
JAVANU	0	1	0	1
JAVANUE	0	1	0	1
JAVENU	0	1	0	1
JAVENUE	0	3	0	3
JAVINU	0	1	0	1
JAYDANU	0	1	0	1
JAYDINU	0	1	0	1
JAYVANU	0	2	0	2
JAYVENEW	0	1	0	1
JAYVENU	0	2	0	2
JAYVENUE	0	1	0	1
JAYZANU	0	1	0	1
JAZENHOV	0	1	0	1
JAZENU	0	1	0	1
JEDINEW	0	1	0	1
TADENU	0	0	1	1
(b) (4) *	0	0	1	1

* This name was entered in error by a study participant. The participant entered another proprietary name we are reviewing in the incorrect field.

Appendix C: Highly Similar Names (i.e., combined POCA score is ≥70%)

No.	Proposed name: Jadenu Strength(s): 90 mg, 180 mg, 360 mg tablets Usual Dose: 7-14 mg/kg/day	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Or Failure prevention reasons
1.	Not Applicable	N/A	Not Applicable

Appendix D: Moderately Similar Names (i.e., combined POCA score is ≥50% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Adagen	60
2.	(b) (4) ***	60
3.	(b) (4) ***	60
4.	Jalyn	58
5.	Janumet	58
6.	J-Tan	58
7.	Geodon	56
8.	Kadian	56
9.	Patanol	56
10.	Zaditor	56
11.	Kazano	55
12.	Tandem	55
13.	Gelatin	54
14.	Adapin	54
15.	Dibenil	54
16.	Fastin	54
17.	Gantanol	54
18.	GG-Cen	54
19.	Janimine	54
20.	Orgadin	54
21.	Two-Dyne	54
22.	Jevtana ***	54

23.	Fe-Tinic	53
24.	Fe-Tinic 150	53
25.	Cardene	52
26.	Bepadin	52
27.	Depodur	52
28.	Detane	52
29.	Gamanil	52
30.	Gel-Tin	52
31.	Genesa	52
32.	Genetuss 2	52
33.	J-Tan D	52
34.	Medent	52
35.	Galzin	52
36.	Januvia	52
37.	Makena	52
38.	Zartan	52
39.	(b) (4) ***	52
40.	Razadyne	52
41.	Saizen	52
42.	(b) (4) ***	52
43.	Tretten	52
44.	(b) (4) ***	51
45.	Feldene	51
46.	Degen II	51
47.	Doriden	51
48.	Geopen	51
49.	Orvaten	51
50.	Vantin	51
51.	Feldene P	51
52.	(b) (4) ***	51
53.	Jardiance ***	51
54.	Xuriden ***	51

55.	Diaderm	50
56.	Banadyne	50
57.	Defen-LA	50
58.	Depinar	50
59.	Dibent	50
60.	Gamophen	50
61.	Ganidin NR	50
62.	Genamin	50
63.	Genaton	50
64.	Genebs	50
65.	Pedituss	50
66.	Genedel	50
67.	Jantoven	50
68.	(b) (4) ***	50
69.	My-O-Den	50
70.	Namenda	50
71.	Orfadin	50
72.	(b) (4) ***	50
73.	Retin-A	50
74.	Rifadin	50
75.	Teveten	50
76.	Xoten	50

Appendix E: Moderately Similar Names (i.e., combined POCA score is ≥50% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Jadenu Strength(s): 90 mg, 180 mg, 360 mg tablets Usual Dose: 7-14 mg/kg/day	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	Depen	54	Depen has two syllables while Jadenu has three syllables. Both names are also orthographically and phonetically different.
2.	Ziagen	54	The prefix, infix and suffix of both Ziagen and Jadenu are significantly different phonetically. The infix of the names appears different from each other.

Appendix F: Low Similarity Names (i.e., combined POCA score is ≤49%)

No.	Name	POCA Score (%)
1.	No names identified	N/A

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
1.	Tadenan	68	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
2.	(b) (4) ***	66	Name denied by DMEPA. (b) (4)
3.	(b) (4) ***	62	Name denied by DMEPA. (b) (4)
4.	Tiadenol	62	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
5.	Viden	60	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
6.	(b) (4) ***	60	Name denied by DMEPA (b) (4)
7.	Evadyne	59	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
8.	Radent	58	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
9.	Ridenol	58	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.

10.	Gamene	57	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
11.	(b) (4) ***	57	Name denied by DMEPA. (b) (4)
12.	Jeridin	57	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
13.	Zaditen	57	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
14.	Adenine	56	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
15.	(b) (4) ***	56	Name denied by DMEPA. (b) (4)
16.	Katinko	56	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
17.	Videne	56	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
18.	Platinum	54	Homeopathic use
19.	Talpen	54	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.

20.	Tepadina	54	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
21.	(b) (4)		
22.	Travenol	54	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
23.	Zeatin	54	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
24.	(b) (4) ***	52	Name denied by DMEPA. (b) (4)
25.	Oradent	52	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
26.	Ovadine	52	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
27.	(b) (4) ***	52	Name denied by DMEPA. (b) (4)
28.	Tandem OB	52	OTC Prenatal Vitamins
29.	Vaprino	52	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.

30.	Cardinol	51	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
31.	(b) (4) ***	51	Checked PNL, AIMS, Panorama and L:Drive. No information available
32.	Tridane	51	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
33.	Vasaten	51	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
34.	Zavedos	51	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
35.	(b) (4) ***	60	Name was denied by DMEPA. (b) (4)
36.	(b) (4) ***	50	Secondary name provided by sponsor
37.	(b) (4) ***	50	Name was denied by DMEPA (b) (4)
38.	Didone	50	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
39.	Gadaderm	50	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.

40.	Genatuss	50	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
41.	(b) (4) ***	50	Name denied by DMEPA. (b) (4)
42.	(b) (4) ***	50	Name denied by DMEPA. (b) (4)
43.	Mogadon	50	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
44.	Rosadan	50	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
45.	Tabcin	50	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

NEIL H VORA
08/22/2014

LUBNA A MERCHANT on behalf of YELENA L MASLOV
08/22/2014

LUBNA A MERCHANT
08/22/2014