

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

211150Orig1s000

PROPRIETARY NAME REVIEW(S)

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:	March 7, 2019
Application Type and Number:	NDA 211150
Product Name and Strength:	Wakix (pitolisant) tablets, 4.45 mg and 17.8 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Bioprojet Pharma (Bioprojet)
Panorama #:	2018-28016726
DMEPA Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA

Contents

1	INTRODUCTION	1
1.1	Regulatory History.....	1
1.2	Product Information.....	1
2	RESULTS.....	2
2.1	Misbranding Assessment	2
2.2	Safety Assessment	2
3	CONCLUSION	4
3.1	Comments to Bioprojet Pharma.....	4
4	REFERENCES	5
	APPENDICES	6

1 INTRODUCTION

This review evaluates the proposed proprietary name, Wakix***, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A, respectively. Bioprojet submitted an external name study, conducted by (b) (4) for this proposed proprietary name.

1.1 REGULATORY HISTORY

Bioprojet previously submitted the proposed proprietary name, Wakix*** on December 9, 2016. We found the name, Wakix*** conditionally acceptable under IND 111842 on March 31, 2017.^a

Bioprojet submitted the name, Wakix*****, for review under NDA 211150 on December 14, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 14, 2018.

- Intended Pronunciation: way-kicks
- Active Ingredient: pitolisant
- Indication of Use: Treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy and treatment of cataplexy in adult patients with narcolepsy
- Route of Administration: Oral
- Dosage Form: Tablets
- Strengths: 4.45 mg and 17.8 mg
- Dose and Frequency: The recommended dose is 35.6 mg administered orally once daily (two 17.8 mg tablets) in the morning upon waking.

Patients should be titrated to 35.6 mg once daily as follows:

Week 1: initiate treatment with a dose of 8.9 mg (two 4.45 mg tablets) once daily

Week 2: increase dose to 17.8 mg (one 17.8 mg tablet) once daily

Week 3: increase to the recommended dose of 35.6 mg (two 17.8 mg tablets) once daily

- How Supplied: 30-count bottles
- Storage: Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F)

^aWhaley, E. Proprietary Name Review for Wakix (IND 111842). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 Mar 31. Panorama No. 2016-11813282.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Wakix*** would not misbrand the proposed product. In an email communication dated January 14, 2019, the Division of Psychiatry Products (DPP) expressed concerns with the proposed proprietary name Wakix noting that the proposed *name may overstate the efficacy of the product and imply a broader indication beyond what is proposed in the application*. These concerns were shared with OPDP and subsequently discussed in a meeting with OPDP, DPP and DMEPA. Upon further evaluation, OPDP maintained their non-objection, and DPP and DMEPA agree with OPDP.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Wakix***.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name^b.

2.2.2 Components of the Proposed Proprietary Name

Bioprojet indicated in their submission that the proposed proprietary name, Wakix***, has no derivation. We note that under the IND submission, the Sponsor stated the proposed name, Wakix, is derived from the word “awake”. 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 are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 10, 2019 e-mail, the Division of Psychiatry Products (DPP) forwarded concerns relating to Wakix*** at the initial phase of the review (see Section 2.1, above).

2.2.4 FDA Name Simulation Studies

One hundred two (102) practitioners participated in DMEPA’s prescription studies for Wakix***. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

^b USAN stem search conducted on January 2, 2019.

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

Our POCA search^c identified 25 names with the combined score of $\geq 55\%$ or individual orthographic or phonetic score of $\geq 70\%$. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 7 names not previously analyzed. These names are included in Table 1 below.

2.2.6 *Names Retrieved for Review Organized by Name Pair Similarity*

Table 1 lists the number of names retrieved from our POCA and (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	0
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	2
Low similarity name pair: combined match percentage score $\leq 54\%$	5

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

Our analysis of the 7 names contained in Table 1 determined none of the names will pose a risk for confusion with Wakix*** as described in Appendices C through H.

2.2.8 *Communication of DMEPA's Analysis at Midpoint of Review*

DMEPA communicated our findings to the Division of Psychiatry Products (DPP) via e-mail on March 7, 2019. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Psychiatry Products (DPP) on March 7, 2019, they stated no additional concerns with the proposed proprietary name, Wakix***.

^c POCA search conducted on December 29, 2018 in version 4.3.

3 CONCLUSION

The proposed proprietary name, Wakix***, is acceptable.

If you have any questions or need clarifications, please contact Phuong B. Nguyen, OSE Project Manager, at 240-402-5827.

3.1 COMMENTS TO BIOPROJET PHARMA

We have completed our review of the proposed proprietary name, Wakix***, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your submission, received on December 14, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. **USAN Stems** (<https://www.ama-assn.org/about/united-states-adopted-names-approved-stems>)

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.

3. **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).

4. **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#>).

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.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP 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.^d

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).

^d National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

- 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 55% 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 $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 54\%$.

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. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.

- Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names^e. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
 - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information are often located in close proximity to the drug name itself on prescriptions and medication orders, and the information 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 to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such 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 (See Table 5) 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.
- 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.

^e Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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 $\geq 70\%$).

Answer the questions in the checklist below. Affirmative answers to some of 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 does not share a common strength or dose.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	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 as 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 $\geq 55\%$ to $\leq 69\%$).

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 or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, 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: 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.
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	- Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. - Similar sounding doses: 15 mg is similar in sound to 50 mg	
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> 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 as 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 $\leq 54\%$).

Names with low similarity 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.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Wakix* Study (Conducted on January 11, 2019)**

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u> <i>Wakix 17.8mg po once daily</i>	Wakix 4.45 mg Take two tablets by mouth once daily
<u>Outpatient Prescription:</u> <i>Wakix 4.45mg</i> <i>#60</i> <i>ii tabs po QD</i>	Dispense 60

FDA Prescription Simulation Responses (Aggregate Report)

				304 People Received Study
				102 People Responded
Study Name: Wakix				
Total	60	16	26	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
WAKIS	1	0	0	1
WAKIX	59	3	26	88
WAYKICKS	0	2	0	2
WAYKICS	0	2	0	2
WAYKITZ	0	1	0	1
WAYKIX	0	4	0	4
WAYQICKS	0	1	0	1
WAYQIK	0	1	0	1
WEIKIX	0	1	0	1
WHEYKIX	0	1	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is $\geq 70\%$)

No.	Proposed name: Wakix Established name: pitolisant Dosage form: Tablets Strengths: 4.45 mg and 17.8 mg Usual Dosage: 8.9 mg to 35.6 mg orally once daily	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	N/A		

Appendix D: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Xalix	60
2.	(b) (4) ***	59

Appendix E: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Wakix Established name: pitolisant Dosage form: Tablets Strengths: 4.45 mg and 17.8 mg Usual Dosage: 8.9 mg to 35.6 mg orally once daily	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.	N/A		

Appendix F: Low Similarity Names (e.g., combined POCA score is $\leq 54\%$)

No.	Name	POCA Score (%)
1.	Lidex	54
2.	Plavix	53
3.	Wymox	50
4.	Bacid	35
5.	Ultiva	24

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.	N/A		

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion^f.

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

^f Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
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***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	March 31, 2017
Application Type and Number:	IND 111842
Product Name and Strength:	Wakix (pitolisant) tablet, 4.45 mg, 17.8 mg
Product Type:	Single-ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Bioprojet Pharma
Panorama #:	2016-11813282
DMEPA Primary Reviewer:	Ebony Whaley, PharmD, BCPPS
DMEPA Team Leader:	Lolita White, PharmD

Contents

1	INTRODUCTION.....	1
1.1	Regulatory History	1
1.2	Product Information	1
2	RESULTS.....	1
2.1	Misbranding Assessment	1
2.2	Safety Assessment.....	2
3	CONCLUSIONS	4
3.1	Comments to the Applicant.....	5
4	REFERENCES	6
	APPENDICES	7

1 INTRODUCTION

This review evaluates the proposed proprietary name, Wakix, from a safety and misbranding perspective. 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 December 9, 2016 proprietary name submission.

- Intended Pronunciation: Way – kicks
- Active Ingredient: pitolisant
- Indication of Use: (b) (4)
- Route of Administration: Oral
- Dosage Form: Tablet
- Strength: 4.45 mg, 17.8 mg
- Dose and Frequency: Wakix should be used at the lowest effective dose, depending on individual patient response and tolerance, according to an up-titration scheme without exceeding the dose of 35.6 mg/day:
 - o Week 1: initial dose of 8.9 mg (two 4.45 mg tablets) per day
 - o Week 2: the dose may be increased to 17.8 mg (one 17.8 mg tablet) per day (b) (4)
 - o Week 3: the dose may be increased to 35.6 mg (two 17.8 mg tablets) per day
 - o At any time the dose can be decreased (down to 4.45 mg per day) or increased (up to 35.6 mg per day) according to the physician assessment and patient response.
- How Supplied: The 4.45 mg and 17.8 mg Wakix tablets will be provided in HDPE bottles of 30 tablets.
- Storage: Store at 20°-25°C (68°-77°F). (b) (4)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Neurology Products (DNP) concurred with the findings of OPDP's assessment of the proposed name.

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^a.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Wakix, is derived from the word “awake”. 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 are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Eighty-one practitioners participated in DMEPA’s prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. 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, December 27, 2016 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

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 $\geq 55\%$ retrieved from our POCA search^b. These names are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	20
Low similarity name pair: combined match percentage score $\leq 54\%$	2

^a USAN stem search conducted on December 20, 2016.

^b POCA search conducted on December 20, 2016 in version 4.0.

2.2.6 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength

The proposed product, Wakix, will be available in strength of 4.45 mg and 17.8 mg. Since these are not a typical strengths that are commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with an overlap in strength and potential orthographic, spelling, and phonetic similarities with Wakix that were not identified in POCA.

Table 1A. eDRLS Search Results^c	POCA Score (%)
N/A	N/A

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

Our analysis of the 23 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on March 24, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNP on March 27, 2017, they stated no additional concerns with the proposed proprietary name, Wakix.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Corwin Howard, OSE project manager, at (240) 402-8654.

3.1 COMMENTS TO THE APPLICANT

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

A request for proprietary name review for Wakix should be submitted once the NDA is submitted.

If any of the proposed product characteristics as stated in your December 9, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

^c eDRLS search conducted on December 20, 2016.

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.

3. *Electronic Drug Registration and Listing System (eDRLS) database*

The electronic Drug Registration and Listing System (eDRLS) was established to support the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP 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.^d

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).

^d National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

- 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 55% 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 54\%$.

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. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).

- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
 - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names^e. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
 - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information 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 to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such 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 (See Table 5) 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.

- 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.

^e Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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 $\geq 70\%$).

Answer the questions in the checklist below. Affirmative answers to some of 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 does not share a common strength or dose.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?

Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	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 $\geq 55\%$ to $\leq 69\%$).

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 or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, 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: 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
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	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. - Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. - Similar sounding doses: 15 mg is similar in sound to 50 mg	
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for 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?

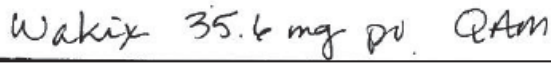
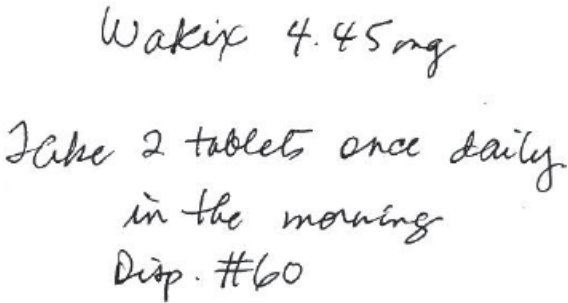
Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

Names with low similarity 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.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Wakix Study (Conducted on 12/29/2016)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u> 	Wakix 4.45 mg Take 2 tablets by mouth once daily in the morning
<u>Outpatient Prescription:</u> 	Dispense #60

FDA Prescription Simulation Responses

Study Name: Wakix Total					302 People Received Study 81 People Responded
	28	28	25		
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL	
WAKICKS	0	2	0	2	
WAKITZ	0	1	0	1	
WAKIX	27	4	25	56	
WAYKICKS	0	2	0	2	
WAYKICS	0	1	0	1	
WAYKITZ	0	1	0	1	
WAYKIX	0	14	0	14	
WAYQUIX	0	1	0	1	

WEKIX	0	1	0	1
WEYKICKS	0	1	0	1
WKIX	1	0	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is $\geq 70\%$)

No.	Proposed name: Wakix Established name: pitolisant Dosage form: Tablet Strength(s): 4.45 mg, 17.8 mg Usual Dose: Wakix should be used at the lowest effective dose, depending on individual patient response and tolerance, according to an up-titration scheme without exceeding the dose of 35.6 mg/day: (b) (4)	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	Wakix	100	Subject of review

Appendix D: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Oraqix (Phonetic score 75%)	65
2.	X-Wax (Orthographic score 72%)	60

Appendix E: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Wakix Established name: pitolisant Dosage form: Tablet Strength(s): 4.45 mg, 17.8 mg Usual Dose: Wakix should be used at the lowest effective dose, depending on individual patient response and tolerance, according to an up-titration scheme without exceeding the dose of 35.6 mg/day: (b) (4)	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.	Ak-Dex (Phonetic score 75%)	68	Orthographic: The prefixes and infixes of this name pair have sufficient orthographic differences. The third letters of the name pair ('k' vs 'D') are different in shape. Ak-Dex also contains a hyphen, which further differentiates if included. Phonetic: The first and second syllables of this name pair sound different.
2.	Lasix (Phonetic score 76%)	68	Orthographic: The prefixes of this name pair have sufficient orthographic differences. Wakix has an upstroke letter 'k' in the 3rd position and Lasix has a rounded letter 's' in the 3rd position. Phonetic: The first syllable and the onset of the second syllables of this name pair sound different.

No.	Proposed name: Wakix Established name: pitolisant Dosage form: Tablet Strength(s): 4.45 mg, 17.8 mg Usual Dose: Wakix should be used at the lowest effective dose, depending on individual patient response and tolerance, according to an up-titration scheme without exceeding the dose of 35.6 mg/day: (b) (4)	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
3.	Wal-Fex	60	Orthographic: The infixes of this name pair have sufficient orthographic differences. Wal-Fex also contains a hyphen, which further differentiates, if included. Phonetic: The first and second syllables of this name pair sound different.
4.	Iquix (Phonetic score 71%)	58	Orthographic: The prefixes of this name pair have sufficient orthographic differences. Wakix has an upstroke letter 'k' in the 3rd position and Iquix has a rounded letter 'u' in the 3rd position. Phonetic: The first syllables of this name pair sound different.
5.	Gattex (Phonetic score 78%)	57	Orthographic: The prefixes of this name pair have sufficient orthographic differences. Phonetic: The first syllable and the onset of the second syllable of this name pair sound different.

No.	Proposed name: Wakix Established name: pitolisant Dosage form: Tablet Strength(s): 4.45 mg, 17.8 mg Usual Dose: Wakix should be used at the lowest effective dose, depending on individual patient response and tolerance, according to an up-titration scheme without exceeding the dose of 35.6 mg/day: (b) (4)	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
6.	Bitex (Phonetic score 73%)	56	Orthographic: The prefixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different.
7.	Videx (Phonetic score 72%)	56	Orthographic: The prefixes and infixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different.
8.	(b) (4) *** (Phonetic score 73%)	56	Orthographic: (b) (4) Phonetic: (b) (4)

Appendix F: Low Similarity Names (e.g., combined POCA score is $\leq 54\%$)

No.	Name	POCA Score (%)
1.	Kwai (Orthographic score 78%)	40

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.	Latex (Phonetic score 81%)	60	This product is not a drug. It is a stable dispersion (emulsion) of polymer microparticles in an aqueous medium.
2.	Salpax	56	NDA 009008 was withdrawn FR effective as of 8/5/1996. No generic equivalents are available.
3.	Vanex (Phonetic score 70%)	55	This product is discontinued and there are no generics equivalents available.
4.	Otex (Phonetic score 70%)	46	Foreign drug marketed in United Kingdom.

Appendix H: Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
1.	Amix	63
2.	Latrix	60
3.	Xanax	57

No.	Name	POCA Score (%)
4.	Ami-Tex	56
5.	Amrix	56
6.	Baci-Rx	56
7.	Matrix	56

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
1.	Amerfresh Antiperspirant Deodorant
2.	Axe
3.	Axe Dark Temptation Invisible Solid
4.	Axe Essence
5.	Axe Sharp Focus Invisible Solid
6.	Degree
7.	Degree for Men Clean
8.	Degree for Men Cool Comfort
9.	Degree for Men Cool Rush
10.	Degree for Men Extreme Blast
11.	Degree for Men Power
12.	Degree for Men Sport
13.	Degree For Women Classic Romance
14.	Degree For Women Delicious Bliss
15.	Degree For Women Sexy Intrigue

No.	Name
16.	Degree Fresh Oxygen
17.	Degree Girl Friends Forever
18.	Degree Girl Just Dance
19.	Degree Nature Effects Honeysuckle and Tea Tree Oil
20.	Degree Nature Effects Orange Flower and Cranberry
21.	Degree Women
22.	Degree Women Sheer Powder
23.	Degree Women Shower Clean
24.	Family Dollar Celsius
25.	RE9 Advanced
26.	Suave Men Sport
27.	Walgreens Active Stick

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/s/

EBONY A WHALEY
03/31/2017

LOLITA G WHITE
04/01/2017