

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**205433Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**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\*\*\***

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<b>Date of This Review:</b>	June 2, 2014
<b>Application Type and Number:</b>	NDA 205433
<b>Product Name and Strength:</b>	Kitabis Pak (Tobramycin) 300 mg Inhalation Solution
<b>Product Type:</b>	Single Ingredient
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	Pulmoflow, Inc.
<b>Submission Date:</b>	March 5, 2014 and May 12, 2014
<b>Panorama #:</b>	2014-17047
<b>DMEPA Primary Reviewer:</b>	Jacqueline Sheppard, PharmD
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## Contents

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

## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Kitabis Pak, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by [REDACTED] <sup>(b) (4)</sup> for this product.

### 1.1 PRODUCT INFORMATION

The following product information is provided in the March 5, 2014 and May 12, 2014 proprietary name submission.

- Intended Pronunciation: ki-tab-is pak
- Active Ingredient: tobramycin
- Indication of Use: management of cystic fibrosis patients with *P. aeruginosa*
- Route of Administration: Inhalation
- Dosage Form: Inhalation solution
- Strength: 300 mg/ 5 mL
- Dose and Frequency: 300 mg inhaled via nebulizer twice daily in repeated cycles of 28 days on drug followed by 28 days off drug
- How Supplied: 56 vials of Tobramycin Inhalation solution co-packaged with one reusable nebulizer
- Storage: Stored under refrigeration at 2° to 8° C (36° to 46° F). Upon removal from refrigerator, solution pouches may be stored at room temperature for up to 28 days. Product should not be exposed to intense light.
- Container and Closure Systems: Foil laminal overwrap of vials of 5 mL filling capacity

## 2 RESULTS

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

### 2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Anti-Infective Products (DAIP) concurred with the findings of OPDP's promotional 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<sup>1</sup>.

### **2.2.2 Components of the Proposed Proprietary Name**

The Applicant originally submitted the proposed name, Kitabis, on March 5, 2014, and did not provide a derivation or intended meaning for the proposed name, Kitabis 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 are misleading or can contribute to medication error.

Upon further evaluation of the proposed name, we recommended the Applicant consider naming the proposed product using a proprietary name in conjunction with the modifier 'pak'. The use of the modifier, pak, will help alert health care practitioners that the product consists of the drug and the component used to prepare and administer the drug. We communicated this recommendation to the Applicant on May 7, 2014. Therefore, the Applicant submitted an amendment on May 12, 2014 to 'Kitabis (b)(4)'. The proposed name is comprised of multiple words that contain two components: 1) the proposed root name, Kitabis, and 2) the modifier, Pak. Because it is not uncommon for prescribers to drop the modifier component of a name, DMEPA considers the name 'Kitabis Pak' and 'Kitabis' in our analysis.

### **2.2.3 FDA Name Simulation Studies**

93 practitioners participated in DMEPA's prescription studies. One interpretation overlapped with (b)(4). This misinterpretation is evaluated as part of our overall Failure Modes and Effects Analysis (FMEA) in section 2.2.5.

None of the other interpretations overlapped 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 written studies, 28 of 63 participants correctly interpreted the prescription. Common misinterpretations in the written studies included misinterpretation of the letter 'b' in the suffix as an 'l' or 'h'. In the verbal prescription study, none of the 30 participants correctly interpreted the prescription. Common misinterpretations in the verbal study included misinterpretation of the infix 'tab' as 'dev,' 'dip,' 'tiv,' 'niv,' and 'nat,." The prefix (b)(4) was misinterpreted as (b)(4). 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, March 19, 2014 e-mail, the Division of Anti-infective Products (DAIP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

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<sup>1</sup>USAN stem search conducted on March 28, 2014.

**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  $\geq 50\%$  retrieved from our POCA search organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation or by (b) (4) Inc..

<b>Table 1. POCA Search Results</b>	<b>Number of Names</b>
Highly similar name pair: combined match percentage score $\geq 70\%$	3
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	142
Low similarity name pair: combined match percentage score $\leq 49\%$	4

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

We evaluated the potential for confusion between Kitabis Pak and (b) (4), in detail due to the misinterpretation in the FDA prescription study (see Section 2.2.3 and Appendix C).



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

DMEPA communicated our findings to the Division of Anti-infective Products (DAIP) via e-mail on May 27, 2014. At that time we also requested additional information or concerns that could inform our review. As of May 30, 2014, DAIP has not communicated any additional concerns with the proposed proprietary name, Kitabis Pak.

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<sup>2</sup> (b) (4)

### **3 CONCLUSIONS**

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Karen Townsend, OSE project manager, at 301-796-5413.

#### **3.1 COMMENTS TO THE APPLICANT**

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

If any of the proposed product characteristics as stated in your March 5, 2014 and May 12, 2014 submission are altered, the name must be resubmitted for review.

## 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](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.<sup>3</sup>

**\*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?

<sup>3</sup> 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  $\geq 70\%$ .
  - Moderately similar pair: combined match percentage score  $\geq 50\%$  to  $\leq 69\%$ .
  - Low similarity: combined match percentage score  $\leq 49\%$ .

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  $\geq 70$  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  $\geq 70\%$ ).**

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>	
<b>Y/N</b>	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>	<b>Y/N</b>	Do the names have different number of syllables?
<b>Y/N</b>	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>	<b>Y/N</b>	Do the names have different syllabic stresses?
<b>Y/N</b>	Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i> ), is there a different number or placement of upstroke/downstroke letters present in the names?	<b>Y/N</b>	Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?
<b>Y/N</b>	Is there different number or placement of cross-stroke or dotted letters present in the names?	<b>Y/N</b>	Across a range of dialects, are the names consistently pronounced differently?
<b>Y/N</b>	Do the infixes of the name appear dissimilar when scripted?		
<b>Y/N</b>	Do the suffixes of the names appear dissimilar when scripted?		

**Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is  $\geq 50\%$  to  $\leq 69\%$ ).**

<p>Step 1</p>	<p>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).</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>For any combination drug products, consider whether the strength or dose may be expressed using only one of the components.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> <li>○ 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.</li> <li>○ Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.</li> <li>○ Similar sounding doses: 15 mg is similar in sound to 50 mg</li> </ul>
<p>Step 2</p>	<p>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 <b>with</b> overlapping or similar strengths or doses.</p>

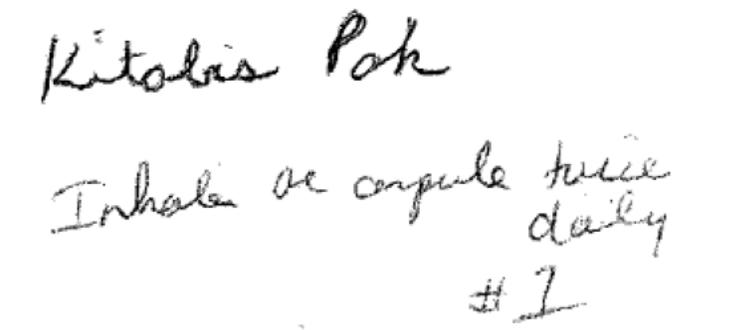
<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names begin with different first letters?</li> </ul> <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> <li>• Are the lengths of the names dissimilar* when scripted?</li> </ul> <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> <li>• Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/downstroke letters present in the names?</li> <li>• Is there different number or placement of cross-stroke or dotted letters present in the names?</li> <li>• Do the infixes of the name appear dissimilar when scripted?</li> <li>• Do the suffixes of the names appear dissimilar when scripted?</li> </ul>	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names have different number of syllables?</li> <li>• Do the names have different syllabic stresses?</li> <li>• Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?</li> <li>• Across a range of dialects, are the names consistently pronounced differently?</li> </ul>
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**Table 5: Low Similarity Name Pair Checklist (i.e., combined score is  $\leq 49\%$ ).**

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. Kitabis Study (Conducted on March 20, 2014)**

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> 	<p>Kitabis Pak</p> <p>Inhale one ampule twice a day</p> <p>#1</p>
<p><u>Outpatient Prescription:</u></p> 	

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

**Study Name: Kitabis Pak**

<b>OUTPATIENT</b>	<b>VOICE</b>	<b>INPATIENT</b>
KITABIS PAK (5)	CADIBIS ? PACK (1)	KITABIR PAK (1)
KITOBIS PAK (20)	CANABIS PACK (1)	KITABIS (2)
KITOBIS POK (2)	CANIDIS PACK (2)	KITABIS PACK (1)
KITOBIS POK INHALER (1)	(b)(4) 2)	KITABIS PAK (23)
KITOLIS PAK (3)	CANNIDAS PAK (1)	KITABLIS PAK (1)
KITOLOS PAK (1)	CATABIS PACK (1)	KITALICS PAK (1)
	CIDIVES PAK (1)	KITALIR PAK (1)
	KEDAVIS PACK (1)	RITABIS PAK (1)
	KEDEVIS PACK (1)	
	KEDIDIS PACK (1)	
	KENEMIS PACK (1)	
	KENIVISPAK (1)	
	KENNETUS PAK (1)	
	KETABUS PACK (1)	
	KETAVIS (1)	
	KETAVIS PACK (1)	
	KETIBIS PACK (1)	
	KETIDUS PACK (1)	
	KETIVIS PACK (1)	
	KETIVIS PAK (1)	
	KIDAVIST PACK (1)	
	KIDIPIX PACK (1)	
	KINEDYS PACK (1)	
	KINIVIS PACK (1)	
	KITIBUS (1)	
	KITIMISS PACK (1)	
	KITIVISS PACK (1)	
	KITIVIST PAK (1)	

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

No.	Proposed name: Kitabis Pak Strength: 300 mg/5ml Usual Dose: 300 mg BID	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion
2.	Kimidess	70	<p><b>Orthographic:</b> The upstroke “t” in the infix of Kitabis and the “dess” in the suffix of Kimidess give sufficient orthographic difference.</p> <p><b>Phonetic:</b> The second syllable “tab” in Kitabis is phonetically dissimilar from the second syllable “mid” in Kimidess.</p>

(b) (4)

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

No.	Proposed Name	POCA Score (%)
1.	Tanabid SR	60
2.	Ventavis	60
3.	Ditate-DS	58
4.	Keftab	58
5.	Quisaris	58
6.	(b) (4) ***	57
7.	Micardis	57
8.	Minitabs	57
9.	Tannate-1	57

No.	Proposed Name	POCA Score (%)
10.	Antabuse	56
11.	Cialis	56
12.	Cotab AX	56
13.	Flutabs	56
14.	Fortabs	56
15.	Ketamine	56
16.	K-tab	56
17.	Rixubis	56
18.	Vitabee	55
19.	(b) (4) ***	55
20.	CAM-AP-ES	54
21.	Cancidas	54
22.	Ceta Plus	54
23.	Decabid	54
24.	Kabiven	54
25.	Kinevac	54
26.	Phenabid	54
27.	Tavist	54
28.	Kutrase	53
29.	Betalin S	52
30.	Gadavist	52
31.	Ketalar	52
32.	Kyprolis	52
33.	Synagis	52
34.	Trivaris	52
35.	Kinrix	51
36.	Pentids	51
37.	Vitaped	51
38.	Baby Gas	50
39.	(b) (4) ***	50

No.	Proposed Name	POCA Score (%)
40.	Hista-Tabs	50
41.	Ilaris	50
42.	(b) (4) ***	50
43.	Kineret	50
44.	Koate DVI	50
45.	Letairis	50
46.	Libritabs	50
47.	Q-tapp SR	50
48.	Sleep Tab	50
49.	Sudatuss-2	50
50.	Tepanil	50
51.	Triotann-S	50
52.	Tussi-12D	50
53.	Tussitab	50
54.	Vitamin D	50
55.	Vitamin K	50
56.	Vitapap	50

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

No.	Proposed name: Kitabis Strength: 300 mg/5ml Usual Dose: 300 mg inhalation twice 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.	K-lyte DS	62	<p><b>Orthographic:</b> The infix and suffix of this name pair have sufficient orthographic differences</p> <p><b>Phonetic:</b> The first and second syllables of this name pair sound different. Additionally, the modifier of K-lyte may be dropped which gives Kitabis an extra syllable.</p>
2.	Catapres	60	<p><b>Orthographic:</b> The suffix of this name pair have sufficient orthographic differences</p> <p><b>Strength:</b> Catapres is available in multiple strengths so the strength must be written on the prescription. Kitabis is a single strength product strength so the strength may be omitted.</p>
3.	Sitavig	60	<p><b>Orthographic:</b> The suffix of this name pair has sufficient orthographic differences</p> <p><b>Phonetic:</b> The first and third syllables of this name pair have sufficient phonetic differences.</p>
4.	Ketodan	58	<p><b>Orthographic:</b> The suffix of this name pair has sufficient orthographic differences.</p> <p><b>Phonetic:</b> The second and third syllables of the name pair have sufficient phonetic differences.</p>
5.	Mytab Gas	58	<p><b>Orthographic:</b> The prefix and suffix of the name pair have sufficient orthographic differences.</p> <p><b>Phonetic:</b> The first syllable of the name pair has sufficient phonetic difference.</p>
6.	Citanest	57	<p><b>Orthographic:</b> The suffix of the name pair has sufficient orthographic difference.</p> <p><b>Phonetic:</b> The first and second syllables of the name pair have sufficient phonetic difference.</p>

No.	Proposed name: Kitabis Strength: 300 mg/5ml Usual Dose: 300 mg inhalation twice daily	POCA Score (%)	Prevention of Failure Mode  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
7.	Foltabs	56	<p><b>Orthographic:</b> The prefix and suffix of the name pair have sufficient orthographic differences.</p> <p><b>Phonetic:</b> The first syllable of the name pair has sufficient phonetic difference. Additionally, Kitabis has three syllables compared to the two syllables in Foltabs.</p>
8.	Iodides	54	<p><b>Orthographic:</b> The prefix and infix of the name pair have sufficient orthographic differences.</p> <p><b>Phonetic:</b> The first and second syllables of the name pair have sufficient phonetic differences.</p>
9.	Statuss	54	<p><b>Orthographic:</b> The prefix and suffix of the name pair have sufficient orthographic differences.</p> <p><b>Phonetic:</b> The first and second syllables of the name pair have sufficient phonetic differences. Additionally, Kitabis has three syllables compared to the two syllables in Statuss.</p>
10.	Patanase	52	<p><b>Orthographic:</b> The prefix, infix, and suffix of the name pair have sufficient orthographic differences.</p> <p><b>Phonetic:</b> The first and third syllables of the name pair have sufficient phonetic differences.</p>
11.	Tetravisc	52	<p><b>Orthographic:</b> The infix of the name pair has sufficient orthographic differences.</p> <p><b>Phonetic:</b> The first and second syllables of the name pair have sufficient phonetic differences.</p>
12.	Ketotifen	51	<p><b>Orthographic:</b> The suffix of the name pair has sufficient orthographic difference.</p> <p><b>Phonetic:</b> The second and third syllables have sufficient phonetic differences. Additionally, ketotifen has four syllables compared to the three syllables in Kitabis.</p>
13.	Kinerase	51	<p><b>Orthographic:</b> The infix of the name pair has sufficient orthographic difference.</p> <p><b>Phonetic:</b> The second and third syllables have sufficient phonetic differences.</p>

No.	Proposed name: Kitabis Strength: 300 mg/5ml Usual Dose: 300 mg inhalation twice 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
14.	Xartemis XR	51	<p><b>Orthographic:</b> The prefix and infix of the name pair have sufficient orthographic differences.</p> <p><b>Phonetic:</b> The first and second syllables have sufficient phonetic differences.</p>
15.	Aptivus	50	<p><b>Orthographic:</b> The infix of the name pair has sufficient orthographic differences.</p> <p><b>Phonetic:</b> The first and second syllables have sufficient phonetic differences.</p>
16.	Catarase	50	<p><b>Orthographic:</b> The infix and suffix have sufficient orthographic differences.</p> <p><b>Phonetic:</b> The second syllable has sufficient phonetic difference.</p>
17.	Claravis	50	<p><b>Orthographic:</b> The prefix and infix have sufficient orthographic differences.</p> <p><b>Phonetic:</b> The first and second syllables have sufficient phonetic differences.</p>
18.	E-glades	50	<p><b>Orthographic:</b> The prefix and suffix have sufficient orthographic differences.</p> <p><b>Phonetic:</b> The first and second syllables have sufficient phonetic differences.</p>
19.	Lithotabs	50	<p><b>Orthographic:</b> The prefix and suffix have sufficient orthographic differences.</p> <p><b>Phonetic:</b> The first and second syllables have sufficient phonetic differences.</p>
20.	Nitro-Bid	50	<p><b>Orthographic:</b> The prefix and infix have sufficient orthographic differences.</p> <p><b>Phonetic:</b> The first and second syllables have sufficient phonetic differences.</p>

No.	Proposed name: Kitabis Strength: 300 mg/5ml Usual Dose: 300 mg inhalation twice 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
21.	Restasis	50	<b>Orthographic:</b> The prefix has sufficient orthographic difference. <b>Phonetic:</b> The first and second syllables have sufficient phonetic differences.
22.	Stamoist E	50	<b>Orthographic:</b> The prefix and suffix have sufficient orthographic differences. <b>Phonetic:</b> The first and second syllables have sufficient phonetic differences. Additionally, Kitabis has a third syllable while Stamoist has two syllables and a modifier.
23.	Veetids	50	<b>Orthographic:</b> The prefix and suffix have sufficient orthographic differences. <b>Phonetic:</b> The first and second syllables have sufficient phonetic differences. Additionally, Kitabis has a third syllable while Veetids has two syllables.

**Appendix F:** Low Similarity Names (i.e., combined POCA score is  $\leq 49\%$ )

No.	Name	POCA Score (%)
1.	Ketek	$\leq 49$
2.	Kionex	$\leq 49$
3.	Kytril	$\leq 49$
4.	Ritalin	$\leq 49$

**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.	Kitabis***	100	Subject of this review
2.	(b) (4)***	68	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-238). Product approved under new proprietary name Myrbetriq
3.	Ketaset	67	Veterinary Product
4.	Ketaved	64	Veterinary Product
5.	Clintabs	60	Veterinary Product
6.	(b) (4)***	60	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2010-1086). Product approved under new proprietary name Lazanda
7.	Kefadim	59	International product marketed in Czech Republic, Thailand, Brazil, China, Netherlands, United Kingdom
8.	Ketocid	59	International product marketed in United Kingdom
9.	(b) (4)***	59	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-81). Product approved under new proprietary name Sitavig
10.	Bel-Tabs	58	Unable to find product characteristics in commonly used drug databases.
11.	(b) (4)***	58	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-3054). Product approved under new proprietary name Stendra
12.	(b) (4)***	57	This is a secondary proposed proprietary name and the product is currently listed under proprietary name (b) (4) (OSE # 2009-2348).
13.	Ketoseb P	56	Veterinary Product
14.	(b) (4)***	56	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-3933). Product currently listed under new proprietary name (b) (4)
15.	(b) (4)***	56	Name identified in Safety Evaluator database. Unable to find product characteristics.

No.	Name	POCA Score (%)	Failure preventions
16.	Kentace	55	Unable to find product characteristics in commonly used drug databases.
17.	Mitaban	55	Veterinary Product
18.	Pedituss	55	Unable to find product characteristics in commonly used drug databases.
19.	Dispas	54	Unable to find product characteristics in commonly used drug databases.
20.	(b) (4)***	54	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2009-1620). Product currently listed under new proprietary name Moxeza
21.	Kapidex	54	Name withdrawn from market due to safety concern. Product currently marketed under new proprietary name Dexilant.
22.	Ketonal	54	International product marketed in Israel, Czech Republic, Poland, and Ukraine
23.	Kraftobese	54	Unable to find product characteristics in commonly used drug databases.
24.	Nitrados	54	International product marketed in Ireland and Singapore
25.	Syntaris	54	International product marketed in Belgium, Netherlands, Austria, Czech Republic, Ireland, South Africa, Switzerland, Germany, United Kingdom, and Italy
26.	(b) (4)***	53	Name identified by Safety Evaluator. Unable to find product characteristics.
27.	Sinapils	53	Product withdrawn from the market due to safety concerns Name identified in RxNorm database
28.	Stabec	53	Unable to find product characteristics in commonly used drug databases.
29.	Abetimus	52	Orphan drugs that do not have an application in house
30.	Adidas	52	Product not a drug (deodorant)
31.	Betadex	52	International product marketed in Hong Kong

No.	Name	POCA Score (%)	Failure preventions
32.	(b) (4) ***	52	Name withdrawn by the Applicant – OSE #2010-1726
33.	Diocaps	52	International product marketed in United Kingdom
34.	Heptanes	52	Product not a drug. Raw material.
35.	Ketacine	52	Veterinary Product
36.	Ketaject	52	International product marketed in Phillipines
37.	Ketathesia	52	Veterinary Product
38.	Ketovail	52	International product marketed in United Kingdom
39.	(b) (4)	52	Name withdrawn by the Applicant – OSE #2013-554
40.	Tussi-bid	52	Unable to find product characteristics in commonly used drug databases.
41.	Uni-tris	52	Unable to find product characteristics in commonly used drug databases.
42.	Catalase	51	Product not a drug. Enzyme to speed up a reaction.
43.	(b) (4) ***	51	Name identified by Safety Evaluator. Unable to find product characteristics
44.	(b) (4) ***	51	Secondary name that was never reviewed. Primary name approved, (b) (4). (OSE #2010-482)
45.	Amoxi-tabs	50	Veterinary Product
46.	Caseins	50	Product is not a drug. Allergenic Extract used for diagnostic purposes only.
47.	Codotuss	50	Unable to find product characteristics in commonly used drug databases.
48.	Cotameth	50	Unable to find product characteristics in commonly used drug databases.
49.	Diabetuss	50	Unable to find product characteristics in commonly used drug databases.
50.	Dietrim ES	50	Unable to find product characteristics in commonly used drug databases.
51.	(b) (4) ***	50	Proposed Proprietary Name found

No.	Name	POCA Score (%)	Failure preventions
			unacceptable by DMEPA (OSE# 2013-45).
52.	Esptabs	50	Product is not a drug. Phenolphthalein.
53.	Kefadol	50	Withdrawn application (cefamandole)
54.	Keftid	50	International product marketed in United Kingdom and Ireland
55.	Kelacid***	50	Name identified by Safety Evaluator. Unable to find product characteristics
56.	Ketotard	50	International product marketed in United Kingdom
57.	(b) (4)***	50	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2012-2045).
58.	Nasabid	50	Withdrawn application
59.	Pacaps	50	International product marketed in United Kingdom
60.	Pacis	50	International product marketed in Argentina and Canada
61.	Tisept	50	Product is not a drug (antiseptic hand wash)
62.	Titanium	50	Product is not a drug (metal)
63.	Vigam-S	50	Unable to find product characteristics in commonly used drug databases.
64.	(b) (4)***	50	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2013-98).

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/s/  
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JACQUELINE E SHEPPARD  
06/02/2014

TINGTING N GAO  
06/02/2014

TINGTING N GAO on behalf of JULIE V NESHIEWAT  
06/02/2014