

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

210045Orig1s000

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:	December 6, 2017
Application Type and Number:	NDA 210045
Product Name and Strength:	Consensi (amlodipine besylate/celecoxib) tablets, 2.5/200 mg, 5 mg/200 mg, 10 mg/200 mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Kitov Pharmaceuticals, Ltd
Panorama #:	2017-17496849
DMEPA Safety Evaluator:	Sarah Thomas, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Consensi, 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 submitted an external name study, conducted by Med-ERRS, for Consensi in the previous request for proprietary name review under IND 112830 submitted March 10, 2017.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, (b) (4)*** under IND 112830 on March 10, 2017. However, we found the name, (b) (4)*** unacceptable under IND 112830 (b) (4) on August 29, 2017.^a

Thus, the Applicant submitted the name, Consensi, for review on September 11, 2017.

1.2 PRODUCT INFORMATION

The following product information is provided in the September 11, 2017 proprietary name submission.

- Intended Pronunciation: /kɒn/'sen/saɪ/
- Active Ingredient: Amlodipine Besylate/Celecoxib
- Indication of Use: patients who require (b) (4) treatment (b) (4) of osteoarthritis, and who also require the treatment of hypertension to lower blood pressure.
- Route of Administration: oral
- Dosage Form: tablets
- Strengths: 2.5 mg/200 mg, 5 mg/200 mg, and 10 mg/200 mg
- Dose and Frequency:
 - The usual initial adult dose is 5 mg/200 mg once daily, and the maximum dose is 10 mg/200 mg once daily.
 - Small, fragile, or elderly patients, or patients with hepatic insufficiency may be started on 2.5 mg/200 mg orally daily, and this dose may be used when adding this medication to other antihypertensive therapy.
 - Daily recommended dose of celecoxib in patients with moderate hepatic impairment should be reduced by 50%
 - Not recommended in patients with severe renal or hepatic insufficiency

^aThomas, S. Proprietary Name Review for (b) (4)*** (IND 112830). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 AUG 29. Panorama No. 2017-13680589.

- Poor metabolizers of CYP2C9 substrates should be administered celecoxib with caution and potentially at half the lowest recommended dose
- How Supplied: Bottles of 100 and 500 count tablets
- Storage: Store bottles at room temperature, 20°C to 25°C (68°F to 77°F) [redacted] (b) (4) [redacted] [see USP Controlled Room Temperature]. Dispense in tight, light-resistant containers (USP).

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. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Cardiovascular and Renal Products (DCRP) 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^b.

2.2.2 *Components of the Proposed Proprietary Name*

The Applicant did not provide a derivation or intended meaning for the proposed name, Consensi, 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.

2.2.3 *Comments from Other Review Disciplines at Initial Review*

In response to the OSE, September 27, 2017 e-mail, the Division of Cardiovascular and Renal Products (DCRP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 *FDA Name Simulation Studies*

Ninety-one practitioners participated in DMEPA's prescription studies. Forty-five participants interpreted Consensi correctly in the inpatient and outpatient handwritten 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.

^b USAN stem search conducted on September 27, 2017.

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

Our POCA search^c identified 158 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. 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 search and the Med-ERRS external study. These name pairs 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 $\geq 70\%$	8
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	145
Low similarity name pair: combined match percentage score $\leq 54\%$	16

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

Our analysis of the 169 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 Cardiovascular and Renal Products (DCRP) via e-mail on November 30, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DCRP on December 5, 2017, they stated no additional concerns with the proposed proprietary name, Consensi.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Darrell Lyons, OSE project manager, at 301-796-4092.

^c POCA search conducted on September 27, 2017 in version 4.2. POCA tool updated to incorporate a revised orthographic algorithm.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 11, 2017 submission are altered prior to approval of the marketing application, 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).

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

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

***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)).
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.,

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

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. 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 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 <i>z</i> and <i>f</i>), 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. Consensi Study (Conducted on September 22, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription					
Medication Order: <table border="1" data-bbox="191 457 1136 567"> <tr> <td data-bbox="191 457 305 504">DATE</td> <td data-bbox="305 457 418 504">TIME</td> <td data-bbox="418 457 1136 504" rowspan="2"><i>Consensi 200mg/5mg T tablet po daily</i></td> </tr> <tr> <td data-bbox="191 504 305 567"></td> <td data-bbox="305 504 418 567"></td> </tr> </table> Outpatient Prescription: Patient _____ Date _____ Address _____ R <i>Consensi 200mg/2.5mg</i> <i>Take T tablet po daily</i> <i>#30</i>  Refill(s): _____ Dr. <i>ASB</i> _____ DEA No. _____ Address _____ Telephone _____	DATE	TIME	<i>Consensi 200mg/5mg T tablet po daily</i>			Consensi 200 mg/2.5 mg Take one tablet by mouth daily Dispense #30
DATE	TIME	<i>Consensi 200mg/5mg T tablet po daily</i>				

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Consensi

As of Date 10/24/2017

307 People Received Study
91 People Responded

Study Name: Consensi

	Total	34	27	30	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL	
CENSENSI	0	0	1	1	
COMBENDI	0	0	1	1	
COMENIC	0	0	1	1	
COMENSI	0	0	1	1	
COMSENSI	0	0	4	4	
CONCENSEI	0	1	0	1	
CONCENZAI	0	1	0	1	
CONIENSI	0	0	1	1	
CONSENDI	0	0	1	1	
CONSENSA	0	2	0	2	
CONSENSAE	0	2	0	2	
CONSENSAI	0	1	0	1	
CONSENSAU	0	1	0	1	
CONSENSAY	0	5	0	5	
CONSENSE	3	5	0	8	
CONSENSEA	0	2	0	2	
CONSENSEI	0	1	0	1	
CONSENSEY	0	3	0	3	
CONSENSI	26	0	18	44	
CONSENSI 200MG/2.5MG	1	0	0	1	
CONSERSI	1	0	0	1	
CONSESAY	0	1	0	1	
CONSESI	0	0	1	1	
CONSEVSE	1	0	0	1	
CONSEVSI	1	0	0	1	
CONSINSI	1	0	0	1	

CORILENSI	0	0	1	1
KONSENSAY	0	1	0	1
KONSENSEI	0	1	0	1

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

No.	Proposed name: Consensi Established name: Amlodipine Besylate/Celecoxib Dosage form: Tablets Strength(s): 2.5 mg/200 mg, 5 mg/200 mg, and 10 mg/200 mg Usual Dose: 2.5 mg/200 mg orally daily up to maximum dose of 10 mg/200 mg orally 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.	Cansen	70	International product marketed in Hong Kong per Micromedex database. Per external Med-ERRS study, Cansen is an international product available in Taiwan.
2.	Concerta	70	The suffixes (si vs. ta) of this name pair have sufficient orthographic differences. The second and third syllables ('sen vs. ser, sai vs. ta) sound different. Both products are available as multiple non-overlapping strengths of 2.5 mg/200 mg, 5 mg/200 mg, 10 mg/200 mg versus 18 mg, 27 mg, 36 mg, 54 mg, thus providing differing product characteristics.
3.	Consenin	84	Name identified in external Med-ERRS study. Unable to find product characteristics in commonly used drug databases. Per the external Med-ERRS study, Consenin is an international product available in Turkey.
4.	Consensus	83	Name identified in external Med-ERRS study. Unable to find product characteristics in commonly used drug databases. Per the external Med-ERRS study, Consensus Orthopedics is a company that manufactures joint implants (http://www.consensusortho.com/).
5.	Consion	71	International product marketed in the United Kingdom per Micromedex database.
6.	Constante	73	International product marketed in the Brazil per Micromedex database.
7.	Convenia	72	Veterinary product per DailyMed database.
8.	Monensin	70	Veterinary product per DailyMed database.

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 (%)
9.	(b) (4)***	55

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: Consensi Established name: Amlodipine Besylate/Celecoxib Dosage form: Tablets Strength(s): 2.5 mg/200 mg, 5 mg/200 mg, and 10 mg/200 mg Usual Dose: 2.5 mg/200 mg orally daily up to maximum dose of 10 mg/200 mg orally 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
10.	Aptensio	58	Available as Aptensio XR per Drugs@FDA. This name pair has sufficient orthographic and phonetic differences.
11.	Body Essence	60	Available as Body Essence Body Moisturizer per Micromedex database and Body Essence Raspberry Antibacterial per DailyMed database. This name pair has sufficient orthographic and phonetic differences.
12.	(b) (4) ***	60	This name pair has sufficient orthographic and phonetic differences.
13.	Bosentan	57	This name pair has sufficient orthographic and phonetic differences.
14.	Cancidas	64	This name pair has sufficient orthographic and phonetic differences.
15.	Canesten	62	Per Micromedex database, international products marketed in the United Kingdom, Australia, Canada, and other countries. Per DailyMed database, available as Canesten V. The Canesten V and Consensi name pair has sufficient orthographic and phonetic differences.
16.	Caseins	68	Per Micromedex database, casein refers to a group of milk phosphoproteins found in dairy products. These phosphoproteins are rich in essential amino acids and can be used as nutrients in laboratory animals and humans. Per DailyMed database, casein injection is used as a diagnostic and therapeutic allergenic extract in allergenic testing and immunotherapy. This name pair has sufficient orthographic and phonetic differences.

17.	Cavirinse	59	This name pair has sufficient orthographic and phonetic differences. Cavirinse (sodium fluoride) solution, 0.2%, is a Rx discontinued dental rinse (discontinued ~2005 per RedBook). Because sodium fluoride solution/dental rinse are unapproved products, no generic equivalents are available. Another 0.2% sodium fluoride solution is available per RedBook but is marketed under Prevident Dental Rinse. Although we do not anticipate prescribers to write for Cavirinse (discontinued with no approved generic equivalents), in the case where Cavirinse is prescribed on a prescription, Cavirinse was available in a single strength (0.2%) versus Consensi will be supplied in multiple non-overlapping strengths (2.5 mg/200 mg, 5 mg/200 mg, and 10 mg/200 mg), which will require the listing of a strength for Consensi on a prescription. This provides sufficient differentiating product characteristics.
18.	Centussin	61	Available as Centussin DHC per Google search. This name pair has sufficient orthographic and phonetic differences.
19.	Ceresin	50	This name pair has sufficient orthographic and phonetic differences.
20.	Chenix	55	This name pair has sufficient orthographic and phonetic differences.
21.	Cholestin	52	This name pair has sufficient orthographic and phonetic differences.
22.	(b) (4)***	60	This name pair has sufficient orthographic and phonetic differences.
23.	Cinvanti***	62	This name pair has sufficient orthographic and phonetic differences.
24.	Clindets	61	This name pair has sufficient orthographic and phonetic differences.
25.	Cogentin	62	This name pair has sufficient orthographic and phonetic differences.
26.	Colace W/sennosides	50	This name pair has sufficient orthographic and phonetic differences.
27.	Coly Mycin S	58	This name pair has sufficient orthographic and phonetic differences.
28.	Coly-Mycin S	58	This name pair has sufficient orthographic and phonetic differences.

29.	Combivent	58	This name pair has sufficient orthographic and phonetic differences.
30.	Concentraid	63	This name pair has sufficient orthographic and phonetic differences.
31.	Concept Ob	61	This name pair has sufficient orthographic and phonetic differences.
32.	Conex	60	This name pair has sufficient orthographic and phonetic differences.
33.	Congestac	60	This name pair has sufficient orthographic and phonetic differences.
34.	Congestaid II	52	This name pair has sufficient orthographic and phonetic differences.
35.	Congestant	57	This name pair has sufficient orthographic and phonetic differences.
36.	(b) (4)***	56	This name pair has sufficient orthographic and phonetic differences.
37.	Constilac	58	This name pair has sufficient orthographic and phonetic differences.
38.	Contac Sinus	60	This name pair has sufficient orthographic and phonetic differences.
39.	Conte-Pak-4	56	This name pair has sufficient orthographic and phonetic differences.
40.	Contragesic	59	This name pair has sufficient orthographic and phonetic differences.
41.	Conzip	58	This name pair has sufficient orthographic and phonetic differences.
42.	Corisin	56	This name pair has sufficient orthographic and phonetic differences.
43.	Cosamin	58	Name identified in RxNorm database. Cosamin described as glucosamine hydrochloride, chondroitin sulfate sodium, and manganese ascorbate product in Micromedex database and Cosamin ASU, Cosamin DS, and Cosamin VERDE in Micromedex Redbook database, but unable to find product characteristics for "Cosamin" in any of the commonly used drug databases. Additionally, Consensi and Cosamin have sufficient orthographic and phonetic differences.
44.	Cosamin Ds	58	This name pair has sufficient orthographic and phonetic differences.
45.	Cosentyx	63	This name pair has sufficient orthographic and phonetic differences.
46.	Cosmegen	57	This name pair has sufficient orthographic and phonetic differences.

47.	(b) (4) ***	67	This name pair has sufficient orthographic and phonetic differences.
48.	Ctx3 Rinse	62	This name pair has sufficient orthographic and phonetic differences.
49.	Ctx4 Rinse	62	This name pair has sufficient orthographic and phonetic differences.
50.	Decongest	55	This name pair has sufficient orthographic and phonetic differences.
51.	De-congestine	51	This name pair has sufficient orthographic and phonetic differences.
52.	Femcon Fe	60	This name pair has sufficient orthographic and phonetic differences.
53.	Ginsenoside	59	Available as "Ginsenoside RG1 Rejuvenating Moisturizing (glycerin) Cream" and "RUBY CELL 4U RG3 PURE- ginsenosides soap" per DailyMed database. Unable to find product characteristics for "Ginsenoside" in any of the commonly used drug databases. Additionally, Ginsenoside and Consensi have sufficient orthographic and phonetic differences.
54.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
55.	Lidosense	63	This name pair has sufficient orthographic and phonetic differences.
56.	Lotensin	60	This name pair has sufficient orthographic and phonetic differences.
57.	Micronase	48	This name pair has sufficient orthographic and phonetic differences.
58.	Mono-Gesic	55	This name pair has sufficient orthographic and phonetic differences.
59.	Ms contin	60	This name pair has sufficient orthographic and phonetic differences.
60.	Nicosyn	52	This name pair has sufficient orthographic and phonetic differences.
61.	Oseni	62	This name pair has sufficient orthographic and phonetic differences.
62.	Ponstel	55	This name pair has sufficient orthographic and phonetic differences.
63.	Quasense	63	This name pair has sufficient orthographic and phonetic differences.
64.	Ruconest	55	This name pair has sufficient orthographic and phonetic differences.
65.	Sani-Clens	58	This name pair has sufficient orthographic and phonetic differences.

66.	Senexon S	60	Available as "Senexon-S" per DailyMed and Micromedex Redbook databases. This name pair has sufficient orthographic and phonetic differences.
67.	Senokot-S	55	This name pair has sufficient orthographic and phonetic differences.
68.	Senosol-SS	56	This name pair has sufficient orthographic and phonetic differences.
69.	Sensi	64	Available as "Sensi Care Body Cream", "Sensi Care Clear Zinc", "Sensi Care Incontinence Wipes", "Sensi Care Moisturizing Body cream", "Sensi Care Protective Barrier", and "Sensi-Care Body cream" in the DailyMed database. Consensi and these names have sufficient orthographic and phonetic differences. Per the external Med-ERRS study, Sensi is a line of adult diapers (http://www.sensi.co.id/products/adult-diaper/).
70.	Sensicaine	52	Available as "Sensicaine TM Extra Topical Anesthetic (benzocaine) gel" per DailyMed database. This name pair has sufficient orthographic and phonetic differences.
71.	Sensi-Care	56	Available as "Crest Sensi-Care (sodium fluoride) rinse", "Sensi Care Moisturizing Body (petrolatum) cream", and "Sensi-Care Body (petrolatum, dimethicone) cream" per DailyMed database. This name pair has sufficient orthographic and phonetic differences.
72.	Sensipar	58	This name pair has sufficient orthographic and phonetic differences.
73.	Sensodyne	56	This name pair has sufficient orthographic and phonetic differences.
74.	Sensorcaine	48	This name pair has sufficient orthographic and phonetic differences.
75.	Strensiq	58	This name pair has sufficient orthographic and phonetic differences.
76.	Tensilon	58	This name pair has sufficient orthographic and phonetic differences.
77.	Triesence	56	This name pair has sufficient orthographic and phonetic differences.
78.	Vicodin ES	58	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
79.	Canasa	50
80.	Canase	52

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
81.	1-Eicosene	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
82.	Beconase	53	Brand discontinued with no generic equivalents available per Drugs@FDA and Micromedex Redbook databases.
83.	Breonesin	54	Brand discontinued with no generic equivalents available per Micromedex Redbook database.
84.	Canesten Af	58	Canesten AF Once Daily is an international product marketed in the United Kingdom per Micromedex Tox and Drug Product Lookup database.
85.	Canesten Vc	58	International product marketed in the United Kingdom per Micromedex Tox and Drug Product Lookup database.
86.	Cansis	65	International product marketed in Argentina per Micromedex database.
87.	Cenestin	60	Brand discontinued with no generic equivalents available per Drugs@FDA, Micromedex Redbook, and Clinical Pharmacology databases.
88.	Clintabs	57	Veterinary product per DailyMed database.
89.	Codafen	57	International product marketed in Ireland and the United Kingdom per Micromedex Tox and Drug Product Lookup database.
90.	Codelson	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
91.	(b) (4)***	60	Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA on (b) (4) (Panorama #: (b) (4)). IND (b) (4) has been withdrawn status in DARRTS.
92.	Co-Gesic	60	Brand discontinued with no generic equivalents available per Drugs@FDA, Micromedex Redbook, and Clinical Pharmacology databases.
93.	Cognex	56	Brand discontinued with no generic equivalents available per Drugs@FDA, Micromedex Redbook, and Clinical Pharmacology databases.
94.	Combi-Pen-48	55	Veterinary product per DailyMed database.

No.	Name	POCA Score (%)	Failure preventions
95.	(b) (4)***	55	Proposed proprietary name submitted for review on (b) (4) under IND (b) (4). Following a teleconference, the proposed proprietary name changed from (b) (4)*** to (b) (4)***. (b) (4)*** is evaluated in Appendix D of this review.
96.	Comtess	60	International product per Micromedex Tox and Drug Product Lookup database marketed in the United Kingdom, Germany, and many other countries.
97.	Comtussin Hc	56	Brand discontinued with no generic equivalents available per Micromedex Redbook database.
98.	Condasin	68	Brand discontinued with no generic equivalents available per Clinical Pharmacology database.
99.	Condrin	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases for name "Condrin." However, identified name "Condrin-LA" in Micromedex database as a discontinued product with no generic equivalents available.
100.	Conex La	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
101.	Conffits	69	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
102.	Congespirin	56	Brand discontinued with no generic equivalents available per Micromedex Redbook database.
103.	Congess	68	Per Micromedex database, Congess is a formerly marketed guaifenesin and pseudoephedrine hydrochloride product. Micromedex Redbook database reports as Congess JR and Congess SR, which are discontinued products with no generic equivalents available.
104.	Congess Jr.	58	Brand discontinued with no generic equivalents available per Micromedex Redbook database.
105.	Congess Sr	66	Brand discontinued with no generic equivalents available per Micromedex Redbook and Clinical Pharmacology databases.
106.	Coniine	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
107.	(b) (4)***	65	Proposed name submitted for review under IND (b) (4) and then withdrawn on (b) (4). Product approved under name (b) (4).
108.	Conpec Dm	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
109.	Contimin	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
110.	Contuss	64	Brand discontinued with no generic equivalents available per Micromedex Redbook database.
111.	Cophene No. 2	60	Brand discontinued with no generic equivalents available per Micromedex Redbook database.
112.	Cophene-X	56	Brand discontinued with no generic equivalents available per Micromedex Redbook database.
113.	Cornsilk	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
114.	Coronis	58	International product marketed in the Turkey per Micromedex database.
115.	Co-Tussin	62	Brand discontinued with no generic equivalents available per Micromedex Redbook database.
116.	Dhc continus	59	International product marketed in the United Kingdom, Ireland, Poland, and other countries per Micromedex Tox and Drug Product Lookup database.
117.	Econosone	61	International product marketed in the United Kingdom per Micromedex Tox and Drug Product Lookup database.
118.	Eicosenoic Acid	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
119.	Ephensin-La	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
120.	(b) (4)***	57	Proposed proprietary name for NDA (b) (4) found unacceptable by DMEPA on (b) (4) (Panorama #: (b) (4)). Product approved under new proprietary names, (b) (4).

No.	Name	POCA Score (%)	Failure preventions
121.	(b) (4) ***	58	Proposed proprietary name submitted for review on (b) (4) under IND (b) (4). We determined that the proprietary name submission was incomplete on (b) (4) because the submission did not contain the determination of the product dose. No subsequent proprietary name requests have been submitted and IND (b) (4) is active per DARRTS.
122.	K-C Suspension	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
123.	Keavance	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
124.	Mst continus	55	International product marketed in Ireland, Mexico, the United Kingdom, and other countries per Micromedex database.
125.	Nomifensine	56	"Nomifensine maleate" found in Micromedex Tox and Drug Product Lookup database as a 50 mg capsule. Per Google search, Nomifensine maleate was a norepinephrine-depamine reuptake inhibitor developed in the 1960s and then test marketed in the U.S. Nomifensine was withdrawn from the market in 1992 due to risk of hemolytic anemia.
126.	(b) (4) ***	62	Proposed proprietary name found unacceptable by DMEPA under IND (b) (4). IND (b) (4) is active per DARRTS, and no new names have been submitted for review.
127.	(b) (4) ***	59	We found the proposed proprietary name conditionally acceptable on (b) (4) under IND (b) (4) (Panorama #: (b) (4)). Sponsor then withdrew this name on (b) (4) and submitted new proposed proprietary name, (b) (4) ***. We found (b) (4) *** conditionally acceptable on (b) (4) under IND (b) (4) (Panorama #: (b) (4)) and IND is listed as active in DARRTS.
128.	Ponstan	56	International product marketed in the United Kingdom, Canada, Mexico, and other countries.

No.	Name	POCA Score (%)	Failure preventions
129.	Sennoside B	56	Name identified in RxNorm database. Unable to find product characteristics in commonly use drug databases. Per Google search, "Sennoside B is an anthranoid. Anthranoid derivatives are used all over the world as a treatment for constipation."
130.	Sensei	62	International product marketed in Chile per Micromedex database. Per the external Med-ERRS study, Sensei is an international product available in Colombia and Chile.
131.	Sensipak	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
132.	Silicones	52	Active ingredient in many international products marketed in Argentina, Chile, and other countries per Micromedex Tox and Drug Product Lookup database.
133.	Tensium	55	International product marketed in the United Kingdom and Argentina.
134.	Unitensen	60	Brand discontinued and no generic equivalent are available per Drugs@FDA database (e.g., no TE code).
135.	(b) (4) ***	56	Proposed proprietary name found unacceptable by DMEPA under NDA (b) (4). Product approved under new proprietary name, (b) (4).
136.	(b) (4) ***	57	Proposed proprietary name found unacceptable by DMEPA under IND (b) (4). Subsequently, the proposed proprietary name (b) (4) *** was submitted for review and first found conditionally acceptable on (b) (4) but then found unacceptable on (b) (4). IND (b) (4) is active per DARRTS, and no new names have been submitted for review.

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 (%)
137.	Ancestim	57
138.	Antepsin	56
139.	(b) (4)***	56
140.	Fenesin	57
141.	Fenesin Ir	55
142.	Genesis	58
143.	K-Vescent	55
144.	Mononessa	56
145.	Mycocide Ns	56
146.	(b) (4)***	58
147.	(b) (4)***	60
148.	(b) (4)***	59
149.	Pentids '200'	60
150.	Pentids '250'	60
151.	Pentids '400'	60
152.	Pentids '800'	60
153.	Peptones	55
154.	(b) (4)***	55
155.	Q-Tussin Pe	58
156.	Scandonest	56
157.	Scot-Tussin	58
158.	Sinuson Ii	56
159.	Sinuvent	56
160.	Solfenacin	56
161.	Somnicin	56
162.	(b) (4)***	58
163.	Tannate 12D S	55
164.	Transanosil	56
165.	T-Tussin Pe	57
166.	Tussin Pe	58
167.	Vancenase	56
168.	(b) (4)***	56
169.	Vonvendi	66

^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

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

No.	Name
1.	N/A

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/s/

SARAH E THOMAS
12/06/2017

CHI-MING TU
12/07/2017

PROPRIETARY NAME REVIEW

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

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

Date of This Review: August 30, 2017
Application Type and Number: IND 112830
Product Name and Strength: (b) (4) (amlodipine besylate and celecoxib) tablets,
2.5 mg/200 mg, 5 mg/200 mg, and 10 mg/200 mg
Product Type: Multi-Ingredient product
Rx or OTC: Rx
Applicant/Sponsor Name: Kitov Pharmaceuticals, Ltd
Panorama #: 2017- 13680589
DMEPA Primary Reviewer: Sarah Thomas, PharmD
DMEPA Team Leader: Chi-Ming (Alice) Tu, PharmD, BCPS
DMEPA Deputy Director (Acting): Danielle Harris, PharmD, BCPS
DMEPA Division Director: Todd Bridges, RPh

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