

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

206333Orig1s000

PROPRIETARY NAME REVIEW(S)

Proprietary Name Memorandum

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 23, 2015
Requesting Office or Division:	Division of Dermatology and Dental Products (DDDP)
Application Type and Number:	NDA 206333
Product Name and Strength:	Kybella (deoxycholic acid) Injection, 20 mg/2 mL (10 mg/mL)
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Kythera Biopharmaceuticals
Submission Date:	January 20, 2015
Panorama #:	2015-47515
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, RPh
DMEPA Team Leader:	Kendra Worthy, PharmD
DMEPA Associate Director:	Lubna Merchant, MS, PharmD

1 INTRODUCTION

The proposed proprietary name, Kybella, was reviewed by DMEPA on August 5, 2014¹ and was found that it could result in medication errors due to confusion with another product (i.e. Carbella***) under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Kybella, was dependent upon which underlying application was approved first. The applicant subsequently withdrew the name Kybella and submitted the proposed name (b) (4)***, which was found acceptable by DMEPA on December 14, 2014². Nevertheless, on January 20, 2015 the applicant withdrew the name (b) (4)*** and re-submitted the proposed name Kybella for evaluation.

We note that the application for the proposed name Carbella*** (NDA 206030) received a complete response (CR) letter on October 23, 2014. Therefore, the proposed name Carbella*** is no longer a concern since the applicant would have to re-submit the proposed name when they respond to the CR letter.

2 METHODS AND DISCUSSION

For re-assessments of the proposed proprietary name, DMEPA searched the POCA databases³ to identify new names with orthographic and phonetic similarity that were not identified in the previous OSE proprietary name review. We note that none of the proposed product characteristics for Kybella have changed. The searches of the databases yielded three new names (Jadelle, (b) (4)), thought to look or sound similar to Kybella and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with either of the new names identified. This analysis determined that the name similarity between Kybella and Jadelle, (b) (4)*** was unlikely to result in medication error for the reasons presented in Appendix A and B.

¹ Mena-Grillasca, CM. Proprietary Name Review for Kybella (NDA 206333). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2014 AUG 05. OSE RCM No.: 2014-17390.

² Mena-Grillasca, CM. Proprietary Name Review for (b) (4) (NDA 206333). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2014 DEC 12. OSE RCM No.: 2014-36970.

³ Databases searched: Drugs@FDA and Names Entered by Safety Evaluators

DMEPA searched the USAN stem list⁴ to determine if the name contains any USAN stems since the last USAN update. The March 19, 2015 stems search did not find any USAN stems in the proposed proprietary name.

Therefore, this memorandum is to communicate that DMEPA finds the proposed proprietary name, Kybella, is acceptable from both a misbranding and safety perspective.

If you have further questions or need clarifications, please contact Janet Anderson, OSE project manager, at 301-796-0675.

2 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your January 20, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

⁴ USAN Stems List contains all the recognized USAN stems.
<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page>

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

No.	Proposed name: Kybella Established name: Deoxycholic Acid Dosage form: Injection Strength(s): 20 mg/2 mL (10 mg/mL) Usual Dose: up to 50 injections of 0.2 mL/cm ² each	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
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(b) (4)

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

No.	Name	POCA Score (%)	Failure preventions
3.	Jadelle	52	Discontinued product with no generic equivalents available.

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/s/

CARLOS M MENA-GRILLASCA
03/23/2015

KENDRA C WORTHY
03/23/2015

LUBNA A MERCHANT
03/23/2015

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)

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Date of This Review: December 12, 2014
Application Type and Number: NDA 206333
Product Name and Strength: (b) (4) (deoxycholic acid) Injection, 20 mg/2 mL (10 mg/mL)
Product Type: Single ingredient product
Rx or OTC: Rx
Applicant/Sponsor Name: Kythera Biopharmaceuticals
Submission Date: September 29, 2014
Panorama #: 2014-36970
DMEPA Primary Reviewer: Carlos M Mena-Grillasca, RPh
DMEPA Team Leader: Kendra Worthy, PharmD
DMEPA Associate Director: Lubna Merchant, MS, PharmD

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/s/

CARLOS M MENA-GRILLASCA
12/12/2014

KENDRA C WORTHY
12/12/2014

LUBNA A MERCHANT
12/12/2014

PROPRIETARY NAME REVIEW

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

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Date of This Review:	July 31, 2014
Application Type and Number:	NDA 206333
Product Name and Strength:	Kybella (deoxycholic acid) Injection, 10 mg/mL
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Kythera Biopharmaceuticals
Submission Date:	May 23, 2014
Panorama #:	2014-17390
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, RPh
DMEPA Associate Director:	Lubna Merchant, MS, PharmD
DMEPA Director (Acting):	Kellie Taylor, PharmD, MPH

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Kybella, 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 the (b) (4), for this product.

1.1 REGULATORY HISTORY

The sponsor previously submitted the proposed proprietary name (b) (4) to IND 079726. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name (b) (4) unacceptable due to orthographic or phonetic similarities and shared product characteristics with the proprietary names, (b) (4), in OSE Review #2013-923, dated September 30, 2013.

Thus, the sponsor submitted the name Kybella for review on May 23, 2014.

1.2 PRODUCT INFORMATION

The following product information is provided in the May 23, 2014 proprietary name submission.

- Intended Pronunciation: kye be' lah
- Active Ingredient: deoxycholic acid
- Indication of Use: Improvement in the appearance of moderate to severe submental convexity or fullness associated with submental fat in adults
- Route of Administration: Subcutaneous
- Dosage Form: Injection
- Strength: 10 mg/mL
- Dose and Frequency: Up to 10 mL or 100 mg per treatment session (up to 50 injections of 0.2 mL/cm² each). Up to 6 treatment sessions at intervals no less than 4 weeks apart.
- How Supplied: Packs of Four 2 mL single-use vials
- Storage: 15 – 30°C (59-86°F)
- Container and Closure Systems: n/a

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 Dermatology and Dental Products (DDDP) 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 name¹.

2.2.2 *Components of the Proposed Proprietary Name*

The Applicant did not provide a derivation or intended meaning for the proposed name Kybella 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 *FDA Name Simulation Studies*

One hundred four practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. Eighty-three participants interpreted the proposed name correctly (outpatient n=41, inpatient n=28, voice n=14). Five participants from the voice study misinterpreted the 'K' for a 'C'. Eight participants from the voice study misinterpreted the 'y'; five for an 'i' and three for an 'ai'. Five participants from the voice study misinterpreted the 'b' for a 'v'. Three participants from the inpatient study misinterpreted the 'e' for and 'i'. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 *Comments from Other Review Disciplines at Initial Review*

In response to the OSE, June 4, 2014 e-mail, the Division of Dermatology and Dental Products (DDDP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

¹USAN stem search conducted on July 3, 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 search¹ organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified by (b) (4)

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	3
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	64
Low similarity name pair: combined match percentage score $\leq 49\%$	16

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

We determined 82 of the 83 names contained in Table 1 will not pose a risk for confusion as described in Appendices C through G. However, the proposed name could be confused with Carbella***.

The proposed proprietary name, Kybella, is almost identical in spelling and pronunciation to the proposed name, Carbella*** (carbamazepine) injection. These names share 5 out of 7 letters, which appear in identical positions within each name. The names Kybella (kye be' lah) and Carbella*** (kar bel' ah) are comprised of three syllables each, with the stress on the second syllable. The first syllable of each name share the same 'k' sound and the 'ye' vs. 'a' sounds. The second and third syllables of each name sound identical. Furthermore, FDA's Phonetic and Orthographic Computer Analysis (POCA) calculates a 73% phonetic match for this name pair. The similar spelling and pronunciation make the names nearly indistinguishable in speech or writing. In addition, both products are injectable drugs. Therefore, we object to the proposed name based on 21 CFR 201.10(c)(5), which states "The labeling of a drug may be misleading by reason of designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient".

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

DMEPA communicated our findings to the Division of Dermatology and Dental Products (DDDP) via e-mail on July 10, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from

¹ POCA search conducted on July 3, 2014.

the DDDP on July 10, 2014, they stated no additional concerns with the proposed proprietary name Kybella.

3 CONCLUSIONS

The proposed proprietary name is acceptable from a promotional perspective but not acceptable from a safety perspective. The proposed name is vulnerable to name confusion with Carbella***. Therefore, the decision to deny the name will be communicated to the Applicant via letter (See Section 3.1).

If you have further questions or need clarifications, please contact Teena Thomas, OSE project manager, at 301-796-0549.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name Kybella and conclude that this name could result in medication errors due to confusion with another product that is also under review. Therefore, the ultimate acceptability of your proposed proprietary name, Kybella, is dependent upon which underlying application is approved first. If another product is approved prior to your product, with a name that would be confused with your proposed name Kybella, you will be requested to submit another name.

We have taken into consideration that you intend to distribute Kybella directly to be dispensed from a physician's office and that the product is not intended to be sold to or dispensed by retail or hospital pharmacies. However, the distribution plan may not reduce risk associated with the confusion of similar names. We have reports of name confusion with other products marketed under restricted distribution systems.^{1,2} Therefore, our safety concern is not diminished with your distribution plan for this product since the products could be prescribed and dispensed in the same medication use system.

¹ Institute for Safe Medication Practices. Safety briefs: Don't Confuse TRACLEER (bosentan) with TRICOR (fenofibrate). ISMP Med Saf Alert Acute Care. 2003;8(13):2.

² Institute for Safe Medication Practices. Safety briefs: Mifepristone (MIFEPREX) and Misoprostol (CYTOTEC) mix-up. ISMP Med Saf Alert Community/Ambulatory Care. 2003;2(1):1.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present.

Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

1. **Promotional Assessment:** For prescription drug products, the promotional review of the proposed name is conducted by OPDP. For over-the-counter (OTC) drug products, the promotional review of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP or DNCE provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. **Preliminary Assessment:** We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.¹

***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?

- 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 $\geq 70\%$.

¹ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

- 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 ≥ 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>	
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	Y/N	Across a range of dialects, are the names consistently

	letters present in the names?		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 $\geq 50\%$ to $\leq 69\%$).

Step 1	<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"> ○ 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	<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</p>

less likely to confusion between moderately similar names <u>with</u> overlapping or similar strengths or doses.	
<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> Do the names begin with different first letters? <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"> Are the lengths of the names dissimilar* when scripted? <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> 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? 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> 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 ≤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. Kybella Study (Conducted on June 13, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Kybella Inject up to 50 subcutaneous injections of 0.2ml/cm² in the submental area</i></p>	<p>Kybella Bring to clinic Disp. 5 vials</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Kybella Bring to clinic #5 vials</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

As of Date 7/3/2014

266 People Received Study

104 People Responded

Study Name: Kybella

Total	41	32	31	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
CAPMALAR	0	1	0	1
CAVELA	0	1	0	1
CHIAVELLA	0	1	0	1
CLANALA	0	1	0	1
CUTBELLA	0	1	0	1
KAIBELLA	0	3	0	3
KIBELLA	0	1	0	1
KIMELA	0	2	0	2
KIPELLA	0	1	0	1
KIVELA	0	1	0	1
KYBELA	0	2	0	2
KYBELLA	41	14	26	81
KYBELLA INJECT	0	0	1	1
KYBELLA INJECTION	0	0	1	1
KYBILLA	0	0	3	3
KYPELLA	0	1	0	1
KYVELLA	0	2	0	2

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

No.	Proposed name: Kybella Strength(s): 10 mg/mL Usual Dose: up to 50 injections of 0.2 mL/cm ² each	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Or Failure prevention reasons
1.	Kybella	100	Proposed proprietary name subject of this review.
2.	K-Y Jelly	75	K-Y is a line of Over-the-counter personal lubricants. Orthographic: The letter 'j' in K-Y Jelly could be written as a down stroke or up stroke; either presentation would look different than a lower case letter 'b' in Kybella. In addition, the ending down stroke 'y' in K-Y Jelly looks different than the ending 'a' in Kybella. Phonetic: Kybella has 3 syllables vs. 4 syllables in K-Y Jelly. The middle and ending of the names sound different when spoken.

(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.	Name	POCA Score (%)
4.	Savella	63
5.	Khedeza	60
6.	Pirmella 1/35 Pirmella 7/7/7	58
7.	Vivelle Dot	54
8.	Activella	53
9.	Akbeta	52
10.	Cymbalta	52

No.	Name	POCA Score (%)
11.	Covera HS	51
12.	Detrol LA	51
13.	Zydelig***	50
14.	Kenalog-10 Kenalog-20	50
15.	Otezla	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: Kybella Strength(s): 10 mg/mL Usual Dose: up to 50 injections of 0.2 mL/cm ² each	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
16.	Camila	60	Dose: xx mL vs. 1 tablet or UAD Orthographic: The infix of this name pair has sufficient orthographic differences. Phonetic: The second syllables of this name pair sound different when spoken.
17.	Kadcycla	60	Orthographic: The infix of this name pair has sufficient orthographic differences. Phonetic: The second syllables of this name pair sound different when spoken.

(b) (4)

No.	Proposed name: Kybella Strength(s): 10 mg/mL Usual Dose: up to 50 injections of 0.2 mL/cm2 each	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
19.	Kytril	57	Orthographic: The suffix of this name pair has sufficient orthographic differences. Phonetic: The names have different number of syllables (2 vs. 3). The second syllable in Kytril sound different than the second and third syllables in Kybella.
20.	Cryselle	56	Dose: xx mL vs. 1 tablet or UAD Orthographic: The suffix of this name pair has sufficient orthographic differences. Phonetic: The names have different number of syllables (2 vs. 3). The second syllable in Cryselle sound different than the second and third syllables in Kybella.
21.	Ketalar	56	Orthographic: The infix of this name pair has sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different when spoken.
22.	Kwell	56	Orthographic: The infix of this name pair has sufficient orthographic differences. Phonetic: The names have different number of syllables (2 vs. 3). The second syllable in Kwell sound different than the second and third syllables in Kybella.
23.	Synera	56	Dose: xx mL vs. 1 patch or UAD Orthographic: The infix and suffix of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different when spoken.
24.	Keppra	54	Orthographic: The infix of this name pair has sufficient orthographic differences. Phonetic: The names have different number of syllables (2 vs. 3). The second syllable in Keppra sound different than the second and third syllables in Kybella.

No.	Proposed name: Kybella Strength(s): 10 mg/mL Usual Dose: up to 50 injections of 0.2 mL/cm2 each	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
25.	Skyla	54	Orthographic: The infix and suffix of this name pair have sufficient orthographic differences. Phonetic: The names have different number of syllables (2 vs. 3). The second syllable in Skyla sound different than the second and third syllables in Kybella.
26.	Kurvelo	53	Dose: xx mL vs. one tablet or UAD Orthographic: The infix and suffix of this name pair have sufficient orthographic differences. Phonetic: The first syllables of this name pair sound different when spoken.
27.	Pylera	52	Dose: xx mL vs. 3 capsules Orthographic: The suffix of this name pair has sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different when spoken.
28.	Scytera	52	Dose: xx mL vs. apply or UAD Orthographic: The suffix of this name pair has sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different when spoken.
29.	Vyfemla	52	Dose: xx mL vs. one tablet or UAD Orthographic: The infix of this name pair has sufficient orthographic differences. Phonetic: The second syllable of this name pair sound different when spoken.

(b) (4)

No.	Proposed name: Kybella Strength(s): 10 mg/mL Usual Dose: up to 50 injections of 0.2 mL/cm2 each	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
31.	Emla	50	Dose: xx mL vs. xx g Orthographic: The prefix and infix of this name pair have sufficient orthographic differences. Phonetic: The names have different number of syllables (2 vs. 3). The first syllable in Emla sound different than the first and second syllables in Kybella.
32.	Keralac	50	Dose: xx mL vs. apply to affected area or UAD Orthographic: The infix of this name pair has sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different when spoken.
33.	Klebcil	50	Orthographic: The prefix and infix of this name pair have sufficient orthographic differences. Phonetic: The names have different number of syllables (2 vs. 3). All the syllables of this name pair sound different when spoken.
34.	Lycelle	50	Dose: xx mL vs. apply or UAD Orthographic: The infix of this name pair has sufficient orthographic differences. Phonetic: The names have different number of syllables (2 vs. 3). The second syllable in Lycelle sounds different to the second and third syllables in Kybella.
35.	Norel LA	50	Dose: xx mL vs. 1 tablet Orthographic: The infix of this name pair has sufficient orthographic differences. Phonetic: The first syllable of this name pair sound different when spoken.

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

No.	Name	POCA Score (%)
36.	Aventyl	≤ 49
37.	Belladona	≤ 49
38.	Byetta	≤ 49
39.	Duloxetine	≤ 49
40.	Effexor	≤ 49
41.	Kaletra	≤ 49
42.	Kerlone	≤ 49
43.	Ketoconazole	≤ 49
44.	Korlym	≤ 49
45.	Krystexxa	≤ 49
46.	Kyprolis	≤ 49
47.	Lyrica	≤ 49
48.	Opium	≤ 49
49.	Pregabalin	≤ 49
50.	Rulox	≤ 49
51.	Venlafaxine	≤ 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
52.	(b) (4) ***	66	Alternate name for NDA 021945. NDA was approved under the name Makena.
53.	(b) (4) ***	65	Alternate name for ANDA 090794. ANDA was approved under the name Estarylla.
54.	(b) (4) ***	62	Name found unacceptable for NDA 204683. NDA was approved under the name Khedezla.

No.	Name	POCA Score (%)	Failure preventions
55.	Q-Bid LA	62	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
56.	(b) (4) ***	60	Alternate name for ANDA 090721. ANDA was approved under the name Falmina.
57.	(b) (4) ***	60	Proposed name for the product subject of this review under IND 079726. Name found unacceptable in OSE review 2013-923, dated September 30, 2013.
58.	(b) (4) ***	59	Name found unacceptable for NDA 022470. NDA was approved under the name Nexcede.
59.	Pyrelle	57	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
60.	(b) (4) ***	56	Name found unacceptable for NDA (b) (4). The proposed name (b) (4) *** was found conditionally acceptable in OSE review 2008-16, dated January 9, 2008.
61.	(b) (4) ***	56	Name found unacceptable for IND 103694. NDA 203389 was approved under the name Procysbi.
62.	(b) (4) ***	56	Alternate name for NDA 022580. NDA was approved under the name Qsymia.
63.	(b) (4) ***	55	Name found unacceptable for ANDA (b) (4) in OSE review 2014-16944, dated June 13, 2014. The applicant has not submitted a new proposed name for review. The ANDA status is Pending as of 9/28/2010.
64.	(b) (4) ***	55	Alternate name for ANDA 202296. ANDA was approved under the established name.
65.	Qdall AR	55	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
66.	(b) (4) *** (b) (4) ***	54	Names found unacceptable for ANDA 090948 and ANDA 090946. These ANDAs were approved under the names Dasetta 1/35 and Dasetta 7/7/7, respectively.
67.	(b) (4) ***	53	Alternate name for NDA 021359. NDA was approved under the name Rectiv.
68.	Alkabel	52	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
69.	Dynex LA	52	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
70.	Kovia	52	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
71.	(b) (4) *** (b) (4) ***	52	Names withdrawn by the applicant for ANDA 200897 and ANDA 202086. These ANDAs status are Pending as of 1/7/2014 and 1/3/2014, respectively.
72.	Cybolin 12	51	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
73.	(b) (4) ***	50	Name withdrawn by the applicant for NDA 022522. NDA was approved under the name Daliresp.
74.	Cobal	50	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
75.	Crytselle	50	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
76.	(b) (4) ***	50	Alternate name for ANDA 090716. The proposed name Setlakin is currently under review by DMEPA.

No.	Name	POCA Score (%)	Failure preventions
77.	(b) (4) ***	50	Name found unacceptable for ANDA (b) (4). The ANDA status is Pending as of 6/21/2013.
78.	K Lyte CL	50	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
79.	Ketaflo	50	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
80.	(b) (4) ***	50	Proposed name for ANDA 078515. Unable to find information regarding the proposed name. ANDA approved under the established name.
81.	Quala	50	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
82.	(b) (4) ***	50	Name identified in 'Name entered by safety evaluator' database. Unable to find this name in any internal database.

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/s/

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