CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210875Orig1s000

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:	April 28, 2020
Application Type and Number:	NDA 210875
Product Name and Strength:	Kynmobi (b) (4) sublingual film, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Sunovion Pharmaceuticals Inc (Sunovion)
Panorama #:	2020-39055498
DMEPA Primary Reviewer:	Justine Kalonia, PharmD
DMEPA Team Leader:	Briana Rider, PharmD, CPPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Kynmobi, which was found unacceptable under NDA 210875 on July 24, 2019 and February 18, 2020.[ab] The proposed proprietary name, Kynmobi, was found to be vulnerable to medication errors due to confusion with another product, (b) (4)***, under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Kynmobi, was dependent upon which underlying application was approved first.

We note that the goal date for NDA 210875 is May 21, 2019, whereas the underlying application for (b) (4) status. Therefore, if the proposed proprietary name, Kynmobi, is granted approval under NDA 210875 on or before May 21, 2019, this application approval will precede approval of the application with the conflicting proposed name, (b) (4)***.

Thus, Sunovion resubmitted the proposed proprietary name, Kynmobi, for review on April 2, 2020.

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The April 9, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Finally, DMEPA evaluated the status of the underlying application of the conflicting name, (b) (4)***, and determined that if NDA 210875 for Kynmobi is approved on or before the May 21, 2019, this application approval will precede approval of the application with the conflicting proposed name, (b) (4)*** given the underlying application for (b) (4)*** (b) (4) status.

Based upon our safety assessment of the proposed proprietary name, Kynmobi, the application goal date for NDA 210875, and the status of the underlying application for (b) (4)***, we find Kynmobi conditionally acceptable.

2.2 COMMUNICATION OF DMEPA'S ANALYSIS

DMEPA communicated our findings to the Division of Division of Neurology 1 (DN 1) via e-mail on April 21, 2020. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology 1 (DN 1)

[a] Owens, L. Proprietary Name Review Memo for Kynmobi (NDA 210875). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JUL 24. Panorama No. 2018-22076836-1.

[b] Morris, C. Proprietary Name Review for Kynmobi (NDA 210875). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 FEB 18. Panorama No. 2019-35948893.

on April 28, 2020, they stated no additional concerns with the proposed proprietary name, Kynmobi.

3 CONCLUSIONS

We conclude that the proposed proprietary name, Kynmobi, is acceptable.

If you have any questions or need clarifications, please contact Casmir Ogbonna, OSE project manager, at 301-796-5272.

3.1 COMMENTS TO SUNOVION PHARMACEUTICALS INC

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

If any of the proposed product characteristics as stated in your submission, received on April 2, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

If your application receives a complete response, please submit a new request for review of your proposed proprietary name when you respond to the application deficiencies.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JUSTINE H KALONIA
04/28/2020 08:43:41 AM

BRIANA B RIDER
04/28/2020 08:52:32 AM

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:	February 18, 2020
Application Type and Number:	NDA 210875
Product Name and Strength:	Kynmobi (apomorphine hydrochloride) sublingual film, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Sunovion Pharmaceuticals Inc (Sunovion)
Panorama #:	2019-35948893
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Team Leader:	Briana Rider, PharmD, CPPS
DMEPA Deputy Director:	Danielle Harris, PharmD

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The proposed proprietary name, Kynmobi, was previously submitted for review on September 1, 2015. We found the name, Kynmobi, conditionally acceptable under IND 110955 on December 9, 2015.[a] Thus, upon submission of NDA 210875, Sunovion re-submitted the proposed proprietary name, Kynmobi, on April 2, 2018. On June 8, 2018, we found the name conditionally acceptable[b]; however, NDA 210875 received a Complete Response (CR) Letter on January 29, 2019.

Since that time, we identified a conflict with another pending proposed proprietary name under review (OSE RCM# 2018-22076836-1).[c] The proposed name, Kynmobi, could result in medication errors due to confusion with (b) (4)***. Our evaluation of this name pair altered our previous conclusion regarding the acceptability of the proposed proprietary name, Kynmobi.

We notified Sunovion via letter on July 25, 2019 that the proposed proprietary name, Kynmobi, is unacceptable due to potential medication errors due to confusion with another product's proposed proprietary name that is also under review. We also informed Sunovion, the ultimate acceptability of the proposed proprietary name, Kynmobi, is dependent upon which underlying application is approved first.

As part of the Class 2 resubmission in response to the CR, Sunovion re-submitted the name, Kynmobi, for review on November 21, 2019.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 21, 2019.

- Intended Pronunciation: kin moe' bee
- Active Ingredient: apomorphine hydrochloride
- Indication of Use: Acute, intermittent treatment of OFF episodes associated with Parkinson's disease (PD) (b) (4)

[a] Harris, J. Proprietary Name Review for Kynmobi (IND 110955). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 DEC 09. Panorama No. 2015-1367954.

[b] Morris, C. Proprietary Name Review for Kynmobi (NDA 210875). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JUN 08. Panorama No. 2018-22076836.

[c] Owens, L. Proprietary Name Review MEMO for Kynmobi (NDA 210875). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JUL 24. Panorama No. 2018-22076836-1.

- Route of Administration: sublingual
- Dosage Form: sublingual film
- Strength: 10 mg, 15 mg, 20 mg, 25 mg, 30 mg
- Dose and Frequency: 10 mg (b) (4) up to 5 times daily
- How Supplied:
    - Titration Kit containing 10 sublingual films (2 sublingual films per strength)
    - Carton for each strength containing 30 sublingual films
- Storage: Store at 20°–25°C (68°–77°F); excursions permitted between 15°–30°C (59°–86°F).
- Reference Listed Drug/Reference Product: Apokyn, NDA 21264

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Kynmobi would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Neurology 1 (DN 1) concurred with the findings of OPDP's assessment for Kynmobi.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Sunovion did not provide a derivation or intended meaning for the proposed proprietary name, Kynmobi, 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, December 5, 2019 e-mail, the Division of Neurology 1 (DN 1) did not forward any comments or concerns relating to Kynmobi at the initial phase of the review.

[d] USAN stem search conducted on December 3, 2019.

2.2.4 FDA Name Simulation Studies

Eighty-seven practitioners participated in DMEPA's prescription studies for Kynmobi. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[e] identified 8 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name reviews.[a,b] We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 1 name not previously analyzed. This name is 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 updated (b) (4) external study. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	0
Low similarity name pair: combined match percentage score ≤54%	2

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

We determined 2 of the 3 names will not pose a risk for confusion with Kynmobi as described in Appendices C through H. However, the proposed proprietary name could be confused with another pending proposed proprietary name, (b) (4) ***. The rationale for the risk of confusion is described in our Memo/Decision Amendment dated July 24, 2019[c].

[e] POCA search conducted on December 3, 2019 in version 4.3.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Neurology 1 (DN 1) via e-mail on February 14, 2020. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology 1 (DN 1) on February 18, 2020, they stated no additional concerns with the proposed proprietary name, Kynmobi.

3 CONCLUSION

The proposed proprietary name, Kynmobi, is not acceptable from a safety perspective. The proposed proprietary name, Kynmobi, is vulnerable to name confusion with another product that is also under review, (b) (4) ***. Therefore, the decision to deny the name will be communicated to Sunovion via letter (See Section 3.1).

If you have further questions or need clarifications, please contact Casmir Ogbonna, OSE project manager, at 301-796-5272.

3.1 COMMENTS TO SUNOVION PHARMACEUTICALS INC

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

Kynmobi vs. pending proprietary name

The proposed proprietary name, Kynmobi, could result in medication errors due to confusion with another product that is also under review. As previously described in our July 25, 2019 correspondence, the ultimate acceptability of your proposed proprietary name, Kynmobi, 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 Kynmobi, you will be requested to submit another name.

We acknowledge that our conclusion differs from that of the (b) (4) external study submitted in support of the proposed proprietary name. However, the pending proprietary name is also under review and thus was not identified by the (b) (4) external study.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

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 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. [f]

[f] 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 ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤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[g]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

   Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders, which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

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

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

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

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

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths 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.

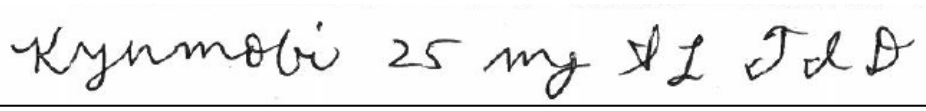
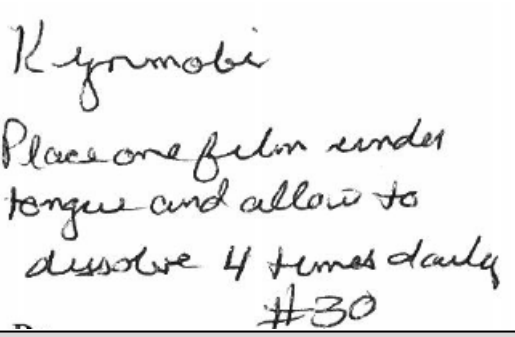
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤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. Kynmobi Study (Conducted on December 6, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	**Kynmobi** 10 mg Place 1 film under the tongue and allow to dissolve 4 times daily #30
Outpatient Prescription:  	
CPOE Study Sample (Font: sans-serif, 12 point, bold)	
Kynmobi	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Kynmobi
As of Date 12/27/2019

210 People Received Study
87 People Responded

Study Name: Kynmobi

Total	16	18	20	33	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
CHIMOBY	0	0	1	0	1
CHINMOBY	0	0	1	0	1
GINMOBI	0	0	1	0	1
KENMOBI	0	0	5	0	5
KENMOVI	0	0	1	0	1
KIMOBY	0	0	1	0	1
KINMOBEE	0	0	1	0	1
KINMOBI	0	0	7	0	7
KINMOBIE	0	0	1	0	1
KINMOBY	0	0	1	0	1
KYNMOBI	14	18	0	30	62
KYNMOBI 25 MG	0	0	0	1	1
KYNMOVI	0	0	0	1	1
KYONMOBI	1	0	0	0	1
KYRUMOBI	1	0	0	0	1
KZNMOBI	0	0	0	1	1

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

No.	**Proposed name:** Kynmobi **Established name:** apomorphine hydrochloride **Dosage form:** sublingual film **Strength(s):** 10 mg, 15 mg, 20 mg, 25 mg, 30 mg **Usual Dose:** 10 mg (b) (4) up to 5 times 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.**
N/A			

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

No.	Name	POCA Score (%)
N/A		

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

No.	**Proposed name:** Kynmobi **Established name:** apomorphine hydrochloride **Dosage form:** sublingual film **Strength(s):** 10 mg, 15 mg, 20 mg, 25 mg, 30 mg **Usual Dose:** 10 mg (b) (4) up to 5 times 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**
N/A			

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

No.	Name	POCA Score (%)
1.	Kinlytic	46
2.	Kinevac	44

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
N/A			

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

No.	Name	POCA Score (%)
N/A		

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

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/s/

JOHN C MORRIS
02/18/2020 12:26:43 PM

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02/18/2020 01:56:40 PM

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02/19/2020 08:13:06 AM

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:	July 24, 2019
Application Type and Number:	NDA 210875
Product Name and Strength:	Kynmobi (apomorphine) sublingual film 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sunovion Pharmaceuticals Inc.
Panorama #:	2018-22076836-1
DMEPA Safety Evaluator:	Lissa C. Owens, PharmD
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Team Leader:	Idalia E. Rychlik, PharmD
DMEPA Associate Director:	Mishale Mistry, PharmD, MPH

1 INTRODUCTION

This memorandum is to amend the previous decision regarding the acceptability of the proposed proprietary name, Kynmobi, which was found conditionally acceptable under NDA 210875 on June 8, 2018.[a] We note that a conflict exists with another similar pending proposed proprietary name that is currently under review.

2 DISCUSSION

DMEPA had previously reviewed the proposed proprietary name, Kynmobi, under NDA 210875 and issued a ***CONDITIONALLY ACCEPTABLE*** letter for this name. Since that time, we have identified a conflict with another pending proposed proprietary name that is currently under review. The proposed name, Kynmobi, could result in medication errors due to confusion with (b) (4)***. Our evaluation of this name pair has altered our previous conclusion regarding the acceptability of the proposed proprietary name. The rationale for the risk of confusion is described below.

Kynmobi vs. (b) (4)***

The proposed proprietary name, Kynmobi, may be confused with another pending proposed proprietary name that is also under review, (b) (4) due to orthographic and phonetic similarity, as well as overlapping product characteristics.

Orthographically, both names have the same (b) (4)
(b) (4)

The orthographic and phonetic similarity of this name pair is further supported by FDA's Phonetic and Orthographic Computer Analysis (POCA), which calculates a combined score of 72% for this name pair, suggesting that there is highly similarity between these names.

In addition to the orthographic and phonetic similarities, Kynmobi and (b) (4)*** share (b) (4) characteristics, which can further increase the potential for wrong drug errors. (b) (4)
(b) (4)

[a] Morris, C. Proprietary Name Review for Kynmobi (NDA 210875). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 JUN 8. Panorama No. 2018-22076836.

We note that this decision differs from our previous decision regarding the acceptability of the proposed proprietary name, Kynmobi. However, when Kynmobi was previously evaluated, the proposed proprietary name, (b) (4)***, was not yet submitted for review by the Agency.

2.1 Communication of DMEPA's Analysis

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on July 23, 2019.

3 CONCLUSIONS

The proposed proprietary name is not acceptable from a safety perspective. The proposed name is vulnerable to name confusion with (b) (4)***.

If you have any questions or need clarifications, please contact Monique Killen, OSE project manager, at 240-402-1985.

3.1 COMMENTS TO THE APPLICANT

Your proposed name was found conditionally acceptable on June 8, 2018. Since that time, we have determined that your proposed proprietary name, Kynmobi, could result in medication errors due to confusion with another product that is currently under review. Therefore, the ultimate acceptability of your proposed proprietary name, Kynmobi, 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 of Kynmobi, you will be requested to submit another name.

[b] Schiff GD Mirica MM, Dhavle AA, Galanter WL, Lambert B, Wright A. A Prescription for Enhancing Electronic Prescribing Safety. Health Affairs 2018; 37(11): 1877-1883

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/s/

LISSA C OWENS
07/24/2019 12:19:12 PM

JOHN C MORRIS
07/24/2019 12:28:09 PM

MISHALE P MISTRY on behalf of IDALIA E RYCHLIK
07/24/2019 12:30:43 PM

MISHALE P MISTRY
07/24/2019 12:32:01 PM

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:	June 8, 2018
Application Type and Number:	NDA 210875
Product Name and Strength:	Kynmobi (apomorphine) sublingual film 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sunovion Pharmaceuticals Inc.
Panorama #:	2018-22076836
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Team Leader:	Lolita White, PharmD

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Kynmobi, on September 1, 2015. DMEPA found the name, Kynmobi, conditionally acceptable under IND 110955 on December 9, 2015.[a]

Thus, the Applicant submitted the name, Kynmobi, for review under NDA 210875 on April 2, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on April 2, 2018.

- Intended Pronunciation: kin moe' bee
- Active Ingredient: apomorphine
- Indication of Use: acute, intermittent treatment of "OFF" episodes associated with Parkinson's disease (PD) (b) (4)
- Route of Administration: sublingual
- Dosage Form: sublingual film
- Strength: 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg
- Dose and Frequency: 10 mg (b) (4) up to five times daily
- How Supplied: Each sublingual film is individually packaged in a sealed foil pouch. Trade product is sufficient for one month of dosing in which 30 individual pouches are packaged in a trade carton (30 unit dose foil pouches per carton)
- Storage: Controlled room temperature
- Reference Listed Drug: Apokyn, NDA 021264

2 RESULTS

[a] Harris, J. Proprietary Name Review for Kynmobi (IND 110955). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 DEC 09. Panorama No. 2015-1367954.

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 Neurology Products (DNP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Kynmobi 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, April 24, 2018 e-mail, DNP 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

Forty-four practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search identified 9 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 2 names not previously analyzed. These names are included in Table 1 below.

[b] USAN stem search conducted on May 16, 2018.

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 (b) (4) external study. We also included the name Kynamro in our evaluation based on the comments provided by DNP at the midpoint of our review (see Section 2.2.8). 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 ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	4
Low similarity name pair: combined match percentage score ≤54%	8

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

Our analysis of the 12 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 DNP via e-mail on May 22, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DNP on May 22, 2018, they submitted the following concern, "Kynamro is proprietary name of an oligonucleotide drug product that is also an injection. Hope no confusion with Kynmobi." We considered the risk for confusion between the name pair, Kynmobi vs Kynamro, in our evaluation. We previously analyzed the name pair on December 19, 2015 under IND 110955 (OSE RCM 2015-1367954) and determined this name pair is not at risk for confusion due to orthographic, phonetic, and product characteristics differences. Specifically, the letters in the suffix of this name pair (mobi vs amro) provide sufficient orthographic differences. Phonetically, the second (moe vs am) and third (bee vs roe) syllables of this name pair sound different. Additionally, the products do not directly overlap in strength (10 mg, 15 mg, 20 mg, 25 mg, and 30 mg vs 200 mg/mL), dosage form (sublingual film vs injection), route of administration (sublingual vs subcutaneous), or frequency of administration (up to 5 times daily vs once weekly). Furthermore, Kynamro has a REMS program restricting healthcare providers to be specially certified, trained and enrolled in KYNAMRO REMS program to prescribe and dispense the product. For the reasons outlined above, we find the risk of confusion between this name pair is sufficiently minimized, thus, we continue to agree with the findings from our previous analysis of this name pair and find the name pair acceptable (see Appendix E).

3 CONCLUSION

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Monique Killen, OSE project manager, at 240-402-1985.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on April 2, 2018, 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.

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. [c]

[c] 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 ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤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[d]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

   Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

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

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

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

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

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths 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.

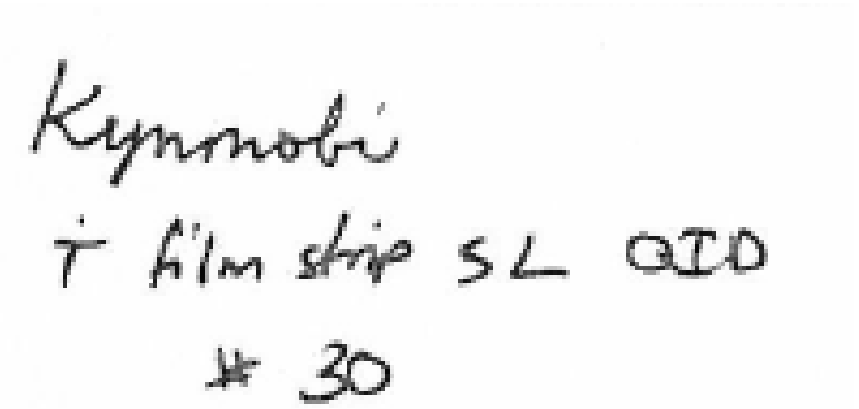
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤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. Kynmobi Study (Conducted on April 20, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Kynmobi 10 mg Use 1 film strip SL QID #30

Study Name: Kynmobi
As of Date 5/16/2018

298 People Received Study
44 People Responded

Study Name: Kynmobi

Total	11	15	18	44
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
KENMOBI	0	4	0	4
KENMOBIE	0	1	0	1
KENMOBY	0	2	0	2
KINMOBEE	0	1	0	1
KINMOBI	0	3	0	3
KINMOBY	0	3	0	3
KINMOYBE	0	1	0	1
KYMMOBI	1	0	1	2
KYMMOLI	0	0	1	1
KYNMBI	0	0	1	1
KYNMOBI	5	0	10	15
KYNMOHI	0	0	2	2
KYNMOLI	0	0	1	1
KYNMORI	0	0	1	1
KYNMOTI	0	0	1	1
KYNNOBI	2	0	0	2
KYNONOBI	2	0	0	2
KYNOWOBI	1	0	0	1

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

No.	Proposed name: Kynmobi Established name: apomorphine Dosage form: sublingual film Strength(s): 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg Usual Dose: 10 mg (b) (4) up to 5 times 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.
	n/a		

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

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

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

No.	Proposed name: Kynmobi Established name: apomorphine Dosage form: sublingual film Strength(s): 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg Usual Dose: 10 mg (b) (4) up to 5 times 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
2.	Kynamro	62	This name pair has sufficient orthographic and phonetic differences. Orthographically, the letters in the suffixes of this name pair (mobi vs amro) provide sufficient orthographic differences Phonetically, the second (moe vs am) and third (bee vs roe) syllables of this name pair sound different. The following differences in product characteristics also minimize the potential for error: The products do not directly overlap in strength (10 mg, 15 mg, 20 mg, 25 mg, and 30 mg vs. 200 mg/mL), dosage form (sublingual film vs. injection), route of administration (sublingual vs subcutaneous), or frequency of administration (up to 5 times daily vs. once weekly). Additionally, Kynamro has a REMS program restricting healthcare providers to be specially certified, trained and enrolled in KYNAMRO REMS program to prescribe and dispense the product.

No.	Proposed name: Kynmobi Established name: apomorphine Dosage form: sublingual film Strength(s): 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg Usual Dose: 10 mg (b) (4) up to 5 times 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
3.	(b) (4) ***	60	This name pair has sufficient orthographic and phonetic differences. Orthographically, the prefix letters 'Kyn' vs (b) (4) provide sufficient orthographic differences. Phonetically, the first syllables (kin vs (b) (4)) sound different. The following differences in product characteristics also minimize the potential for error: The products do not directly overlap in dosage form (sublingual film vs (b) (4)) or route of administration (sublingual vs (b) (4)). Additionally, the comparator name, (b) (4), was found unacceptable in OSE RCM# (b) (4).
4.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
5.	Combigan	52
6.	Combivir	52
7.	Focalin	22
8.	Kinret	41
9.	Mobidin	50
10.	Orkambi	54
11.	Sinemet	45
12.	Ting	19

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/s/

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06/08/2018

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06/12/2018