CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

211996Orig1s000
212161Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	February 4, 2019
Application Type and Number:	NDA 211996
Product Name and Strength:	Vyndaqel (tafamidis meglumine) Capsules, 20 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Foldrx Pharmaceuticals Inc., a wholly owned subsidiary of Pfizer Inc. (Foldrx)
Panorama #:	2018-27612673
DMEPA Safety Evaluator:	Maximilian Straka, PharmD, FISMP
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, FISMP, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Vyndaqel, 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. Foldrx did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Foldrx previously submitted the proposed proprietary name, Vyndaqel, on January 13, 2012 for tafamidis meglumine 20 mg capsules under NDA 202737 for a polyneuropathy indication. The Division of Medication Error Prevention and Analysis found the proposed name acceptable on April 10, 2012[a], however, the application received a complete response on June 15, 2012.

(b) (4)

Foldrx now resubmitted the proposed proprietary name, Vyndaqel on November 28, 2018 for tafamidis meglumine 20 mg capsules under NDA 211996 for a cardiomyopathy indication for our review.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 28, 2018.

- Intended Pronunciation: VIN-dah-kel
- Active Ingredient: tafamidis meglumine
- Indication of Use: Vyndaqel is indicated to reduce (b) (4) cardiovascular-related hospitalization in patients with wild type or hereditary transthyretin amyloid cardiomyopathy (ATTR-CM).
- Route of Administration: Oral
- Dosage Form: Capsules
- Strength[c]: 20 mg

[a] Ford, R. Proprietary Name Review for Vyndaqel (NDA 202737) Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2012 APR 10. Panorama No. 2012-149.

(b) (4)

(b) (4)

- Dose and Frequency: Four 20 mg capsules (80 mg) once daily
- How Supplied: Vyndaqel is supplied in the following package configurations:

(b) (4)

  - 10 x 12 blister cards (120 count) aluminum foil blister with aluminum foil lidding
- Storage: Store at controlled room temperature 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Vyndaqel would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Cardiovascular and Renal Products (DCRP) concurred with the findings of OPDP's assessment for Vyndaqel.

2.2 SAFETY ASSESSMENT

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

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

Foldrx did not provide a derivation or intended meaning for the proposed proprietary name, Vyndaqel, 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 21, 2018 e-mail, the Division of Cardiovascular and Renal Products (DCRP) did not forward any comments or concerns relating to Vyndaqel at the initial phase of the review.

[d] USAN stem search conducted on December 11, 2018.

2.2.4 FDA Name Simulation Studies

Ninety-three (93) practitioners participated in DMEPA's prescription studies for Vyndaqel. 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 66 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%**.** These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. 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%	63
Low similarity name pair: combined match percentage score ≤54%	2

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

Our analysis of the 66 names contained in Table 1 determined none of the names will pose a risk for confusion with Vyndaqel as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Cardiovascular and Renal Products (DCRP) via e-mail on January 31, 2019. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Cardiovascular and Renal Products (DCRP) on February 4, 2019, they stated no additional concerns with the proposed proprietary name, Vyndaqel.

[e] POCA search conducted on December 11, 2018 in version 4.3.

3 CONCLUSION

The proposed proprietary name, Vyndaqel, is acceptable.

If you have any questions or need clarifications, please contact Wana Manitpisitkul, OSE project manager, at 240-402-4156.

3.1 COMMENTS TO FOLDRX PHARMACEUTICALS INC., A WHOLLY OWNED SUBSIDIARY OF PFIZER INC.

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

If any of the proposed product characteristics as stated in your submission, received on November 28, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

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

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

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

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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

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

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

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

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

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

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

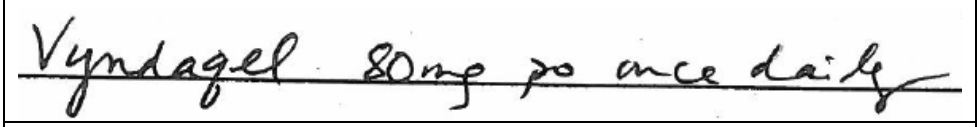
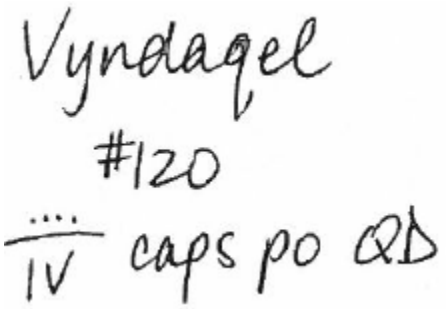
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Vyndaqel Study (Conducted on January 11, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Vyndaqel Take four capsules by mouth once daily
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Vyndaqel

As of Date 1/23/2019

304 People Received Study

93 People Responded

Study Name: Vyndaqel

Total	53	14	26	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
VINACAL	0	1	0	1
VINDACAL	0	5	0	5
VINDACEL	0	1	0	1
VINDACLOW	0	1	0	1
VINDAKAL	0	1	0	1
VINDAKEL	0	2	0	2
VINDEKEL	0	1	0	1
VINDICAL	0	1	0	1
VINDIKEL	0	1	0	1
VYDAGEL	2	0	0	2
VYNDAGEL	20	0	15	35
VYNDAQEL	31	0	11	42

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

No.	**Proposed name:** Vyndaqel **Established name:** tafamidis meglumine **Dosage form:** Capsules **Strength(s):** 20 mg **Usual Dose:** Four 20 mg capsules (80 mg) by mouth once daily.	POCA Score (%)	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Vyndaqel***	100	This name is the subject of this review. DMEPA previously found the proposed proprietary name, Vyndaqel, acceptable for tafamidis meglumine 20 mg capsules under NDA 202737 for a polyneuropathy indication on April 10, 2012, however, NDA 202737 received a complete response on June 15, 2012. Vyndaqel is also the marketed name for tafamidis meglumine capsules outside the US.

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 (%)
2.	Fentanyl-100	62
3.	Fentanyl-12	62
4.	Fentanyl-25	62
5.	Fentanyl-37	62
6.	Fentanyl-50	62
7.	Fentanyl-62	62
8.	Fentanyl-75	62
9.	Fentanyl-87	62

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:** Vyndaqel **Established name:** tafamidis meglumine **Dosage form:** Capsules **Strength(s):** 20 mg **Usual Dose:** Four 20 mg capsules (80 mg) by mouth once daily.	POCA Score (%)	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
10.	Avandamet	57	This name pair has sufficient orthographic and phonetic differences.
11.	Clindagel	60	This name pair has sufficient orthographic and phonetic differences. Orthographically, the prefix (‘Vyn’ vs. ‘Clin’) of this name pair provide some orthographic differences. Phonetically, the first syllable of this name pair (‘VIN’ vs. ‘Clin’) and the third syllable (‘kel’ vs. ‘gel’) sound different.
12.	Dyanavel	66	This name pair has sufficient orthographic and phonetic differences.
13.	Fentanyl	62	This name pair has sufficient orthographic and phonetic differences.
14.	Pentacel	63	This name pair has sufficient orthographic and phonetic differences.
15.	Vanatol	61	This name pair has sufficient orthographic and phonetic differences.
16.	Vandazole	66	This name pair has sufficient orthographic and phonetic differences.
17.	Vectical	58	This name pair has sufficient orthographic and phonetic differences.
18.	Venelex	56	This name pair has sufficient orthographic and phonetic differences.
19.	(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 (%)
20.	Evadyne	50
21.	Simbadol	52

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

No.	Name	POCA Score (%)	Failure preventions
22.	Avandaryl	64	Brand discontinued with no generic equivalents available.
23.	Bentasil	60	International product marketed in Canada
24.	Cyndal	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
25.	Cyndal Hd	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
26.	Endafed	56	Brand discontinued with no generic equivalents available.
27.	Endal	56	Brand discontinued with no generic equivalents available.
28.	Mantadil	58	Brand discontinued with no generic equivalents available.
29.	Mindal	56	Brand discontinued with no generic equivalents available.
30.	Phendacof	56	Brand discontinued with no generic equivalents available.
31.	Sympatol	56	International product formerly marketed in Germany, Italy, Switzerland, and Austria.
32.	Tindal	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
33.	Vanachol	58	Brand discontinued with no generic equivalents available.
34.	Vanceril	58	Brand discontinued with no generic available. NDA 017573, withdrawn FR effective 6/16/2006.
35.	Vanex-La	57	Brand discontinued with no generic equivalents available.
36.	Vendone	58	Brand discontinued with no generic equivalents available.
37.	Vental	62	Brand discontinued with no generic equivalents available.
38.	Vetadryl	56	Veterinary product
39.	Virbantel	56	Veterinary product

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 (%)
40.	10 Benzagel	60
41.	5 Benzagel	60
42.	Avanafil	56
43.	Aventyl	56
44.	Benadryl	55
45.	Bendeka	58
46.	Benzagel	60
47.	Benziq Ls	56
48.	Daptacel	58
49.	Dentagel	63
50.	Donnagel	57
51.	Dynafed	56
52.	Dynapen	56
53.	Dynex La	58
54.	(b) (4)***	58
55.	(b) (4) **	58
56.	Genteal	56
57.	Inderal	56
58.	Lenzagel	60
59.	Nembutal	56
60.	Pandel	58
61.	Pentasol	56
62.	Renagel	56
63.	Synarel	59
64.	Tanderil	57
65.	Xenical	58
66.	Zydaclin	56

[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/

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PROPRIETARY NAME REVIEW

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

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

Date of This Review:	March 19, 2019
Application Type and Number:	NDA 212161
Product Name and Strength:	Vyndamax (tafamidis) Capsules, 61 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Foldrx Pharmaceuticals Inc., a wholly owned subsidiary of Pfizer Inc. (Foldrx)
Panorama #:	2019-28945647
DMEPA Safety Evaluator:	Maximilian Straka, PharmD, FISMP
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, FISMP, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Vyndamax, 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. Foldrx did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Foldrx submitted the proposed proprietary name, [redacted] (b) (4)

Subsequently, Foldrx submitted the proposed proprietary name, Vyndaqel, on November 28, 2018 for tafamidis meglumine 20 mg capsules under NDA 211996. DMEPA found the proposed proprietary name, Vyndaqel, acceptable on February 4, 2019[b].

Foldrx submitted the proposed proprietary name, Vyndamax, on January 28, 2019 for tafamidis (free acid) 61 mg capsules under NDA 212161 for review.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 28, 2019.

- Intended Pronunciation: VIN-dah-max
- Active Ingredient: tafamidis
- Indication of Use: Vyndamax is indicated to reduce [redacted] (b) (4) cardiovascular-related hospitalization in patients with wild type or hereditary transthyretin amyloid cardiomyopathy (ATTR-CM).
- Route of Administration: Oral
- Dosage Form: Capsules
- Strength: 61 mg
- Dose and Frequency: 1 capsule by mouth once daily
- How Supplied: Vyndamax soft gelatin capsules are supplied in the following package configurations:
    - 10 x 3 blister cards (30 count) aluminum foil blister with aluminum foil lidding.

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[a] Lyons, D. Advice/Information Request for Vyndaqel. Silver Spring (MD): FDA, CDER, OSE, PMS (US); 2018 AUG 10. IND 071880

[b] Straka, M. Proprietary Name Review for Vyndaqel (NDA 211996). Silver Spring (MD): FDA, CDER OSE, DMEPA (US); 2019 FEB 4. OSE RCM No.: 2018-27612673.

(b) (4)

- Storage: Vyndamax capsules should be stored in the original package at controlled room temperature 20°C-25°C (68°F-77°F) with excursions permitted to 15°C -30°C (59°F-86°F).

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Vyndamax would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Cardiovascular and Renal Products (DCRP) concurred with the findings of OPDP's assessment for Vyndamax.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Foldrx did not provide a derivation or intended meaning for the proposed proprietary name, Vyndamax, 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. We note the proposed name, Vyndamax, shares the prefix letter string 'Vynda-' with the proprietary name, Vyndaqel, proposed by Foldrx, under NDA 211996, for the tafamidis meglumine 20 mg capsule formulation, which implies the products are related. We considered whether use of the shared letter string poses any medication error concerns. In the case of Vyndamax versus Vyndaqel, we note that the products contain the same active moiety, and the proposed names have adequately distinguishing suffixes. Furthermore, the products have overlapping indications for use, dosage forms, and routes and frequencies of administration. Although the product strengths and doses differ, we determined these differences can be managed with labels and labeling. Thus, we do not object to this naming strategy in this case.

[c] USAN stem search conducted on February 5, 2019.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, February 6, 2019 e-mail, the Division of Cardiovascular and Renal Products (DCRP) did not forward any comments or concerns relating to Vyndamax at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One hundred and two (102) practitioners participated in DMEPA's prescription studies for Vyndamax. 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[d] identified 86 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%**.** These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. 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%	8
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	77
Low similarity name pair: combined match percentage score ≤54%	1

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

Our analysis of the 86 names contained in Table 1 determined none of the names will pose a risk for confusion with Vyndamax as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Cardiovascular and Renal Products (DCRP) via e-mail on March 13, 2019. At that time we also requested additional information or

[d] POCA search conducted on January 31, 2019 in version 4.3.

concerns that could inform our review. Per e-mail correspondence from the Division of Cardiovascular and Renal Products (DCRP) on March 19, 2019, they stated no additional concerns with the proposed proprietary name, Vyndamax.

3 CONCLUSION

The proposed proprietary name, Vyndamax, is acceptable.

If you have any questions or need clarifications, please contact Wana Manitpisitkul, OSE project manager, at 240-402-4156.

3.1 COMMENTS TO FOLDRX PHARMACEUTICALS INC., A WHOLLY OWNED SUBSIDIARY OF PFIZER INC.

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

If any of the proposed product characteristics as stated in your submission, received on January 28, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

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.[e]

[e] 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[f]. 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

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

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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

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

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

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

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

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

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

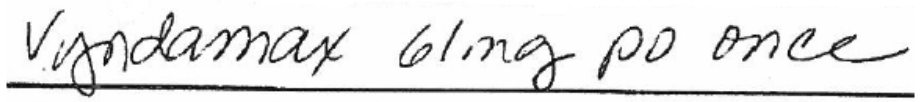
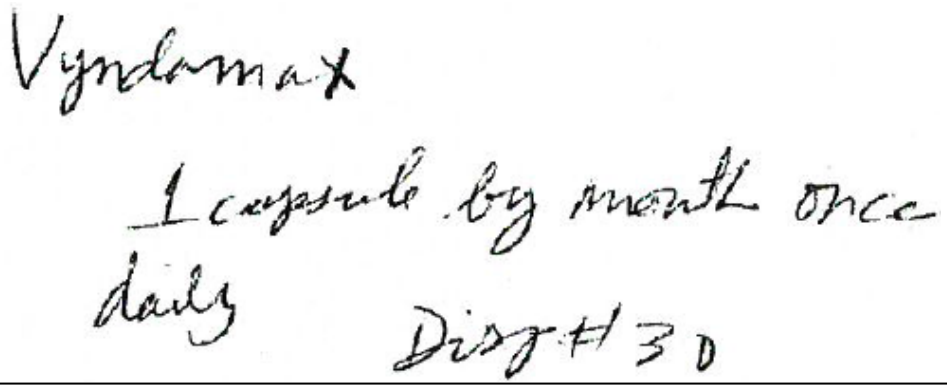
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Vyndamax Study (Conducted on February 12, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Vyndamax Take 1 capsule by mouth once daily. Dispense # 30
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Vyndamax

As of Date 2/26/2019

302 People Received Study

102 People Responded

Study Name: Vyndamax

Total	24	57	21	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
VANDAMAX	0	1	0	1
VENDAMAX	0	7	0	7
VENDOMAX	0	1	0	1
VENOMAX	0	1	0	1
VIGNDAMAX	0	0	1	1
VINDAMAX	0	40	0	40
VINDOMAX	0	1	0	1
VINEMAX	0	1	0	1
VYDAMAX	1	0	0	1
VYNDAMAX	11	3	20	34
VYNDAMOX	1	0	0	1
VYNDARMAX	1	0	0	1
VYNDOMAX	10	0	0	10
ZINDAMAX	0	2	0	2

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

No.	**Proposed name:** Vyndamax **Established name:** tafamidis **Dosage form:** Capsules **Strength(s):** 61 mg **Usual Dose:** 1 capsule by mouth once daily	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Clindamax	74	Orthographically, the prefix (Clin vs. Vyn) of this name provides sufficient orthographic differences. Clindamax also has an upstroke letter "l" in the second position while Vyndamax has a downstroke letter "y" in the second position. Phonetically, the first syllable of this name pair (Clin vs. VIN) sound different. Additionally, Vyndamax comes in a single strength (61 mg) and dosage form (capsules) while Clindamax is available in multiple strengths (1% and 2%) and dosage forms (cream, gel, lotion). Therefore, a strength and dosage form is needed on a Clindamax order for dispensing, which provides differentiating product characteristics thus minimizes the potential for wrong drug errors. The products also differ in routes of administration (vaginal and topical vs. oral) and frequency of administration (once or twice daily vs. once daily), which further minimizes the potential for wrong drug errors when indicated on a prescription.
2.	Indomax	73	International product formerly marketed in the UK.
3.	M-End Max	76	Brand discontinued with no generic equivalents available.
4.	M-End Max D	74	Brand discontinued with no generic equivalents available.

No.	**Proposed name:** Vyndamax **Established name:** tafamidis **Dosage form:** Capsules **Strength(s):** 61 mg **Usual Dose:** 1 capsule by mouth once daily	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
5.	Nydamax	80	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases. A Google search for Nydamax yields limited information and incomplete product characteristics. We are unable to find an actual drug product marketed under the name, Nydamax.
6.	Tindamax	82	Orthographically, the prefix of this name provides sufficient orthographic differences. Tindamax has an upstroke letter "T" in the first position while Vyndamax has a downstroke letter "y" in the second position. Phonetically, the first syllable of this name pair (Tin vs. VIN) sound different.
7.	Ventmax Sr	70	International product marketed in Italy and the UK.
8.	Vyndamax***	100	This name is the subject of this review.

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:** Vyndamax **Established name:** tafamidis **Dosage form:** Capsules **Strength(s):** 61 mg **Usual Dose:** 1 capsule by mouth once daily	POCA Score (%)	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
9.	Amimax	58	This name pair has sufficient orthographic and phonetic differences.
10.	Angiomax	58	This name pair has sufficient orthographic and phonetic differences.
11.	Avandamet	68	This name pair has sufficient orthographic and phonetic differences.
12.	Duomax	55	This name pair has sufficient orthographic and phonetic differences.
13.	Fosamax	58	This name pair has sufficient orthographic and phonetic differences.
14.	Inomax	60	This name pair has sufficient orthographic and phonetic differences.
15.	Namenda Xr	59	This name pair has sufficient orthographic and phonetic differences.
16.	Peptimax 200	56	This name pair has sufficient orthographic and phonetic differences.
17.	Peptimax 400	56	This name pair has sufficient orthographic and phonetic differences.
18.	Peptimax 800	56	This name pair has sufficient orthographic and phonetic differences.
19.	Pseudo max	56	This name pair has sufficient orthographic and phonetic differences.
20.	Sed-max	62	This name pair has sufficient orthographic and phonetic differences.
21.	Symax	57	This name pair has sufficient orthographic and phonetic differences.
22.	Topamax	56	This name pair has sufficient orthographic and phonetic differences.
23.	Vanatab Ac	59	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Vyndamax **Established name:** tafamidis **Dosage form:** Capsules **Strength(s):** 61 mg **Usual Dose:** 1 capsule by mouth once daily	POCA Score (%)	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
24.	Vanatab Dm	56	This name pair has sufficient orthographic and phonetic differences.
25.	Varivax	55	This name pair has sufficient orthographic and phonetic differences.
26.	Vigamox	65	This name pair has sufficient orthographic and phonetic differences.
27.	Volmax	58	This name pair has sufficient orthographic and phonetic differences.
28.	Vyndaqel***	62	This name pair has sufficient orthographic and phonetic differences. Orthographically, the suffixes of this name pair have sufficient orthographic differences. Vyndaqel has a downstroke letter “q” and an upstroke letter “l” which is not present in Vyndamax. Phonetically, the third syllable of this name pair (-kel vs. -max) sound different.
29.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
30.	Zenapax	62	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 (%)
31.	Vectibix	48

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
32.	Animax	60	Veterinary product.
33.	Clindamed	55	Veterinary product.
34.	Dectomax	62	Veterinary product.
35.	Deramaxx	57	Veterinary product.
36.	Diphenmax	59	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
37.	Drymax	60	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
38.	Enzymax	67	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
39.	Fentamox	69	International product formerly marketed in the UK.
40.	(b) (4)***	58	Proposed proprietary name for (b) (4)
41.	Ivermax	55	Veterinary product.
42.	Lincomix	56	Veterinary product.
43.	Lysimax	60	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
44.	Mometamax	60	Veterinary product.
45.	Monomax Sr	56	International product formerly marketed in the UK.
46.	Painmd max	66	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
47.	Pen-G max	57	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
48.	(b) (4)***	64	Proposed proprietary name for (b) (4)
49.	Renormax	57	Brand discontinued with no generic equivalents available. NDA 020420 withdrawn FR effective 9/17/2001.
50.	Rondameth	56	Brand discontinued with no generic equivalents available.

No.	Name	POCA Score (%)	Failure preventions
51.	Vetromax	63	Veterinary product.
52.	Viazem Xl	55	International product formerly marketed in Sweden and Denmark.
53.	Xanthomax	64	International product formerly marketed in the UK.

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

No.	Name	POCA Score (%)
54.	(b) (4)***	60
55.	Asmanex	58
56.	Clavamox	56
57.	Dandrex	56
58.	Declinax	55
59.	Demadex	62
60.	Derma-Pax	58
61.	Desquam-X	56
62.	Desquam-X 10	56
63.	Desquam-X 5	56
64.	Dexampex	58
65.	Diamox	57
66.	Dimetane-Dx	58
67.	Dynabac	58
68.	Dyna-Hex	58
69.	(b) (4)***	56
70.	(b) (4)***	58
71.	Genapax	60
72.	(b) (4)***	56
73.	(b) (4)***	56
74.	Mentax	56
75.	Pandex	56
76.	Pneumovax 23	58
77.	Ponderax	58
78.	Ryanodex	58
79.	Sedalmex	60
80.	(b) (4)***	58

[g] 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

No.	Name	POCA Score (%)
81.	Sonamox	62
82.	Symbyax	64
83.	Synjardy Xr	55
84.	Zostavax	56
85.	Zymine Dxr	56
86.	Zymine Xr	56

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/s/

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