CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

217684Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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:	November 15, 2023
Application Type and Number:	NDA 217684
Product Name and Strength:	Vigafyde (vigabatrin) oral solution, 100 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Pyros Pharmaceuticals, Incorporated (Pyros)
PNR ID #:	2023-1044725314
DMEPA 2 Safety Evaluator:	Beverly Weitzman, PharmD
DMEPA 2 Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2: Acting Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Pyros previously submitted the proposed proprietary name, (b) (4) under IND 157997 on November 14, 2022. However, we found the name, (b) (4) unacceptable on May 12, 2023[a] due to:

- similarity in spelling and orthographic and phonetic similarities with approved product (b) (4)
- similarity in spelling and orthographic and phonetic similarity with marketed product (b) (4)
- orthographic and phonetic similarities with marketed product (b) (4)
- orthographic similarity with approved product (b) (4)
- orthographic similarity with marketed product (b) (4)

Subsequently, Pyros submitted the proposed proprietary name, (b) (4) under IND 157997 on May 24, 2023. We found the name, (b) (4) unacceptable on August 18, 2023[b] because, as proposed, (b) (4)

Thus, Pyros submitted the name, Vigafyde, for review under NDA 217684 on August 25, 2023.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name review request and prescribing information received on August 25, 2023.

- Intended Pronunciation: VIG-uh-fide
- Active Ingredient: vigabatrin
- Indication of Use: Infantile Spasms - monotherapy in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.
- Route of Administration: oral
- Dosage Form: oral solution
- Strength: 100 mg/mL
- Dose and Frequency: The initial daily dosing is 50 mg/kg/day given in two divided doses (25 mg/kg twice daily); subsequent dosing can be titrated by 25 mg/kg/day to 50

[a] Weitzman, B. Proprietary Name Review for (b) (4) (IND 157997). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2023 MAY 12. PNR ID No. 2022-1044724842.

[b] Weitzman, B. Proprietary Name Review for (b) (4) (IND 157997). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2023 AUG 18. PNR ID No. 2023-1044725155.

mg/kg/day increments every 3 days, up to a maximum of 150 mg/kg/day given in two divided doses (75 mg/kg twice daily).

Table 2 provides the volume of the 100 mg/mL dosing solution that should be administered as individual doses in infants of various weights.

Table 2. Infant Dosing Table

Weight [kg]	Starting Dose 50 mg/kg/day	Maximum Dose 150 mg/kg/day
3	75 mg (0.75 mL) twice daily	225 mg (2.25 mL) twice daily
4	100 mg (1 mL) twice daily	300 mg (3 mL) twice daily
5	125 mg (1.25 mL) twice daily	375 mg (3.75 mL) twice daily
6	150 mg (1.5 mL) twice daily	450 mg (4.5 mL) twice daily
7	175 mg (1.75 mL) twice daily	525 mg (5.25 mL) twice daily
8	200 mg (2 mL) twice daily	600 mg (6 mL) twice daily
9	225 mg (2.25 mL) twice daily	675 mg (6.75 mL) twice daily
10	250 mg (2.5 mL) twice daily	750 mg (7.5 mL) twice daily
11	275 mg (2.75 mL) twice daily	825 (8.25 mL) twice daily
12	300 mg (3 mL) twice daily	900 (9 mL) twice daily
13	325 mg (3.25 mL) twice daily	975 mg (9.75 mL) twice daily
14	350 mg (3.5 mL) twice daily	1050 mg (10.5 mL) twice daily
15	375 mg (3.75 mL) twice daily	1125 mg (11.25 mL) twice daily
16	400 mg (4 mL) twice daily	1200 mg (12 mL) twice daily

In patients with infantile spasms, VIGAFYDE should be withdrawn if a substantial clinical benefit is not observed within 2 to 4 weeks. If, in the clinical judgment of the prescriber, evidence of treatment failure becomes obvious earlier than 2 to 4 weeks, treatment should be discontinued at that time *[see Warnings and Precautions (5.1)]*.

In a controlled clinical study in patients with infantile spasms, vigabatrin was tapered by decreasing the daily dose at a rate of 25 mg/kg to 50 mg/kg every 3 to 4 days *[see Warnings and Precautions (5.5)]*.

(b) (4)

(b) (4)

Information about how to adjust the dose in infants with renal impairment is unavailable.

(b) (4)

- How Supplied: Vigafyde 100 mg/mL oral solution is a clear, colorless to light yellow, peppermint-flavored oral solution in a 150 mL bottle. The oral syringe and (b) (4) are provided separately by the pharmacy.
- Storage: Store at room temperature (b) (4) or in a refrigerator (b) (4).
- Reference Listed Drug: Sabril (NDA 022006)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Vigafyde would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Vigafyde. The Division of Neurology 2 (DN 2) did not concur with OPDP's assessment. DN 2 expressed *"concerns regarding the use of Vigafyde [sic] for the proposed oral solution of vigabatrin. Fides is the Latin root, translating to trust, faith or confidence. The use of -fyde as a suffix suggests these attributes, which have promotional marketing attributes."*

Thus, we requested that OPDP reassess the name based on the comments from DN 2. Upon reassessment, OPDP maintained their non-objection to the name, stating the following:

> OPDP maintains our non-objection to "Vigafyde" from a promotional perspective. The proposed indication is for the treatment of infantile spasms in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss. The OPDP PNR team discussed that the proposed proprietary name could evoke "-fyde," which by extension could potentially evoke "confidence." Confidence is defined as "faith or belief that one will act in a right, proper, or effective way" (https://www.merriam-webster.com/dictionary/confidence; accessed 10/2/2023). FDA approval of this drug would mean that it was demonstrated to be safe and effective for the intended use. Hence, the team concluded that if "confidence" is evoked, it would not be false or misleading from a promotional perspective because the drug would have demonstrated effectiveness for its intended use and be expected to "act in [an]…effective way." Therefore, OPDP has determined that the proposed name is not false or misleading from a promotional perspective.

We shared OPDP's reassessment with DN 2, and they had no further comment.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

[c] USAN stem search conducted on September 6, 2023.

2.2.2 Components of the Proposed Proprietary Name

Pyros indicated in their submission that the proposed proprietary name, Vigafyde, is composed of the prefix (VIG-) "derived from the active ingredient vigabatrin" and (-fyde) "a unique suffix added to VIG that provided low POCA scores in FDA's POCA tool".

Additionally, the proposed proprietary name, Vigafyde, is comprised of a single word that contains the letter string "af" which is an abbreviation for 'augmented formula or atrial fibrillation/atrial flutter'. Although we typically discourage the inclusion of medical abbreviations in proprietary names, the location of the "af" letter string embedded in the middle of the name is unlikely to be separated from the surrounding letters. Therefore, we determined it is unlikely that the "af" letter string would lead to confusion.

Beyond the "af" abbreviation, the proposed name, Vigafyde does not contain any other 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

On September 28, 2023, the Division of Neurology 2 (DN 2) forwarded concerns relating to Vigafyde at the initial phase of the review (see section 2.1).

2.2.4 FDA Name Simulation Studies

Eighty-two practitioners participated in DMEPA's prescription studies for Vigafyde. 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. However, we note that 13 respondents in the voice study, misinterpreted the "y" in "fyde" as an "i". We did not identify any look-alike or sound-alike name concerns related to this misinterpretation.

Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 57 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

[d] POCA search conducted on September 6, 2023 in version 5.2.

Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	56
Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the 57 names contained in Table 1 determined none of the names will pose a risk for confusion with Vigafyde as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On November 15, 2023, DMEPA 2 communicated our determination to the Division of Neurology 2 (DN 2).

3 CONCLUSION

The proposed proprietary name, Vigafyde, is conditionally acceptable.

If you have any questions or need clarifications, please contact Margee Webster, OSE project manager, at 240-402-0012.

3.1 COMMENTS TO PYROS PHARMACEUTICALS, INCORPORATED

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

If any of the proposed product characteristics as stated in your submission, received on August 25, 2023, 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. https://www.nccmerp.org/about-medication-errors Last accessed 10/05/2020.

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

[f] 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.

   Four 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, verbal pronunciation of the drug name or during computerized provider order entry. 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 vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

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.

   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.

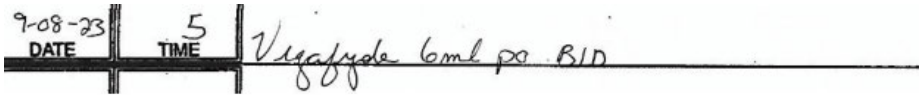
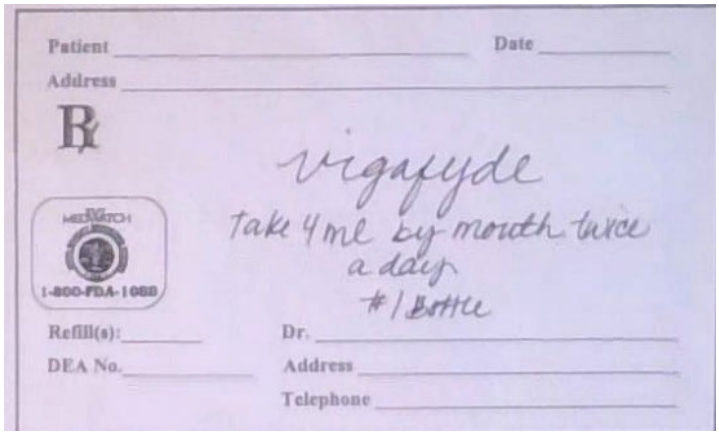
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Vigafyde Study (Conducted on September 8, 2023)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  Outpatient Prescription:  **CPOE Study Sample (displayed as sans-serif, 12-point, bold font)** **Vigafyde**	Vigafyde Take 4 mL by mouth twice a day Dispense 1 bottle

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Vigafyde People Received Study: 252 People Responded: 82					
Total	20	20	14	28	82
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
VEGAFYDE	1	0	0	0	1
VEQAFYDE	1	0	0	0	1
VIDAFIED	0	0	1	0	1
VIGAFIDE	0	0	7	0	7

VIGAFIED	0	0	3	0	3
VIGAFYDA	2	0	0	0	2
VIGAFYDE	6	20	0	28	54
VIGAFYED	0	0	1	0	1
VIGIFIED	0	0	2	0	2
VIQAFYDA	2	0	0	0	2
VIQAFYDE	6	0	0	0	6
VIZAFYDE	1	0	0	0	1
VYAFYDE	1	0	0	0	1

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

No.	**Proposed name:** Vigafyde **Established name:** vigabatrin **Dosage form:** oral solution **Strength(s):** 100 mg/mL **Usual Dose:** The initial daily dosing is 50 mg/kg/day given in two divided doses (25 mg/kg twice daily) titrated up to a maximum of 150 mg/kg/day given in 2 divided doses (75 mg/kg twice 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.	Vigafyde	100	Proposed proprietary name that 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:** Vigafyde **Established name:** vigabatrin **Dosage form:** oral solution **Strength(s):** 100 mg/mL **Usual Dose:** The initial daily dosing is 50 mg/kg/day given in two divided doses (25 mg/kg twice daily) titrated up to a maximum of 150 mg/kg/day given in 2 divided doses (75 mg/kg twice daily).	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Vigpoder	65	Orthographically, the infixes and suffixes of the name pair (afyde vs. poder) look sufficiently different. Specifically, Vigafyde contains the rounded letter ‘a’ in the fourth position followed by the cross-stroke and upstroke/ downstroke letter ‘f’ (depending how scripted) in the fifth position and downstroke letter ‘y’ in the six position, whereas Vigpoder contains the downstroke letter ‘p’ in the fourth position followed the rounded letter ‘o’ in the fifth

No.	**Proposed name:** Vigafyde **Established name:** vigabatrin **Dosage form:** oral solution **Strength(s):** 100 mg/mL **Usual Dose:** The initial daily dosing is 50 mg/kg/day given in two divided doses (25 mg/kg twice daily) titrated up to a maximum of 150 mg/kg/day given in 2 divided doses (75 mg/kg twice daily).	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			position and upstroke letter 'd' in the 6th position which give the names different shapes when scripted. Phonetically, the second syllables (uh vs. poe) and third syllables (fide vs. DARE) sound different when spoken.
2.	Vagifem	64	Orthographically, the suffixes of the name pair (fyde vs. fem) look sufficiently different. Specifically, Vigafyde contains the downstroke letter "y" in the sixth position followed by the upstroke letter "d" in the seventh position, whereas Vagifem does not contain any downstroke or upstroke letters in the sixth and seventh positions which gives the names different shapes when scripted. Additionally, Vigafyde contains the additional letter "e" at the end of the suffix which is not present in Vagifem which provides additional orthographic differentiation. Phonetically, the ending sound of the first syllables (VIG vs. Va), the onset of the second syllables (jeh vs. uh) and the ending sound of third syllables (fide vs. fem) sound different when spoken. Although both products are only available in a single strength that share numerical similarity (100 mg/mL vs. 10 mcg) and may not be specified on an order, the products differ in terms of dosage form (oral solution vs. vaginal insert), route of administration (oral vs. intravaginally), and frequency of administration (twice daily vs. twice weekly) which may provide

No.	**Proposed name:** Vigafyde **Established name:** vigabatrin **Dosage form:** oral solution **Strength(s):** 100 mg/mL **Usual Dose:** The initial daily dosing is 50 mg/kg/day given in two divided doses (25 mg/kg twice daily) titrated up to a maximum of 150 mg/kg/day given in 2 divided doses (75 mg/kg twice daily).	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			additional differentiation if included on an order or prescription.
3.	Vigadrone	62	Orthographically, the suffixes of the name pair (fyde vs. drone) look sufficiently different. Specifically, Vigafyde contains the cross-stroke and upstroke/ downstroke letter 'f' (depending how scripted) in the fifth position and the downstroke letter "y" in the sixth position followed by the upstroke letter "d" in the seventh position, whereas Vigadrone only contains the upstroke in the fifth position and does not contain any downstroke or upstroke letters in the sixth and seventh positions which gives the names different shapes when scripted. Phonetically, the third syllables (fide vs. drone) sound different when spoken.
4.	(b) (4)	60	(b) (4)

No.	**Proposed name:** Vigafyde **Established name:** vigabatrin **Dosage form:** oral solution **Strength(s):** 100 mg/mL **Usual Dose:** The initial daily dosing is 50 mg/kg/day given in two divided doses (25 mg/kg twice daily) titrated up to a maximum of 150 mg/kg/day given in 2 divided doses (75 mg/kg twice daily).	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** (b) (4)
5.	Visudyne	59	This name pair has sufficient orthographic and phonetic differences.
6.	Vepesid	58	This name pair has sufficient orthographic and phonetic differences.
7.	Vitastem	58	This name pair has sufficient orthographic and phonetic differences.
8.	Vanflyta	57	This name pair has sufficient orthographic and phonetic differences.
9.	Onivyde	56	The name pair has sufficient orthographic differences. Phonetically, the first syllables (VIG vs. ON) sound different when spoken. Although the strengths differ (100 mg/mL vs. 50 mg/10 mL (5 mg/mL)), we acknowledge that both products are only available in a single strength; therefore, this information may not be included on a prescription. However, the following product characteristics may help to minimize the risk of error if included on a prescription: • Dosage form: oral solution vs. injection • Route of administration: oral vs. intravenously

No.	**Proposed name:** Vigafyde **Established name:** vigabatrin **Dosage form:** oral solution **Strength(s):** 100 mg/mL **Usual Dose:** The initial daily dosing is 50 mg/kg/day given in two divided doses (25 mg/kg twice daily) titrated up to a maximum of 150 mg/kg/day given in 2 divided doses (75 mg/kg twice daily).	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			• Frequency of administration: twice daily vs. every 2 weeks in combination with 5-fluorouracil and leucovorin (5-FU/LV). Additionally, Onivyde is an injectable oncology drug. Because injectable oncology drugs administered by healthcare professionals typically undergo independent double checks by two pharmacists in the usual clinical setting, the likelihood of both pharmacist overlooking the difference in frequency, route of administration, and dosage form is minimized. Furthermore, current practice guidelines for chemotherapy drugs and supportive medications advise against verbal orders because they can circumvent the independent double check verification.
10.	(b) (4)	56	This name pair has sufficient orthographic and phonetic differences.
11.	Veraciti	55	This name pair has sufficient orthographic and phonetic differences.
12.	Vibativ	55	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 (%)
	N/A	

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

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4)	68	(b) (4)
2.	Vitadye	64	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
3.	Vitaped	64	Brand discontinued with no generic equivalents available. NDA 020176 withdrawn FR effective June 16, 2006.
4.	(b) (4)	60	Proposed proprietary name for IND 157997 was found unacceptable by DMEPA (OSE# 2022-1044724842 dated May 12, 2023). Subsequently, the Applicant proposed a new proprietary name, (b) (4) under IND 157997 which was found unacceptable by DMEPA (OSE# 2023-1044725155 dated August 18, 2023). Thus, the Applicant submitted the proposed name Vigafyde under NDA 217684 (subject of this review).
5.	(b) (4)	58	(b) (4)
6.	Videx Ec	58	Brand discontinued with no generic equivalents available. NDA 021183 withdrawn FR effective September 15, 2022.
7.	Vidopen	58	International product formerly marketed in Ireland and the United Kingdom.
8.	Virazid	58	International product formerly marketed in Spain
9.	Visage	58	Product is not a drug. "Visage" is part of the brand name "Plus Beau Visage" a company that markets hand sanitizing products and sunscreens.
10.	Viskazide	58	Brand discontinued with no generic equivalents available. NDA 018872 withdrawn FR effective September 29, 1995.
11.	Vitadil 2A	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
12.	Vitadil 5A	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
13.	Videne	56	International product marketed in the United Kingdom, Ireland, Switzerland, Thailand, and Hong Kong, and formerly marketed in the Czech Republic.
14.	Vidone	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	Vigam	56	International product marketed in Thailand, Malaysia, Mexico, and Turkey, and formerly marketed in Israel, Argentina, Brazil, Singapore, and the United Kingdom.
16.	Vigam-S	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
17.	Vital E- A + D3	56	Veterinary product
18.	(b) (4)	55	Proposed proprietary name for NDA 208743 found unacceptable by DMEPA (OSE # 2016-8278936 dated August 22, 2016). NDA 208743 approved under the proprietary name Tymlos.

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

	Name	POCA Score (%)
1.	Ridafed	64
2.	Migrafen	62
3.	Novafed A	62
4.	Digifab	60
5.	Dynafed	60
6.	(b) (4)	60
7.	Sudafed Pe	60
8.	Cenafed	58
9.	Genasyme	58
10.	Iveegam En	58
11.	Micaved	58
12.	Ridifed	58
13.	Silafed	58
14.	Sudafed	58
15.	Novafed	57
16.	(b) (4)	56
17.	Biofed-Pe	56
18.	Genaphed	56
19.	Levafen	56

[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

	Name	POCA Score (%)
20.	(b) (4)	56
21.	Evadyne	55
22.	Banadyne	55
23.	Migracet	55
24.	Nexafed	55
25.	Pegasys	55
26.	Sanfed A	55

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/s/

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