

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

220152Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	December 5, 2025
Application Type and Number:	NDA 220152
Product Name, Dosage Form, and Strength:	Nereus (tradipitant) capsules, 85 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Vanda Pharmaceuticals (Vanda)
PNR ID #:	2025-1044726823
DMEPA 1 Safety Evaluator:	Sherly Abraham, R.Ph.
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Nereus, 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. Vanda did not submit an external name study for this proposed proprietary name; however, Vanda did complete and submit their own internal analysis.

1.1 REGULATORY HISTORY

Vanda previously submitted the proposed proprietary name, (b) (4) *** under NDA 220152 on January 15, 2025. However, on April 14, 2025, we found the name, (b) (4) ** unacceptable due to spelling, orthographic similarities and overlapping product characteristics with the proprietary name, (b) (4) .^a

Vanda submitted the proposed proprietary name, (b) (4) *** under NDA 220152 on June 27, 2025. However, on September 24, 2025, we found the name, (b) (4) *** unacceptable due to phonetic similarities and overlapping product characteristics with the proprietary name, (b) (4) .^b

Thus, Vanda submitted the proposed proprietary name, Nereus, for review on November 7, 2025, under NDA 220152.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 7, 2025^c.

Table 1. Relevant Product Information for Nereus	
Intended pronunciation:	nɪr.i.əs ('NEER-ee-us')
Active ingredient:	tradipitant
Indication:	acute prevention of vomiting induced by motion in adults
Dosage Form:	capsules
Strength:	85 mg
Route of administration:	Oral
Dose and frequency:	The recommended dose is 85 mg or 170 mg. The maximum dose in a 24-hour period is 170 mg
How Supplied:	bottles of 36

^a Birkemeier D. Proprietary Name Review for (b) (4) *** (NDA 220152). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2025 APR 14. PNR ID No. 2025-1044726233.

^b Abraham S. Proprietary Name Review for (b) (4) *** (NDA 220152). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2025 SEP 24. PNR ID No. 2025-1044726568.

^c Re: Request for Proprietary Name Review for Nereus (NDA 220152 VLY 686/tradipitant). Washington (DC): Vanda Pharmaceuticals inc. Available from: <\\CDSESUB1\EVSPROD\nda220152\0026\m1\us\proprietary-name.pdf>

Table 1. Relevant Product Information for Nereus	
Storage:	Store at controlled room temperature, 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Nereus would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Nereus. The Division of Gastroenterology (DG) did not comment on the findings of OPDP's assessment for Nereus.

2.2 SAFETY ASSESSMENT

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

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

Vanda indicated in their submission that the proposed proprietary name, Nereus, *"originates from the sea-god in ancient Greek mythology. In classical sources, Nereus is described as the 'Old Man of the Sea,' the eldest son of Pontus (the Sea) and Gaia (the Earth). The name has been preserved in Greek literature from Homer onward and remains a recognized figure in classical mythology, symbolizing the ancient, wise, and dynamic force of the sea."*

This proprietary name is comprised of a single word that contains the letter string "-er-", which is a medical abbreviation for "extended release". We determined that the location of the letter string embedded in the middle of the name is unlikely to be separated from the surrounding letters in a manner that would lead to confusion in this case. Thus, we do not object to the inclusion of the letter string "-er-" in the prefix of the proposed proprietary name.

Beyond this abbreviation, we note Nereus does not contain any other components (i.e., a modifier, dosage form, etc.) that can contribute to medication error.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Gastroenterology (DG) did not forward any comments or concerns relating to Nereus at the initial phase of the review.

^d USAN stem search conducted on November 12, 2025.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Fifty-eight (n=58) practitioners participated in FDA's prescription simulation studies for Nereus. 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 prescription simulation studies.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search^e identified 50 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides 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 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	3
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	35
Low similarity name pair: combined match percentage score $\leq 54\%$	12

2.2.7 SAFETY ANALYSIS OF NAMES IDENTIFIED

Our analysis of the 50 names contained in Table 2 determined none of the names will pose a risk for confusion with Nereus as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On December 4, 2025, DMEPA 1 communicated our determination to the Division of Gastroenterology (DG).

3 CONCLUSION

The proposed proprietary name, Nereus, is conditionally acceptable.

3.1 COMMENTS TO VANDA PHARMACEUTICALS

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

^e POCA search conducted on November 12, 2025 in version 5.15.0

If any of the proposed product characteristics as stated in your submission, received on November 7, 2025, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. *United States Adopted Names (USAN) Stems*

USAN Stems List contains all the recognized USAN stems, available at <https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-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 <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms>).

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>).

Purple Book

The Purple Book is an online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service (PHS) Act. See Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at <https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or>.

Division of Medication Errors Prevention and Analysis pending proprietary name requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis.

5 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, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD 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 ONPD 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 3. 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

Table 3. 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)).

^f National Coordinating Council for Medication Error Reporting and Prevention. <https://www.nccmerp.org/about-medication-errors>. Last accessed 10/05/2020.

Table 3. 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	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, Purple Book, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 54\%$.

Using the criteria outlined in the check list (Tables 4-6) 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 that 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 4).
 - Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
 - o 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 names⁹. 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.
 - o 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 5).
 - Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.
- c. FDA Prescription Simulation Studies: DMEPA also conducts prescription simulation studies using FDA health care professionals.

⁹ 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

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), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) for their comments or concerns with the proposed proprietary name and 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 OPQ 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 Safety Evaluator 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 4. 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? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted 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 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).	
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e., drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components.

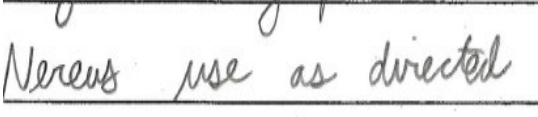
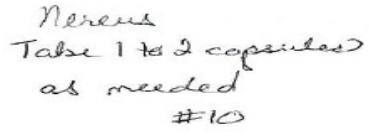
Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).		
	To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be 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 names 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 as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 6. Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

APPENDIX B. PRESCRIPTION SIMULATION SAMPLES AND RESULTS

Figure 1. Nereus Study (Conducted on 11/14/2025)

Handwritten Medication Order Prescription	Verbal Prescription
<u>Medication Order:</u> 	Nereus Take 1 to 2 capsules as needed #10
<u>Outpatient Prescription:</u> 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font) Nereus	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Nereus					
				People Received Study: 154	
				People Responded: 58	
Total	15	18	8	17	58
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
NAIRIS	0	0	1	0	1
NARIAS	0	0	1	0	1
NARYUS	0	0	1	0	1
NEARIAS	0	0	1	0	1
NEARIUS	0	0	1	0	1
NEREAS	0	0	1	0	1
NEREUS	14	18	0	17	49
NEREUY	1	0	0	0	1
NERYUS	0	0	1	0	1
NIREAD	0	0	1	0	1

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is $\geq 70\%$)

No.	Proposed name: Nereus Pronunciation: nɪr.i.əs ('NEER-ee-us') Established name: tradipitant Dosage form: capsules Strength(s): 85 mg Dosage: 85 mg or 170 mg	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.	Nereus	100	This name is the subject of this review.
2.	Nerol	72	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
3.	Nouress	72	Phonetically, the nuclei of the first syllables (Neer vs. Nur) offer some phonetic differences. In addition to the phonetic differences, the following product characteristics would help to mitigate the error: There is no overlap in product dosage form, route of administration, dose, or frequency of use. Nereus is proposed to be marketed as an oral capsule and administered as needed for nausea and vomiting. Nouress is an additive in amino acid/TPN solutions, which in clinical practice is considered a high alert medication requiring special safeguards in various points of the medication use process to reduce the risk of error. Furthermore, additives for TPN solutions are typically ordered by the established name (e.g., cysteine). When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.

APPENDIX E. MODERATELY SIMILAR NAMES (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Nereus Pronunciation: nr.i.əs ('NEER-ee-us') Established name: tradipitant Dosage form: capsules Strength(s): 85 mg Dosage: 85 mg or 170 mg	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.	Xerese	65	This name pair has sufficient orthographic and phonetic differences.
2.	Incruse	64	This name pair has sufficient orthographic and phonetic differences.
3.	Envarsus	58	This name pair has sufficient orthographic and phonetic differences.
4.	Neo-Rx	58	This name pair has sufficient orthographic and phonetic differences.
5.	Norisc	58	This name pair has sufficient orthographic and phonetic differences.
6.	Kineret	56	This name pair has sufficient orthographic and phonetic differences.
7.	Nurtec	56	This name pair has sufficient orthographic and phonetic differences.
8.	Neuraceq	56	This name pair has sufficient orthographic and phonetic differences.
9.	Zerit	56	This name pair has sufficient orthographic and phonetic differences.
10.	Nitrek	55	This name pair has sufficient orthographic and phonetic differences.
11.	Erex	55	This name pair has sufficient orthographic and phonetic differences.
12.	Neupro	55	This name pair has sufficient orthographic and phonetic differences.

APPENDIX F: LOW SIMILARITY NAMES (e.g., combined POCA score is $\leq 54\%$)

No.	Name	POCA Score (%)
1.	Enpresse-21	54
2.	Enpresse-28	54
3.	Narcof	53
4.	Renese	52
5.	Uniserts	52
6.	Neurotensin	48
7.	Nusinersen	46
8.	Regener-Eyes	45
9.	Re-U40	44
10.	Renuee	36

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.	Neral	68	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	Serenus	66	Veterinary product.
3.	Unipres	63	Brand discontinued with no generic equivalents available. ANDA 085893 withdrawn FR effective 08/04/1999.
4.	Entre-S	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
5.	Baros	60	Brand discontinued with no generic equivalents available. NDA 018509 withdrawn FR effective 07/21/2017.
6.	Nariz	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
7.	Neotuss	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
8.	Geref	58	Brand discontinued with no generic equivalents available. NDA 019863 and NDA 020443 withdrawn FR effective June 18, 2009.
9.	Notuss	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
10.	Urese	58	Brand discontinued with no generic equivalents available. NDA 012128 withdrawn FR effective 08/07/1997.
11.	Nerisone	56	International drug product currently marketed in South Africa, France, Hong Kong, and New Zealand and multiple other countries.
12.	Norcet	56	Brand discontinued with no generic equivalents available. ANDA 088871 withdrawn FR effective 09/25/1996.
13.	Nysert	56	Brand discontinued with no generic equivalent available. NDA 050478 withdrawn FR effective, August 1, 1993.
14.	(b) (4) ***	56	Proposed proprietary name for BB-IND (b) (4) found unacceptable by CBER on 9/26/2019. Subsequently, the BLA 125798 was approved under the name Encelto.
15.	(b) (4) ***	43	Proposed proprietary name for IND 125706 found unacceptable by CBER on July 25, 2019. Alternative name Ryoncil*** was found acceptable for this product. The application is inactive as of February 5, 2020.
16.	(b) (4) ***	42	Proposed proprietary name for IND (b) (4) found unacceptable by CBER on February 23, 2023. Subsequently, the proprietary name (b) (4) was found acceptable for IND (b) (4)

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 (%)
1.	Certuss	64
2.	Merzee	58
3.	Uceris	57
4.	Diurese	56
5.	Merrem	56
6.	Entuss	55

^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.

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

/s/

SHERLY ABRAHAM
12/05/2025 02:14:46 PM

DAMON A BIRKEMEIER
12/05/2025 02:26:34 PM

IDALIA E RYCHLIK
12/05/2025 02:35:46 PM