CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

220358Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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:	January 27, 2026
Application Type and Number:	NDA 220358
Product Name, Dosage Form, and Strength:	Bysanti (milsaperidone) tablets, 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Vanda Pharmaceuticals Inc. (Vanda)
PNR ID #:	2025-1044726960
DMEPA 1 Safety Evaluator:	Amy J. Bao, PharmD, MPH
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Bysanti, which was found unacceptable under IND 153819 and NDA 220358 on March 11, 2025.[a] The proposed proprietary name, Bysanti, was found to be vulnerable to medication errors due to confusion with another product, (b) (4) ***, under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Bysanti, was dependent upon which underlying application was approved first.

We note that the goal date for NDA 220358 is February 21, 2026, whereas the underlying application for (b) (4) was withdrawn as of (b) (4).

Thus, Vanda resubmitted the proposed proprietary name, Bysanti, for review on December 29, 2025 under NDA 220358.[b]

2 DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Bysanti, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, we searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The January 2, 2026 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Finally, we evaluated the status of the underlying application (b) (4) of the conflicting name, (b) (4) ***, and determined that due to the withdrawn status of the application as of (b) (4), Bysanti is no longer in conflict with another proposed proprietary name.

Based upon our safety assessment of the proposed proprietary name, Bysanti, the application goal date for NDA 220358, and the status of the underlying application for (b) (4) ***, we find Bysanti conditionally acceptable.

2.2 COMMUNICATION OF DMEPA'S DETERMINATION

On January 27, 2026, DMEPA 1 communicated our determination to the Division of Psychiatry (DP).

3 CONCLUSION

We conclude that the proposed proprietary name, Bysanti, is conditionally acceptable.

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[a] Bao, A. Proprietary Name Review for Bysanti (IND 153819 and NDA 220358). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2025 Mar 11. PNR ID No. 2024-1044725994 and 2025-1044726307.

[b] Request for Proprietary Name Review (Bysanti, NDA 220358). Washington (DC): Vanda Pharmaceuticals Inc.; 2025 Dec 29. Available from: \\CDSESUB1\evsprod\NDA220358\0026\m1\us\118-proprietary-names\vhx-896-request-for-propietary-name-review-clean.pdf.

3.1 COMMENTS TO VANDA PHARMACEUTICALS INC.

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

If any of the proposed product characteristics as stated in your submission, received on December 29, 2025, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCE

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.

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/

AMY J BAO
01/27/2026 11:47:03 AM

YEVGENIYA M KOGAN
01/27/2026 03:05:55 PM

MISHALE P MISTRY
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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)
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Date of This Review:	March 11, 2025
Application Type and Number:	IND 153819 and NDA 220358
Product Name, Dosage Form, and Strength:	Bysanti (milsaperidone) tablets, 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg
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Applicant/Sponsor Name:	Vanda Pharmaceuticals Inc. (Vanda)
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DMEPA 1 Safety Evaluator:	Amy J. Bao, PharmD, MPH
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
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, Bysanti, 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.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on September 20, 2024.[a]

Table 1. Relevant Product Information for Bysanti	
Intended pronunciation:	bye san tee
Active ingredient:	milsaperidone
Indication:	• Treatment of schizophrenia in adults. • Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.
Dosage Form:	tablets
Strength:	1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg
Route of administration:	Oral
Dose and frequency:	(b) (4)

[a] Request for Proprietary Name Review (Bysanti IND 153819). Washington (DC): Vanda Pharmaceuticals Inc.; 2024 Sep 20. Available from: \\CDSESUB1\evsprod\IND153819\0021\m1\us\118-prop-names\req-prop-name-rev.pdf.

Table 1. Relevant Product Information for Bysanti	
How Supplied:	60-count HDPE bottles [redacted (b) (4)]
Storage:	Stored [redacted (b) (4)] with excursions permitted between 15 – 30°C (59 – 86°F).

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Bysanti 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 Bysanti. The Division of Psychiatry (DP) concurred with the findings of OPDP's assessment for Bysanti.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Vanda indicated in their submission that the proposed proprietary name, Bysanti, is partially derived from the name of the ancient Greek city '*Byzantium*' or '*Byzantion*', as well as the Greek word for the name for an inhabitant of Byzantium (i.e., a '*Byzántios*'). This proprietary name is comprised of a single word that contains the letter string "SA", which is the medical abbreviation for "sustained action". Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the location of the abbreviation "SA" in the middle of the proposed proprietary name, Bysanti, makes it unlikely for the "SA" letter

[b] USAN stem search conducted on December 26, 2024.

string to be separated from the surrounding letters in a manner that could lead to confusion. Thus, we do not object to the inclusion of the "SA" letter string in this case.

Beyond this noted abbreviation, we note that Bysanti does not contain any additional components (i.e., 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

The Division of Psychiatry (DP) did not forward any comments or concerns relating to Bysanti at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty (80) practitioners participated in DMEPA's prescription simulation studies for Bysanti.

Two respondents in the Verbal study misinterpreted the proposed proprietary name as (b) (4) and (b) (4), which are similar to the pending proposed proprietary name, (b) (4)***. We further discuss the name pair (Bysanti *versus* (b) (4)***) in Subsection 2.2.7.

The remaining 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[c] identified 107 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥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 ≥70%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	100
Low similarity name pair: combined match percentage score ≤54%	4

[c] POCA search conducted on December 26, 2024 in version 5.9.

2.2.7 SAFETY ANALYSIS OF NAMES WITH POTENTIAL ORTHOGRAPHIC, SPELLING, AND PHONETIC SIMILARITIES

We determined 106 of the 107 names will not pose a risk for confusion with Bysanti as described in Appendices C through H. However, the proposed proprietary name could be confused with (b) (4)***. The rationale for the risk of confusion is described below and in Section 3.1.

Bysanti vs. (b) (4)***

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

(b) (4)

Orthographically, Bysanti and (b) (4) We acknowledge that the names begin with different letters (B *versus* (b) (4) however, given the orthographic similarity of the rest of the name, this difference may not be sufficient to mitigate the risk of confusion.

Phonetically, Bysanti (bye san tee) and (b) (4) Additionally, two participants in the verbal prescription FDA Prescription Simulation Study for Bysanti misinterpreted the proposed name as (b) (4) Furthermore, one participant in the verbal prescription FDA Prescription Simulation Study for Bysanti misinterpreted the proposed name as (b) (4) this difference may not be sufficient to mitigate the risk of confusion.

The similarity of this name pair is further supported by FDA's Phonetic and Orthographic Computer Analysis (POCA) program[d], which calculates a combined orthographic and phonetic score of 71%, suggesting that there is high similarity between these names.

[d] POCA search conducted on search date in version 5.9.

In addition to orthographic and phonetic similarities, Bysanti and (b) (4)*** share overlapping product characteristics, which further increases the potential for wrong drug errors. (b) (4)

We acknowledge that Bysanti and (b) (4)*** differ in frequency of administration (twice daily *versus* (b) (4)). We are concerned that this difference may not prevent confusion between this name pair given the orthographic and phonetic similarities of the names. We are aware of postmarketing reports of errors involving confusion between similarly named drug products, even when frequency of administration differs. For example, name confusion has been reported between Bidex (guaifenesin) and Videx (didanosine) despite their differences in frequency of administration (every 4 hours as needed *versus* once or twice daily).[e]

Furthermore, we recognize that the products have different indications (treatment of schizophrenia and acute treatment of manic or mixed episodes associated with bipolar I disorder in adults *versus* (b) (4) however, we are concerned that this difference in indication may not prevent confusion. Despite widespread recommendations only a small percentage of medications ordered include the indication.[f]

Therefore, based on the totality of the information above, we find the proposed proprietary name, Bysanti, vulnerable to medication errors due to name confusion with (b) (4)***.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On March 11, 2025, DMEPA 1 communicated our determination to the Division of Psychiatry (DP).

3 CONCLUSION

The proposed proprietary name, Bysanti, is not acceptable from a safety perspective. The proposed proprietary name, Bysanti, is vulnerable to name confusion with (b) (4)***. Therefore, the decision to deny the proprietary name will be communicated to Vanda via letter (See Section 3.1).

[e] Institute for Safe Medication Practices. 2010 Sep. Safety Briefs: A new drug name mix-up. ISMP Med Saf Alert Community/Ambulatory Care. 9(9):2.

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

3.1 COMMENTS TO VANDA PHARMACEUTICALS INC.

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

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

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.[g]

*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)).
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.

[g] 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	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 ≥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 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 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.
    - 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[h]. 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 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.

   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, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review.

[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

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? *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?		

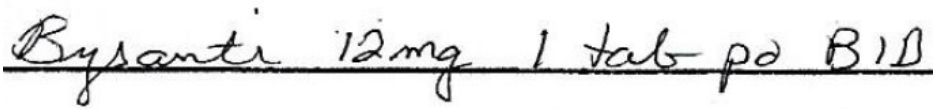
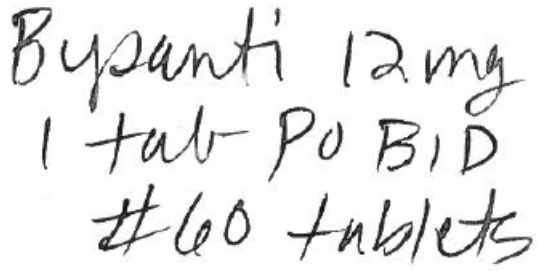
Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses 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	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: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	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?	

Table 6. 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. Bysanti Study (Conducted on 10/1/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Bysanti 12 mg 1 tablet by mouth twice daily Dispense 60 tablets
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Bysanti	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Bysanti People Received Study: 187 People Responded: 80					
Total	19	21	20	20	80
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
AYSANTI	0	0	1	0	1
BICANTI	0	0	1	0	1
BISANTI	0	0	3	0	3
BISANTY	0	0	3	0	3
BYRANTI	1	0	0	0	1
BYSANTEE	0	0	1	0	1
BYSANTI	18	21	8	20	67
BYSENTI	0	0	1	0	1
VISANTI	0	0	1	0	1
VYSANTEE	0	0	1	0	1

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is **≥70%)**

No.	Proposed name: Bysanti Pronunciation: bye san tee Established name: milsaperidone Dosage form: tablets Strength(s): 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg Dosage: 1 mg, 2 mg, 3 mg, 4 mg, 6 mg, 8 mg, 9 mg, 10 mg, or 12 mg by mouth 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.	Bysanti	100	This name is the subject of this review.
2.	Masanti	82	Orthographically, the prefix “By-“ in Bysanti has a rounded letter “B” in the first position and a downstroke letter “y” in the second position, while Masanti has a compound-curve letter “M” in the first position and an in-line letter “a” in the second position, which offers some differences in the shapes of the names. Phonetically, the first syllables (“Bye” *versus* “Mah”) sound different when spoken. Additionally, the products differ in strength (1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg *versus* 200mg-200mg-20mg/5 mL) and dosage form (tablets *versus* suspension), which when included on a prescription may help to further differentiate the products. Additionally, Masanti is a product-line of deactivated, generic over-the-counter products which are available in multiple formulations (Masanti, Masanti Double Strength, Masanti Supreme, and Masanti Antacid) with different ingredients and multiple dosage forms, thus, it would be expected for a consumer or prescriber to evaluate the various labels to select a product.

No.	Proposed name: Bysanti Pronunciation: bye san tee Established name: milsaperidone Dosage form: tablets Strength(s): 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg Dosage: 1 mg, 2 mg, 3 mg, 4 mg, 6 mg, 8 mg, 9 mg, 10 mg, or 12 mg by mouth 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.
			Thus, in this specific case, the risk of name confusion between this name pair is minimized.

APPENDIX D. MODERATELY SIMILAR NAMES (e.g., combined POCA score is **≥55%** to **≤69%)** with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Bosentan	66
2.	(b) (4) ***	64
3.	Betanate	59
4.	(b) (4) ***	56

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: Bysanti Pronunciation: bye san tee Established name: milsaperidone Dosage form: tablets Strength(s): 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg Dosage: 1 mg, 2 mg, 3 mg, 4 mg, 6 mg, 8 mg, 9 mg, 10 mg, or 12 mg by mouth 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.	Mylanta	68	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Bysanti Pronunciation: bye san tee Established name: milsaperidone Dosage form: tablets Strength(s): 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg Dosage: 1 mg, 2 mg, 3 mg, 4 mg, 6 mg, 8 mg, 9 mg, 10 mg, or 12 mg by mouth 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
2.	Tysabri	66	Orthographically, the names begin with different letters (B *versus* T). Additionally, Bysanti contains the cross-stroke letter "t" in the sixth position, while Tysabri contains the upstroke letter "b" in the fifth position, which offers some differences. Phonetically, the onset of the first syllables ("bye" *versus* "ty"), the second syllables ("san" *versus* "sah") and onset of the third syllables ("tee" *versus* "bree") sound different when spoken. Additionally, the products differ in dosage form (tablets *versus* injection), route of administration (oral *versus* intravenous), and frequency of administration (twice daily *versus* every 4 weeks). These product characteristics may provide further differentiation if included on a medication order. Thus, in this specific case, the risk of name confusion between this name pair is minimized.
3.	(b) (4) ***	64	This name pair has sufficient orthographic and phonetic differences.
4.	Nucynta	64	This name pair has sufficient orthographic and phonetic differences.
5.	Nystatin	64	This name pair has sufficient orthographic and phonetic differences.
6.	Vyvanse	64	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Bysanti Pronunciation: bye san tee Established name: milsaperidone Dosage form: tablets Strength(s): 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg Dosage: 1 mg, 2 mg, 3 mg, 4 mg, 6 mg, 8 mg, 9 mg, 10 mg, or 12 mg by mouth 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
7.	Dilantin	62	This name pair has sufficient orthographic and phonetic differences.
8.	Dilantin-125	62	This name pair has sufficient orthographic and phonetic differences.
9.	Santyl	62	This name pair has sufficient orthographic and phonetic differences.
10.	Sylvant	62	This name pair has sufficient orthographic and phonetic differences.
11.	Bio-Statin	60	This name pair has sufficient orthographic and phonetic differences.
12.	Butrans	60	This name pair has sufficient orthographic and phonetic differences.
13.	Cinvanti	60	This name pair has sufficient orthographic and phonetic differences.
14.	Bonsity	59	This name pair has sufficient orthographic and phonetic differences.
15.	Bavencio	58	This name pair has sufficient orthographic and phonetic differences.
16.	Besivance	58	This name pair has sufficient orthographic and phonetic differences.
17.	Besponsa	58	This name pair has sufficient orthographic and phonetic differences.
18.	Breyanzi	58	This name pair has sufficient orthographic and phonetic differences.
19.	Brilinta	58	This name pair has sufficient orthographic and phonetic differences.
20.	Movantik	58	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Bysanti Pronunciation: bye san tee Established name: milsaperidone Dosage form: tablets Strength(s): 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg Dosage: 1 mg, 2 mg, 3 mg, 4 mg, 6 mg, 8 mg, 9 mg, 10 mg, or 12 mg by mouth 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
21.	Qvantig	58	This name pair has sufficient orthographic and phonetic differences.
22.	Vantin	58	This name pair has sufficient orthographic and phonetic differences.
23.	Ms Contin	57	This name pair has sufficient orthographic and phonetic differences.
24.	Pyrantel	57	This name pair has sufficient orthographic and phonetic differences.
25.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
26.	Betalin S	56	This name pair has sufficient orthographic and phonetic differences.
27.	Dixlanta	56	This name pair has sufficient orthographic and phonetic differences.
28.	Gabapentin	56	This name pair has sufficient orthographic and phonetic differences.
29.	Jubbonti	56	This name pair has sufficient orthographic and phonetic differences.
30.	Pizensy	56	This name pair has sufficient orthographic and phonetic differences.
31.	Tascenso	56	This name pair has sufficient orthographic and phonetic differences.
32.	Baqsimi	55	This name pair has sufficient orthographic and phonetic differences.
33.	Survanta	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 (%)
1.	(b) (4) ***	54
2.	(b) (4) ***	53
3.	Banthine	52
4.	Syntaris	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
1.	Balanta	68	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	Dytan-At	68	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
3.	Myoscint	66	Brand discontinued with no generic equivalents available. BLA 103634.
4.	Bi-Tann Dp	64	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
5.	Hsp anti	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	Mesantoin	64	Brand discontinued with no generic equivalents available. NDA 006008 withdrawn FR effective 08/20/2010.
7.	Dytan-D	63	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
8.	Dilantin-30	62	Brand discontinued with no generic equivalents available.
9.	Betastat	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	Bis-Mate	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
11.	Fybranta	60	International product formerly marketed in the United Kingdom
12.	Nystan	60	International product marketed in the United Kingdom
13.	T-Tussin Pe	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
14.	(b) (4) ***	59	Proposed proprietary name under (b) (4) found to be unacceptable by DMEPA due to conflict with another pending name under review at the time, Nivestym, which is now

No.	Name	POCA Score (%)	Failure preventions
			approved (OSE# 2017-13203158 dated July 27, 2017). Subsequently, the proposed proprietary names (b) (4) *** (b) (4) and (b) (4) *** (b) (4) were also found to be unacceptable. A new name has not been submitted for review.
15.	Tussin Pe	59	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
16.	Barstatin 100	58	Brand discontinued with no generic equivalents available. ANDA 062489 withdrawn FR effective 12/18/1992.
17.	Betavent	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
18.	(b) (4) ***	58	Proposed proprietary name for NDA 209570 found unacceptable by DMEPA due to misbranding (OSE# 2017-16447196 dated August 10, 2017). NDA 209570 was approved without a proprietary name.
19.	Bruceantin	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
20.	Synanthic	58	Veterinary product.
21.	Tussanil	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
22.	Bentasil	56	International product formerly marketed in Canada.
23.	Beuthanasia	56	Veterinary product.
24.	(b) (4) ***	56	Proposed proprietary name for IND (b) (4) found to be unacceptable by DMEPA due to misbranding (b) (4) . IND (b) (4) is pending and no new names have been submitted.
25.	(b) (4) ***	56	Proposed proprietary name for IND 110489 found unacceptable by DMEPA (OSE# 2022-1044724459 dated June 23, 2022). BLA 761312 was approved under the proprietary name Lymphir.
26.	Diphentann	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
27.	(b) (4) ***	56	Proposed proprietary name for NDA (b) (4) found unacceptable by DMEPA due to a conflict with a marketed product (b) (4) NDA (b) (4) was withdrawn by the Applicant on (b) (4) .
28.	Ib-Stat	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
29.	Santonin	56	Veterinary product.
30.	Striant	56	Brand discontinued with no generic equivalents available. NDA 021543 withdrawn FR effective 06/15/2020.
31.	(b) (4) ***	56	Proposed proprietary name for NDA (b) (4) found to be conditionally acceptable (b) (4) Entire application was withdrawn by the Applicant on (b) (4).
32.	Tusana D	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
33.	(b) (4) ***	56	Proposed proprietary name withdrawn by the Applicant. BLA 761336 approved under the proprietary name, Anktiva.
34.	(b) (4) ***	56	Proposed proprietary name for IND 120784 found unacceptable, due to a conflict with a marketed product, by DMEPA (OSE# 2019-34271035 dated February 28, 2020). NDA 214487 approved under the proprietary name Tavneos.
35.	(b) (4) ***	55	Proposed proprietary name for NDA 208751 found to be unacceptable by DMEPA (OSE# 2016-8522346-1 dated December 15, 2016). NDA 208751 (now BLA 208751) approved under the proprietary name Fiasp.
36.	(b) (4) ***	55	Proposed proprietary name for IND (b) (4) found to be acceptable (b) (4), however, IND (b) (4) withdrawn as of (b) (4)

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

No.	Name	POCA Score (%)
1.	Ny-Tannic	64
2.	Dytan-Cs	63
3.	Dytan-Cd	60
4.	Sufenta	60
5.	Xtandi	60
6.	Zyban Sr	60
7.	Dibent	59
8.	Mayzent	59

[i] 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 (%)
9.	Dysman	58
10.	Dytan-Hc	58
11.	(b) (4) ***	58
12.	Nasatab	58
13.	Nystamont	58
14.	(b) (4) ***	58
15.	Dasatinib	57
16.	Dyspamet	57
17.	Definity	56
18.	Desitin	56
19.	D-Tann At	56
20.	Dytan	56
21.	Mytesi	56
22.	Nasabid	56
23.	Obestin-30	56
24.	Yesintek	56
25.	Dymista	55
26.	(b) (4) ***	55
27.	Vasaten	55

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/s/

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