CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761363Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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:	9/11/2023
Responsible OND Division:	Division of Cardiology and Nephrology (DCN)
Application Type and Number:	IND 136150 BLA 761363
Product Name and Strength:	Winrevair (sotatercept-csrk) for injection, 45 mg per vial
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc. (Merck)
FDA Received Date:	October 21, 2022 (IND) September 5, 2023 (BLA)
Nexus NPNS ID #:	2022-143 2023-189
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Merck for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761363.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On October 21, 2022 (IND)[a] and September 5, 2023 (BLA)[b], Merck submitted a list of 5 suffixes, in their order of preference, to be used in the nonproprietary name of their product. Table 1 presents a list of suffixes submitted by Merck:

Table 1. Suffixes submitted by Merck***

1.	csrk
2.	(b) (4)
3.	
4.	
5.	

We reviewed Merck's proposed suffixes in the order of preference listed by Merck, along with the supporting data they submitted, using the principles described in the applicable guidance.[c]

2.1 sotatercept-csrk

Merck's first proposed suffix, -csrk, is comprised of 4 distinct letters. We note that the letters 'sr' within the suffix represent the medical abbreviations for 'sustained release'. We considered whether the

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[a] Request for FDA Nonproprietary Name Suffix Review IND 136150. Rahway (NJ): Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.; 2022 Oct 21. Available from: \\CDSESUB1\EVSPROD\ind136150\0173\m1\us\multi-module-info-amendment-21oct2022.pdf

[b] Request for FDA Nonproprietary Name Suffix Review BLA 761363. Rahway (NJ): Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.; 2023 Sep 05. Available from: \\CDSESUB1\EVSPROD\bla761363\0016\m1\us\multi-module-info-amendment-20230905.pdf

[c] Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

inclusion of the letters 'sr' within the suffix could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or based upon known causes of medication errors.

We determined that the proposed suffix -csrk, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMEPA 2 ANALYSIS

These findings were shared with OPDP. On September 7, 2023, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Cardiology and Nephrology (DCN) on September 11, 2023.

4 CONCLUSION

We find Merck's proposed suffix -csrk acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to sotatercept-csrk. DMEPA 2 will communicate our findings to the Applicant via letter.

4.1 Recommendations for Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.

We find the nonproprietary name, sotatercept-csrk, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, sotatercept-csrk will be the proper name designated in the license. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your suffix unacceptable upon our re-evaluation, we will inform you of our findings.

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/

CHI-MING TU
09/12/2023 10:49:46 AM

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)

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Date of This Review:	July 3, 2023
Application Type and Number:	IND 136150 and BLA 761363
Product Name and Strength:	Winrevair (sotatercept-xxxx)[a] for injection, 45 mg per vial and 60 mg per vial
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Merck Sharp & Dohme LLC (Merck)
PNR ID #:	2023-1044724974 and 2023-1044725103
DMEPA 2 Safety Evaluator:	Jody Kundreskas, PharmD
DMEPA 2 Team Leader:	Hina Mehta, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

[a] The non-proprietary name suffix for this product has not yet been determined; therefore, the placeholder sotatercept-xxxx is used throughout this review to refer to the non-proprietary name and suffix for this product.

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Acceleron Pharma Inc. previously submitted the proposed proprietary name, (b) (4)*** on October 8, 2020. This name was found conditionally acceptable under IND 136150 on January 4, 2021. However, on November 2, 2021, Acceleron withdrew the name (b) (4)*** and submitted an alternate name, (b) (4)***, which was found conditionally acceptable on January 5, 2022. On May 3, 2022, IND 136150 was transferred from Acceleron to Merck, following the acquisition of Acceleron by Merck. On June 28, 2022, Merck requested withdrawal of the name (b) (4)*** and submitted (b) (4)*** for review. On January 13, 2023, we found the name, (b) (4)***, unacceptable due to creating a misleading perception (b) (4) (b) (4).

Thus, Merck submitted the name, Winrevair, for review on February 3, 2023 under IND 136150. On April 18, 2023, Merck submitted the name, Winrevair, for review under BLA 761363[b].

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on February 3, 2023 and April 18, 2023.

- Intended Pronunciation: WIN-reh-vair
- Active Ingredient: sotatercept-xxxx
- Indication of Use: for the treatment of adults with Pulmonary Arterial Hypertension (PAH) WHO Group 1 to increase exercise capacity, provide clinical improvement, improve WHO FC, and (b) (4) (b) (4)
- Route of Administration: subcutaneous
- Dosage Form: for injection
- Strength: 45 mg per vial and 60 mg per vial
- Dose and Frequency: The proposed dosage for WINREVAIR is 0.3 mg/kg administered as a single starting dose, followed by 0.7 mg/kg for the second and subsequent doses, unless dose modifications are required. Each WINREVAIR dose should be administered every 3 weeks.

  Maximum daily dose of WINREVAIR is 0.7 mg/kg.

[b] We note that the active ingredient, strength, dose, and route of administration are the same for both applications.

- How Supplied: WINREVAIR is provided as a drug device combination kit which contains the lyophilized powder of the drug in a vial, sterile water for injection in a pre-filled syringe (for reconstitution), and ancillary items to aid in reconstitution and administration. Package includes supporting instructions for use.
- Storage: Store vials refrigerated at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not freeze.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Winrevair 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 Winrevair. The Division of Cardiology and Nephrology (DCN) did not comment on the findings of OPDP's assessment for Winrevair.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Merck did not provide a derivation or intended meaning for the proposed proprietary name, Winrevair, in their submission. This proprietary name is comprised of a single word that contains the letter strings "IN", "IR" and "VA" which are medical abbreviations for the route of administration "intranasal", the modifier "immediate release" and "visual acuity", respectively. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we note the letter strings "IN", "IR" and "VA" are common letter strings in existing drug nomenclature (e.g., Brilinta, Fragmin, Inflectra, Advair, Humira, Levemir, Livalo, Movantik, etc.) and we are unaware of post-market reports of medication errors associated with these specific abbreviations through our routine surveillance. We determined that the location of the letter strings "IN" and "VA" within the proposed name are unlikely to be separated from the surrounding letters or to be misunderstood within the context of a prescription that could lead to confusion. As the letter string "IR" is located at the end of the name, we evaluated the potential risk of misinterpreting the proposed proprietary name as "[drug name similar to Winreva] IR"

[c] USAN stem search conducted on February 10, 2023.

and did not identify any concerns.[d] Therefore, in this case we do not object to the proposed proprietary name based on the inclusion of these medical abbreviations. Winrevair does not contain any other components (i.e., a modifier, route of administration, dosage form, etc.) that can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

The Division of Cardiology and Nephrology (DCN) did not forward any comments or concerns relating to Winrevair at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-eight practitioners participated in DMEPA's prescription studies for Winrevair.

One participant in the Computerized Physician Order Entry (CPOE) study selected the proprietary name Erivedge instead of Winrevair. Erivedge is a direct hit to a currently marketed product. However, we note that the participant entered an incorrect sequence of letters, 'eri' instead of 'win,' when searching for the study name. As a result, CPOE generated a pick list that did not contain Winrevair as a choice. After pausing for 139 seconds, the participant proceeded to incorrectly select Erivedge from the pick list. Thus, in this case, it appears this participant selected a random name on the populated list in order to proceed with the simulation study. This study response is unlikely to be representative of a plausible CPOE based risk and we evaluated this name pair in Appendix F.

The remainder of 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 73 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 and FDA Prescription Simulation Study. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

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

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1

[d] POCA search conducted on February 22, 2023 in version 5.2.

[e] POCA search conducted on February 10, 2023 in version 5.2.

Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	64
Low similarity name pair: combined match percentage score ≤54%	9

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

Our analysis of the 74 names contained in Table 1 determined none of the names will pose a risk for confusion with Winrevair as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On July 3, 2023, DMEPA 2 communicated our determination to the Division of Cardiology and Nephrology (DCN).

3 CONCLUSION

The proposed proprietary name, Winrevair, is conditionally acceptable.

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

3.1 COMMENTS TO MERCK SHARP & DOHME LLC

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

If any of the proposed product characteristics as stated in your submission, received on April 18, 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. [f]

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

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

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

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

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

   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.

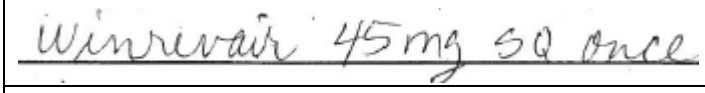
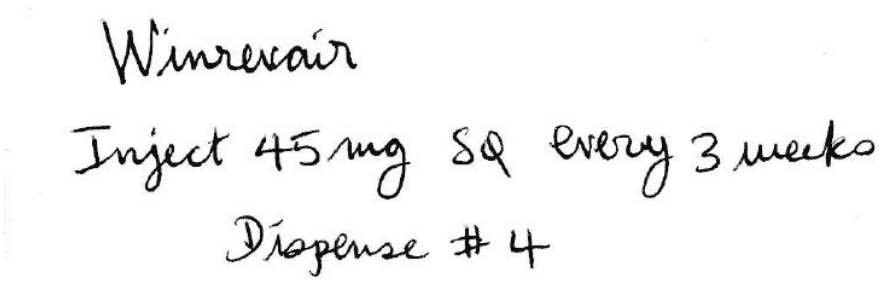
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Winrevair Study (Conducted on February 14, 2023)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Winrevair Inject 45 mg subcutaneously every 3 weeks Dispense 4
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Winrevair	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Winrevair

257 People Received Study

98 People Responded

Total	26	25	22	25	98

INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
ERIVEDGE	0	1	0	0	1
GWENAVERE	0	0	1	0	1
GWYNRAVEER	0	0	1	0	1
VYNRAVER	0	0	1	0	1
WENREBEAR	0	0	1	0	1
WENREVIR	0	0	1	0	1
WENRIVAIR	0	0	1	0	1
WINLABER	0	0	1	0	1
WINRAVER	0	0	2	0	2
WINRAVERE	0	0	1	0	1
WINREKAIR	0	0	0	1	1
WINREREVAIR	1	0	0	0	1
WINREVAIR	22	24	1	23	70
WINREVAR	1	0	1	0	2
WINREVER	0	0	1	0	1
WINREVIR	0	0	3	0	3
WINREXAIR	0	0	0	1	1
WINRIVAIR	2	0	1	0	3
WINRIVAR	0	0	1	0	1
WINRIVARE	0	0	1	0	1
WYNREVER	0	0	1	0	1
WYNRIVER	0	0	1	0	1
WYRIVAIR	0	0	1	0	1

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

No.	**Proposed name:** Winrevair **Established name:** sotatercept-xxxx **Dosage form:** for injection **Strength(s):** 45 mg per vial and 60 mg per vial **Usual Dose:** 0.3 mg/kg as a single starting dose followed by 0.7 mg/kg for the second and subsequent doses. Each dose should be administered every 3 weeks. Maximum dose is 0.7 mg/kg.	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.	Winrevair***	100	This proposed proprietary name is the subject of this review.

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

No.	Name	POCA Score (%)
1.	Winlevi	66
2.	Acnevir	61
3.	Mydriafair	56
4.	Wart Remover	56
5.	Nafazair	55

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:** Winrevair **Established name:** sotatercept-xxxx **Dosage form:** for injection **Strength(s):** 45 mg per vial and 60 mg per vial **Usual Dose:** 0.3 mg/kg as a single starting dose followed by 0.7 mg/kg for the second and subsequent doses. Each dose should be administered every 3 weeks. Maximum dose is 0.7 mg/kg.	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.	Adreview	63	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Winrevair **Established name:** sotatercept-xxxx **Dosage form:** for injection **Strength(s):** 45 mg per vial and 60 mg per vial **Usual Dose:** 0.3 mg/kg as a single starting dose followed by 0.7 mg/kg for the second and subsequent doses. Each dose should be administered every 3 weeks. Maximum dose is 0.7 mg/kg.	**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.	(b) (4)***	63	This name pair has sufficient orthographic and phonetic differences.
3.	Norvir	60	This name pair has sufficient orthographic and phonetic differences.
4.	Inrebic	58	This name pair has sufficient orthographic differences. Phonetically, the last syllables (‘vair’ vs. ‘bik’) sound sufficiently different. These products differ in strength (45 mg per vial and 60 mg per vial vs. 100 mg), route (subcutaneous vs. oral), frequency (once every 3 weeks vs. once daily), and dosage form (for injection vs. capsule).
5.	Invirase	58	Orthographically, these name pairs begin with a different letter (W vs. I), which are differently shaped. The infix (-rev- vs. -vir-) of the name pair provide additional orthographic differences. This name pair have sufficient phonetic differences. These products differ in strength (45 mg per vial and 60 mg per vial vs. 500 mg), route (subcutaneous vs. oral), frequency (once every 3 weeks vs. twice daily), and dosage form (for injection vs. tablet).

No.	**Proposed name:** Winrevair **Established name:** sotatercept-xxxx **Dosage form:** for injection **Strength(s):** 45 mg per vial and 60 mg per vial **Usual Dose:** 0.3 mg/kg as a single starting dose followed by 0.7 mg/kg for the second and subsequent doses. Each dose should be administered every 3 weeks. Maximum dose is 0.7 mg/kg.	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**
6.	Nexavir	58	Orthographically, these name pairs differ in length (9 letters vs. 7 letters). The prefix (Win- vs. Nex-) and infix (-re- vs. -a-) of the name pair provide sufficient differences. This name pair has sufficient phonetic differences.
7.	Prevnar	58	This name pair has sufficient orthographic and phonetic differences.
8.	Prevnar 13	58	This name pair has sufficient orthographic and phonetic differences.
9.	Prevnar 20	58	This name pair has sufficient orthographic and phonetic differences.
10.	Brethaire	57	This name pair has sufficient orthographic and phonetic differences.
11.	Gentafair	57	This name pair has sufficient orthographic and phonetic differences.
12.	Prevacid 24 Hr	56	This name pair has sufficient orthographic and phonetic differences.
13.	Advair	55	This name pair has sufficient orthographic and phonetic differences.
14.	Prevacid	55	This name pair has sufficient orthographic and phonetic differences.
15.	Wigraine	55	Orthographically, the downstroke g in Wigraine versus the lack of downstrokes in Winrevair provide some differences in shape when scripted. In addition, the infix (-re- vs. -rai-) and suffix (-air vs. -ne) provide additional orthographic differences.

No.	**Proposed name:** Winrevair **Established name:** sotatercept-xxxx **Dosage form:** for injection **Strength(s):** 45 mg per vial and 60 mg per vial **Usual Dose:** 0.3 mg/kg as a single starting dose followed by 0.7 mg/kg for the second and subsequent doses. Each dose should be administered every 3 weeks. Maximum dose is 0.7 mg/kg.	**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**
			This name pair has sufficient phonetic differences. These products differ in strength (45 mg per vial and 60 mg per vial vs. 1 mg/100 mg), route (subcutaneous vs. oral), frequency (once every 3 weeks vs. at the first sign of migraine then every 30 minutes after maximum 6 tablets per day and 10 tablets per week), and dosage form (for injection vs. tablet).

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

No.	Name	POCA Score (%)
1.	Niravi	54
2.	Reviparin	54
3.	Invarest	50
4.	Revia	50
5.	Never Pain	49
6.	Neverpain	49
7.	Revina	48
8.	Nevirapine	46
9.	Erivedge	39

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.	Innovar	62	Brand discontinued with no generic equivalents available. NDA 016049 withdrawn FR effective 10/02/1996.
2.	Predair	62	Brand discontinued with no generic equivalents available. ANDA 088415 withdrawn FR effective 09/22/1993.
3.	Prevail	62	This is a brand name for incontinence absorbers, a veterinary product, and a hand sanitizer.
4.	Simeprevir	62	Active ingredient for Olysio (NDA 205123). NDA 205123 withdrawn FR effective 11/19/2018 and no generic equivalents are available.
5.	Asunaprevir	60	Name identified in RxNorm but unable to find name or product characteristics in commonly used drug databases.
6.	Pressair	60	Pressair is used as a modifier to a drug name. It is the name of a device used to deliver powder for oral inhalation. The platform device is a component in multiple drug-device combination products Duaklir Pressair (aclidinium bromide and formoterol fumarate) and Tudorza Pressair (aclidinium bromide) where the drug components contain different active ingredients. It is unlikely that the modifier 'Pressair' would be used alone on a prescription/medication order.
7.	(b) (4) ***	59	Proposed name found conditionally acceptable by DMEPA 05/15/2018 under NDA (b) (4). NDA withdrawn 08/13/2018.
8.	Revanil	58	International product
9.	Boceprevir	57	Active ingredient for Victrelis (NDA 202258). NDA 202258 withdrawn FR effective 11/02/2017 and no generic equivalents are available.
10.	Telaprevir	56	Active ingredient for Incivek (NDA 201917). NDA 201197 withdrawn FR effective 07/21/2017 and no generic equivalents are available.
11.	Swineaid	55	Veterinary product

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

No.	Name	POCA Score (%)
1.	Introvale	66
2.	Retrovir	65
3.	Vantrela Er	65
4.	Amprenavir	62
5.	Indinavir	62
6.	Virovir	62
7.	Cinazi??Re	60
8.	Cinaziã¨Re	60
9.	Denavir	60
10.	(b) (4)***	59
11.	Vitravene	59
12.	Entecavir	58
13.	Lopinavir	58
14.	Maribavir	58
15.	Murine Ear	58
16.	Vitrasert	58
17.	(b) (4)***	58
18.	Fibro-Vein	57
19.	Ingrezza	57
20.	Ritonavir	57
21.	Tipranavir	57
22.	Varibar	57
23.	Vincasar	57
24.	Etravirine	56
25.	Fenesin Ir	56
26.	Pine Tar	56
27.	Remdesivir	56
28.	Trizivir	56
29.	Univer	56
30.	Benefiber	55
31.	Quin-Release	55
32.	Virazole	55
33.	Zanamivir	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

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