CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212728Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	February 14, 2020
Application Type and Number:	NDA (b) (4) & NDA 212728
Product Name and Strength:	(b) (4) and Nurtec ODT (rimegepant) tablet & orally disintegrating tablet, 75 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Biohaven Pharmaceutical Holding Company Ltd (Biohaven)
Panorama #:	2020-36946464 & 2020-36944776
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Team Leader:	Briana Rider, PharmD, CPPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary names, [redacted] and Nurtec ODT, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary names are outlined in the reference section and Appendix A, respectively. Biohaven submitted an external name study conducted by [redacted] for these proposed proprietary names.

1.1 REGULATORY HISTORY

Biohaven previously submitted the proposed proprietary name, [redacted]*** under IND 109866 on September 11, 2018. However, on December 12, 2018 Biohaven withdrew the name, [redacted]***, and submitted the proposed proprietary name, [redacted]***.

Subsequently, on February 21, 2019 Biohaven withdrew the name, [redacted]*** and submitted the proposed proprietary name, [redacted]***, under IND 109866. In an information request, dated April 10, 2019[a], we noted the Sponsor's request for proprietary name review did not indicate whether they considered the risk of confusion among the two proposed dosage forms (oral tablets and orally disintegrating tablets) or their plans to mitigate the potential for confusion.

On April 15, 2019, Biohaven amended their February 21, 2019 request for proprietary name review to propose the proprietary names, [redacted]*** and [redacted]***, under IND 109866 for the oral tablet formulation and the orally disintegrating tablet (ODT) formulation, respectively.

Subsequently, Biohaven submitted the proposed proprietary names, [redacted]*** and [redacted]*** under NDA [redacted] and NDA 212728 on June 28, 2019 and June 27, 2019, respectively. However, we found the names, [redacted]*** and [redacted]*** unacceptable due to similarity in pronunciation and overlapping product characteristics with the product Ridaura (aurofanin).[b] Biohaven was informed of our decision in writing on August 21, 2019[c].

On October 2, 2019, Biohaven submitted a request for reconsideration for the proposed proprietary names, [redacted]*** and [redacted]***. However, we found the information provided by Biohaven to support use of the proposed proprietary names, [redacted]*** and [redacted]***, did not alleviate the safety concerns. Therefore, we continued to find the proposed

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[a] Killen, M. Information Request sent via email to Marainne Frost (Biohaven). 2019 APR 10. Available in DARRTS via: https://darrts fda.gov//darrts/faces/ViewDocument?documentId=090140af804ebee4&_afrRedirect=4636689260914456

[b] Morris, C. Proprietary Name Review for [redacted]*** and [redacted]*** (IND 109886, NDA [redacted] NDA 212728). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 AUG 19. Panorama No.: 2019-29620574, 2019-32766582, 2019-30833121 and 2019-32851235.

[c] Kang S. Proprietary Name Denial Letter for [redacted]*** and [redacted]***. Silver Spring (MD): FDA, CDER, OND, DNP (US); 2019 AUG 21. Available in DARRTS via: https://darrts fda.gov//darrts/faces/ViewDocument?documentId=090140af8050f732&_afrRedirect=1693135089729217

names, [redacted]*** and [redacted]***, unacceptable.[d] Biohaven was informed of our decision in writing on December 23, 2019.[e]

Subsequently, on December 23, 2019, Biohaven submitted the proposed proprietary names [redacted]*** and [redacted]*** and [redacted]*** and [redacted]*** for review. However, since we only review one proprietary name at a time for each application, we sent an Information Request (IR) requesting Biohaven identify their preference for primary and alternate names and to submit an amendment to their request for proprietary name review.[f] On December 30, 2019, Biohaven responded to our IR and asked if they may resubmit the proprietary name under, [redacted]***, which was previously found to be conditionally acceptable under NDA [redacted] (riluzole). On December 31, 2019, we informed Biohaven it is possible to resubmit and previously evaluated name from a different product for these proposed products, but the name would still have to undergo a full evaluation given the change in products and product characteristics, and the name [redacted]*** would have to be withdrawn from consideration under NDA [redacted].[g]

On December 31, 2019, Biohaven formally withdrew the proposed proprietary name [redacted]*** from NDA [redacted].

On January 3, 2020, Biohaven withdrew the proposed names [redacted]*** and [redacted]*** and [redacted]*** and [redacted]*** from consideration under NDA [redacted] and NDA 212728, and submitted the names, [redacted] and Nurtec ODT (subject of this review) under NDA [redacted] and NDA 212728, respectively.

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[d] Morris, C. Proprietary Name Reconsideration Review for [redacted]*** and [redacted]*** (NDA [redacted] NDA 212728). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 DEC 19. Panorama No 2019-34863029 & 2019-34863111.

[e] Killen, M. Proprietary Name Denial Letter for [redacted]*** and [redacted]***. Silver Spring (MD): FDA, CDER, OND, DNP (US); 2019 DEC 23. Available in DARRTS via: https://darrts fda.gov//darrts/faces/ViewDocument?documentId=090140af80532a85&_afrRedirect=383741440545981

[f] Ogbonna, C. Information Request dated December 30, 2019. Available in DARRTS via: https://darrts fda.gov//darrts/faces/ViewDocument?documentId=090140af80533f3c&_afrRedirect=384421474551424

[g] Ogbonna, C. Information Request dated December 31, 2019. Available in DARRTS via: https://darrts fda.gov//darrts/faces/ViewDocument?documentId=090140af805340cb&_afrRedirect=384609143525968

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 3, 2020.

Proposed name	(b) (4)	Nurtec ODT
Intended pronunciation	(b) (4)	ner-tek ODT
Active ingredient	rimegepant	
Indication of use	acute treatment of migraine	
Route of administration	Oral	Sublingual or on the tongue until dissolved
Dosage form	tablet	orally disintegrating tablet
Strength	75 mg	
Dose and frequency	75 mg at onset of migraine, may repeat after 24 hours	
How supplied	(b) (4)	Blister pack containing 8 orally disintegrating tablets
Storage	Controlled room temperature, 20°C to 25°C (68°F to 77°F); with excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP controlled room temperature]	

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary names, (b) (4) and Nurtec ODT.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that (b) (4) and Nurtec ODT would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Neurology 2 (DN 2) concurred with the findings of OPDP's assessment for (b) (4) and Nurtec ODT.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary names, (b) (4) and Nurtec ODT.

2.2.1 *United States Adopted Names (USAN) Search*

There is no USAN stem present in the proposed proprietary names[h].

2.2.2 *Components of the Proposed Proprietary Name*

Biohaven did not provide a derivation or intended meaning for the proposed proprietary names, (b) (4) in their submission. The proprietary name, (b) (4), is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

The proposed proprietary name, Nurtec ODT (b) (4)

2.2.3 *Comments from Other Review Disciplines at Initial Review*

In response to the OSE, January 16, 2020 e-mail, the Division of Neurology 2 (DN 2) did not forward any comments or concerns relating to (b) (4) and Nurtec ODT at the initial phase of the review.

2.2.4 *FDA Name Simulation Studies*

(b) (4)

[h] USAN stem search conducted on January 8, 2020.

Nurtec ODT

Ninety-seven practitioners participated in DMEPA's prescription study for Nurtec ODT. The responses did not directly overlap with any currently marketed products or any products in the pipeline. However, seven inpatient study participants omitted the proposed modifier and two verbal study participants misinterpreted ODT as either OTT (n = 1) or OTD (n = 1). We discuss the risk associated with omission and misinterpretation of the modifier in Section 2.2.5 below.

Appendix B contains the results from the verbal and written prescription studies.

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2.2.5 *Safety Assessment of* [redacted] *ODT*

[redacted] ODT, is currently utilized in the marketplace.[i] It is typically used to convey the meaning "orally disintegrating tablet" for products designed to disintegrate or dissolve rapidly on contact with saliva[j]. Provided the Office of Pharmaceutical Quality (OPQ) determines that the product meets the criteria for an orally disintegrating tablet, [redacted]

As described in Section, 2.2.4, [redacted] ODT, was misinterpreted as OTT and OTD in the January 10, 2020 FDA Prescription Simulation Study. We are unaware of any postmarket reports of medication errors documenting misinterpretation of ODT [redacted] Also, on January 28, 2020, we searched MedicineNet[l] and Abbreviations.com[m], to determine if OTT or OTD are medical abbreviations that may increase the risk for proprietary name confusion or wrong drug medication errors. Our search did not identify any results. Therefore, we are not concerned the [redacted] ODT, will be misinterpreted as another [redacted] or medical abbreviation. [redacted]

Therefore, we find [redacted] ODT, is acceptable for use in this situation.

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[i] ISMP's List of Products with Drug Name Suffixes [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2010 [cited 2019 MAY 22]. https://www.ismp.org/sites/default/files/attachments/2018-04/drugnamesuffixes.pdf

[j] Guidance for Industry: Orally Disintegrating Tablets. Food and Drug Administration. 2008. Available from http://www fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070578.pdf.

[k] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. J Gen Intern Med. 2002; 17(8): 579-587.

[l] MedicineNet medical abbreviation search conducted on January 28, 2020 at https://www.medicinenet.com/common_medical_abbreviations_and_terms/article.htm

[m] Abreviations medical abbreviation search conducted on January 28, 2020 at https://www.abbreviations.com/

2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[n] identified 244 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.

2.2.7 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and the (b) (4) external 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%	12
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	220
Low similarity name pair: combined match percentage score ≤54%	14

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

Our analysis of the 246 names contained in Table 1 determined none of the names will pose a risk for confusion with (b) (4) and Nurtec ODT as described in Appendices C through H.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Neurology 2 (DN 2) via e-mail on February 11, 2020. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology 2 (DN 2) on February 12, 2020, they stated no additional concerns with the proposed proprietary name, (b) (4) and Nurtec ODT.

3 CONCLUSION

The proposed proprietary names, (b) (4) and Nurtec ODT, are acceptable.

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

[n] POCA search conducted on January 8, 2020 in version 4.3.

3.1 COMMENTS TO BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD

We have completed our review of the proposed proprietary names, (b) (4) and Nurtec ODT, and have concluded that these names are acceptable.

If any of the proposed product characteristics as stated in your submission, received on January 3, 2020, are altered prior to approval of the marketing applications, the names 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. [o]

[o] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.

- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[p]. 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

[p] 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. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

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

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

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

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

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

Appendix B: Prescription Simulation Samples and Results

(b) (4)

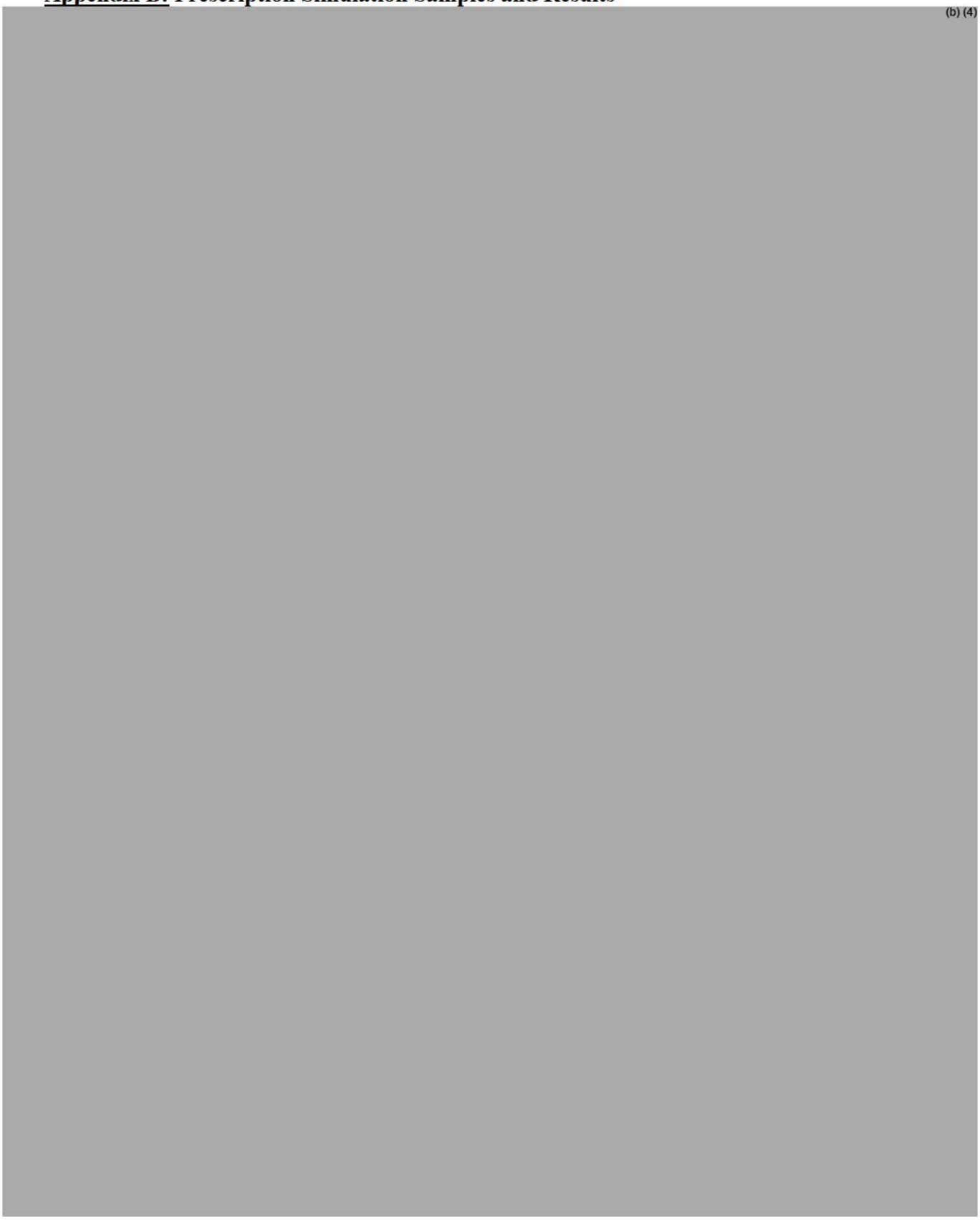


Figure 3. Nurtec ODT Study (Conducted on January 10, 2020)

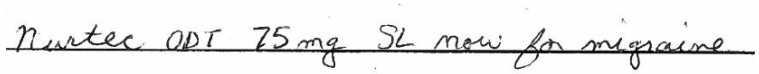
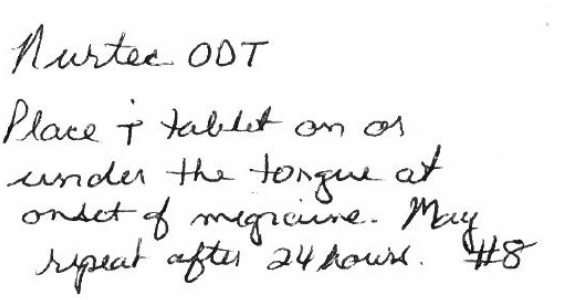
Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Nurtec ODT 75 mg SL now for migraine	Nurtec ODT Place one tablet on or under the tongue at onset of migraine. May repeat after 24 hours. #8
Outpatient Prescription:  Nurtec ODT Place 1 tablet on or under the tongue at onset of migraine. May repeat after 24 hours. #8	
CPOE Study Sample (Font: sans-serif, 12 point, bold)	
Nurtec ODT	

Figure 4. FDA Prescription Simulation Responses (Aggregate Report) for Nurtec ODT

Study Name: Nurtec ODT
As of Date 1/27/2020

211 People Received Study
97 People Responded

Study Name: Nurtec ODT

Total	19	21	19	38	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
NARTEC ODT	0	0	0	2	2
NERTEC ODT	0	0	2	0	2
NERTECH ODT	0	0	2	0	2
NERTEK ODT	0	0	1	0	1
NEUREK ODT	0	0	1	0	1
NEURTEC ODT	0	0	5	0	5
NEURTEK ODT	0	0	1	0	1
NUROTEC ODT	0	0	0	1	1
NURTEC	0	0	0	7	7
NURTEC ODT	18	21	3	27	69
NURTEC ODT 75 MG	0	0	0	1	1
NURTEC OTT	0	0	1	0	1
NURTECH ODT	0	0	1	0	1
NURTEK ODT	0	0	1	0	1
NURTEX ODT	1	0	0	0	1
VERTEK OTD	0	0	1	0	1

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

No.	**Proposed name:** (b) (4) and Nurtec ODT **Established name:** rimegepant **Dosage form:** tablet & orally disintegrating tablet **Strength(s):** 75 mg **Usual Dose:** 1 tablet	**POCA Score (%)** (b) (4)	**POCA Score (%) Nurtec ODT**	**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.	(b) (4)	100	69	Subject of this review.
2.	Nurtec ODT	69	100	Subject of this review.
3.	Norcet	76	60	Product discontinued with no generic equivalents available. ANDA 088871 withdrawn FR effective 09/25/1996.
4.	Purtect	74	68	This name pair has sufficient orthographic and phonetic differences. The suffixes of this name pair (b) (4) versus -ect) have sufficient orthographic differences. Purtect contains the upstroke letter 't' in the last position, whereas (b) (4) does not contain any upstroke letters in the suffix. Additionally, the names begin with different first letters (b) (4) versus P). Phonetically, the first syllables (ner versus pur) of the name pair sound different. (b) (4) Lastly, there is no overlap in strength (75 mg versus 63%; 0.8%), dosage form (tablet/orally disintegrating tablet versus ointment), or route of administration (oral versus topical), which may provide additional differentiation if included.
5.	Zyrtec	73	N/A	This name pair has sufficient orthographic and phonetic differences. Orthographically, the prefixes of this name pair (b) (4) versus Zy-) have sufficient orthographic differences. The

No.	**Proposed name:** (b) (4) and Nurtec ODT **Established name:** rimegepant **Dosage form:** tablet & orally disintegrating tablet **Strength(s):** 75 mg **Usual Dose:** 1 tablet	**POCA Score (%)** (b) (4)	**POCA Score (%) Nurtec ODT**	**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.**
				names begin with different first letters (b) (4) versus Z), and Zyrtec contains the downstroke letter 'y' in the second position whereas (b) (4) doesn't contain any downstroke letters. Phonetically, the onset of the first syllables (b) (4) versus zer) sound different. Furthermore, there is no direct overlap in strength (75 mg versus 10 mg) or frequency of administration (as needed versus once daily), which may provide additional differentiation if included. When all of the aforementioned mitigations are considered in totality, we find the risk of name confusion is mitigated to an acceptable level.

No.	**Proposed name:** (b) (4) and Nurtec ODT **Established name:** rimegepant **Dosage form:** tablet & orally disintegrating tablet **Strength(s):** 75 mg **Usual Dose:** 1 tablet	**POCA Score (%)** (b) (4)	**POCA Score (%) Nurtec ODT**	**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.**
6.	(b) (4) ***	72	56	This name pair has sufficiently different product characteristics and phonetic differences. (b) (4) (b) (4) Lastly, there is no direct overlap in strength (75 mg versus 110 mg [10 mg/mL]), dosage form (tablet/orally disintegrating tablet versus powder for solution), route of administration (oral versus intravenous), or frequency of administration (as needed versus 0, 12, 24, and 48 hours), which may provide additional differentiation if included. When all of the aforementioned mitigations are considered in totality, we find the risk of name confusion is mitigated to an acceptable level.

No.	**Proposed name:** [(b) (4)] and Nurtec ODT **Established name:** rimegepant **Dosage form:** tablet & orally disintegrating tablet **Strength(s):** 75 mg **Usual Dose:** 1 tablet	**POCA Score (%)** [(b) (4)]	**POCA Score (%) Nurtec ODT**	**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.**
7.	Neuraceq	72	N/A	This name pair has sufficient orthographic and phonetic differences. The infixes [(b) (4)] versus -ura-) and suffixes [(b) (4)] versus -ceq) of this name pair have sufficient orthographic differences. [(b) (4)] contains the upstroke letter [(b) (4)] in the infix whereas Neuraceq does not contain any upstroke letters. Conversely, Neuraceq contains the downstroke letter 'q' in the suffix whereas [(b) (4)] does not contain any downstroke letters. Additionally, the lengths of the root name [(b) (4)] and Neuraceq ([(b) (4)] versus 8 letters) are dissimilar when scripted. Phonetically, the second syllables [(b) (4)] versus rah) of the name pair sound different and Neuraceq contains an extra syllable. Furthermore, there is no overlap in strength (75 mg versus 50 to 5000 MBq per mL [1.35 to 135 mCi per mL), dosage form (tablet/orally disintegrating tablet versus solution for injection), route of administration (oral versus intravenous), or dose (75 mg versus 300 MBq), which may provide additional differentiation if included. Lastly, Neuraceq is a radiopharmaceutical that is not expected to be used in the aspects of the US medication-use system where name confusion typically occurs, including prescribing, preparation and handling, distribution, and administration.

No.	**Proposed name:** (b) (4) and Nurtec ODT **Established name:** rimegepant **Dosage form:** tablet & orally disintegrating tablet **Strength(s):** 75 mg **Usual Dose:** 1 tablet	**POCA Score (%)** (b) (4)	**POCA Score (%) Nurtec ODT**	**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.**
				When all of the aforementioned mitigations are considered in totality, we find the risk of name confusion is mitigated to an acceptable level.
8.	Noctec	70	52	Name identified in external study. Unable to find product characteristics in commonly used drug databases.
9.	Artec	70	N/A	Veterinary product.

No.	**Proposed name:** [(b) (4)] and Nurtec ODT **Established name:** rimegepant **Dosage form:** tablet & orally disintegrating tablet **Strength(s):** 75 mg **Usual Dose:** 1 tablet	**POCA Score (%)** [(b) (4)]	**POCA Score (%) Nurtec ODT**	**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.**
10.	[(b) (4)]***	70	N/A	This name pair has sufficient orthographic and phonetic differences. [(b) (4)] Furthermore, the [(b) (4)]*** device is a source of sodium pertechnetate Tc99m for use in the preparation of FDA-approved diagnostic radiopharmaceuticals. [(b) (4)]*** is used in imaging or radiological or radio pharmacy suite. Thus, [(b) (4)]*** will not be ordered on a prescription order.
11.	Tritec	70	N/A	Brand discontinued with no generic equivalents available. NDA 020559 withdrawn FR effective 09/30/2000.
12.	Nutracort	55	70	This name pair has sufficient orthographic and phonetic differences. Orthographically, the suffixes [(b) (4)] vs cort) are different. Specifically Nutracort contains the crossed letter "t" in the suffix, whereas [(b) (4)] doesn't contain any crossed letters in the suffix, which gives the names different shapes when scripted. Additionally, the lengths of the root name [(b) (4)] and Nutracort [(b) (4)]

No.	**Proposed name:** [redacted] and Nurtec ODT **Established name:** rimegepant **Dosage form:** tablet & orally disintegrating tablet **Strength(s):** 75 mg **Usual Dose:** 1 tablet	**POCA Score (%)** [redacted]	**POCA Score (%) Nurtec ODT**	**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.**
				[redacted] versus 9 letters) are dissimilar when scripted. Phonetically, the first syllables [redacted] versus new) and second syllables [redacted] versus tra) of the name pair sound different, and Nutracort contains an extra syllable. Additionally, Nurtec ODT [redacted] Furthermore, there is no direct overlap in the following product characteristics: strength (75 mg vs 0.5%, 1% or 2.5%), dose (1 tab or 75 mg vs sufficient amount), dosage form (tablet/orally disintegrating tablet vs cream/lotion/gel), and route of administration (oral vs topical), which may provide additional differentiation if included.

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 (%) (b) (4)	POCA Score (%) Nurtec ODT
13.	(b) (4) ***	64	N/A
14.	Neuramate	60	N/A
15.	Nitrek	60	N/A
16.	Norpace	60	N/A
17.	Norpace Cr	56	57
18.	Neurolite	55	N/A
19.	Nucynta Er	47	N/A
20.	Zofran odt	N/A	56
21.	Phentercot	N/A	58

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:** (b) (4) and Nurtec ODT **Established name:** rimegepant **Dosage form:** tablet & orally disintegrating tablet **Strength(s):** 75 mg **Usual Dose:** 1 tablet	POCA Score (%) (b) (4)	POCA Score (%) Nurtec ODT	**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**
22.	Nortemp	66	61	This name pair has sufficient orthographic and phonetic differences.
23.	Nordette-21	66	60	This name pair has sufficient orthographic and phonetic differences.
24.	Nordette-28	66	60	This name pair has sufficient orthographic and phonetic differences.
25.	Ceretec	66	N/A	This name pair has sufficient orthographic and phonetic differences. Orthographically, the prefixes (b) (4) look different when scripted. The names begin with different first letters (b) (4) Phonetically, the first syllables (b) (4) and second syllables (b) (4) sound different, and Ceretec contains an additional syllable.

No.	**Proposed name:** [redacted] and Nurtec ODT **Established name:** rimegepant **Dosage form:** tablet & orally disintegrating tablet **Strength(s):** 75 mg **Usual Dose:** 1 tablet	**POCA Score (%)** [redacted]	**POCA Score (%) Nurtec ODT**	**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**
				Furthermore, the Ceretec kit is a source of sodium pertechnetate Tc99m for use in the preparation of FDA-approved diagnostic radiopharmaceuticals. Ceretec is used in imaging or radiological or radio pharmacy suite. Thus, Ceretec will not be ordered on a prescription or medication order.
26.	Uniretic	66	N/A	This name pair has sufficient orthographic and phonetic differences.
27.	Cortic	66	N/A	This name pair has sufficient orthographic and phonetic differences. Orthographically, the names begin with different first letters [redacted] vs C) and Cortic contains the dotted letter 'i', whereas [redacted] Phonetically, the first syllables [redacted] vs core) sound different. Furthermore, there is no direct overlap in the following product characteristics: strength (75 mg vs 0.1%/1%/1%), dosage form (tablet or orally disintegrating tablet vs solution), or route of administration (oral vs otic), which may provide additional differentiation if included.
28.	Neutracett	64	58	This name pair has sufficient orthographic and phonetic differences.
29.	Nulecit	64	N/A	This name pair has sufficient orthographic and phonetic differences.
30.	Zyrtec-D	62	62	This name pair has sufficient orthographic and phonetic differences. See prevention of failure mode for the root name, Zyrtec (Appendix C, Line 5).

No.	**Proposed name:** (b) (4) and Nurtec ODT **Established name:** rimegepant **Dosage form:** tablet & orally disintegrating tablet **Strength(s):** 75 mg **Usual Dose:** 1 tablet	**POCA Score (%)** (b) (4)	**POCA Score (%) Nurtec ODT**	**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**
				Additionally, Nurtec ODT and Zyrtec-D (b) (4)
31.	Nucort	62	60	This name pair has sufficient orthographic and phonetic differences.
32.	Cortef	62	N/A	This name pair has sufficient orthographic and phonetic differences.
33.	Drotic	61	N/A	This name pair has sufficient orthographic and phonetic differences.
34.	Neurontin	60	58	This name pair has sufficient orthographic and phonetic differences.
35.	Noritate	60	57	This name pair has sufficient orthographic and phonetic differences.
36.	Nortrel	60	N/A	This name pair has sufficient orthographic and phonetic differences.
37.	Nortrel 0.5/35-28	60	N/A	This name pair has sufficient orthographic and phonetic differences.
38.	Nortrel 1/35-21	60	N/A	This name pair has sufficient orthographic and phonetic differences.
39.	Nortrel 1/35-28	60	N/A	This name pair has sufficient orthographic and phonetic differences.
40.	Nortrel 7/7/7	60	N/A	This name pair has sufficient orthographic and phonetic differences.
41.	Narcan	60	N/A	This name pair has sufficient orthographic and phonetic differences.
42.	Entocort Ec	58	58	This name pair has sufficient orthographic and phonetic differences.
43.	Nouress	58	N/A	This name pair has sufficient orthographic and phonetic differences.
44.	Norco	58	N/A	This name pair has sufficient orthographic and phonetic differences.
45.	Urea [14C]	57	N/A	This name pair has sufficient orthographic and phonetic differences.
46.	Urea C-13	57	N/A	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** [redacted] and Nurtec ODT **Established name:** rimegepant **Dosage form:** tablet & orally disintegrating tablet **Strength(s):** 75 mg **Usual Dose:** 1 tablet	**POCA Score (%)** [redacted]	**POCA Score (%) Nurtec ODT**	**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**
47.	Multaq	57	N/A	This name pair has sufficient orthographic and phonetic differences. Orthographically, the infixes [redacted] vs lt) and suffixes [redacted] vs aq) are different, which gives the names different shapes when scripted. Phonetically, the first syllables [redacted] vs MUL) sound sufficiently different.
48.	Norlutate	56	57	This name pair has sufficient orthographic and phonetic differences.
49.	Encort	56	50	This name pair has sufficient orthographic and phonetic differences.
50.	Anusert Hc-1	56	N/A	This name pair has sufficient orthographic and phonetic differences.
51.	Senatec	56	N/A	This name pair has sufficient orthographic and phonetic differences. Orthographically, the prefixes [redacted] vs Sen) are different. The names begin with different first letters [redacted] versus S). Phonetically, the first syllables [redacted] vs sen) and second syllables [redacted] vs ah) sound different, and Senatec contains an extra syllable. Furthermore, there is no direct overlap in the following product characteristics: strength (75 mg vs 3%), dose (1 tab or 75 mg vs sufficient amount), dosage form (tablet/orally disintegrating tablet vs lotion), or route of administration (oral vs topical), which may provide additional differentiation if included.
52.	Totect	56	N/A	This name pair has sufficient orthographic and phonetic differences.
53.	Norvasc	56	N/A	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** [redacted] and Nurtec ODT **Established name:** rimegepant **Dosage form:** tablet & orally disintegrating tablet **Strength(s):** 75 mg **Usual Dose:** 1 tablet	**POCA Score (%)** [redacted]	**POCA Score (%) Nurtec ODT**	**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**
				Orthographically, [redacted] contains the cross-stroke letter [redacted] in the infix, whereas Norvasc does not contain any cross-stroke letters in the name, which gives the names different shapes when scripted.
54.	Entercote	55	60	This name pair has sufficient orthographic and phonetic differences.
55.	Norgesic	55	55	This name pair has sufficient orthographic and phonetic differences.
56.	Anucort-Hc	55	N/A	This name pair has sufficient orthographic and phonetic differences.
57.	Anutone-Hc	52	N/A	This name pair has sufficient orthographic and phonetic differences.
58.	Nutrilyte	52	N/A	This name pair has sufficient orthographic and phonetic differences.
59.	Nutrestore	50	N/A	This name pair has sufficient orthographic and phonetic differences.
60.	Cortic-Nd	N/A	67	This name pair has sufficient orthographic and phonetic differences. See prevention of failure mode for the root name, Cortic (Appendix E, Row 27). Additionally, Nurtec ODT and Cortic-Nd [redacted]
61.	Entocort	N/A	63	This name pair has sufficient orthographic and phonetic differences.
62.	Nicorette Ds	N/A	62	This name pair has sufficient orthographic and phonetic differences.
63.	Orapred odt	N/A	60	This name pair has sufficient orthographic and phonetic differences.
64.	Caldecort	N/A	60	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** [redacted] and Nurtec ODT **Established name:** rimegepant **Dosage form:** tablet & orally disintegrating tablet **Strength(s):** 75 mg **Usual Dose:** 1 tablet	**POCA Score (%)** [redacted]	**POCA Score (%) Nurtec ODT**	**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**
65.	Adrenocot	N/A	60	This name pair has sufficient orthographic and phonetic differences.
66.	Nitrocot	N/A	60	This name pair has sufficient orthographic and phonetic differences.
67.	Nuedexta	N/A	60	This name pair has sufficient orthographic and phonetic differences.
68.	Uretron Ds	N/A	60	This name pair has sufficient orthographic and phonetic differences.
69.	Gynecort	N/A	60	This name pair has sufficient orthographic and phonetic differences.
70.	Aricept odt	N/A	59	This name pair has sufficient orthographic and phonetic differences.
71.	Penecort	N/A	59	This name pair has sufficient orthographic and phonetic differences.
72.	Nasacort	N/A	58	This name pair has sufficient orthographic and phonetic differences.
73.	Nescon Pd	N/A	58	This name pair has sufficient orthographic and phonetic differences.
74.	Novacort	N/A	58	This name pair has sufficient orthographic and phonetic differences.
75.	Eldecort	N/A	58	This name pair has sufficient orthographic and phonetic differences.
76.	Marten-Tab	N/A	56	This name pair has sufficient orthographic and phonetic differences. Orthographically, the last letters (c vs n) look sufficiently different. Phonetically, both syllables (ner vs mar) and (tek vs ten) sound different. Additionally, the names Nurtec ODT and Marten-Tab [redacted]
77.	Neuroforte-R	N/A	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** [redacted] and Nurtec ODT **Established name:** rimegepant **Dosage form:** tablet & orally disintegrating tablet **Strength(s):** 75 mg **Usual Dose:** 1 tablet	**POCA Score (%)** [redacted]	**POCA Score (%) Nurtec ODT**	**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**
78.	Norcuron	N/A	56	This name pair has sufficient orthographic and phonetic differences.
79.	Norditropin	N/A	56	This name pair has sufficient orthographic and phonetic differences.
80.	Norquest Fe	N/A	56	This name pair has sufficient orthographic and phonetic differences. Additionally, Nurtec ODT and Norquest Fe [redacted]
81.	Notuss Dc	N/A	56	This name pair has sufficient orthographic and phonetic differences.
82.	Nucofed	N/A	56	This name pair has sufficient orthographic and phonetic differences.
83.	Morphabond	N/A	55	This name pair has sufficient orthographic and phonetic differences.
84.	Neutragard	N/A	55	This name pair has sufficient orthographic and phonetic differences.
85.	Meticorten	N/A	55	This name pair has sufficient orthographic and phonetic differences.
86.	Ultra-technekow Dte***	N/A	49	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 (%) [redacted]	POCA Score (%) Nurtec ODT
N/A			

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

No.	Name	POCA Score (%) (b) (4)	POCA Score (%) Nurtec ODT	Failure preventions
87.	Ultec	67	N/A	International product formerly marketed in Hong Kong and the UK.
88.	Kuretek	66	N/A	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
89.	Nordette	66	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
90.	Wartec	66	N/A	International product marketed in multiple countries.
91.	Neotic	62	N/A	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
92.	Norcept-E 1/35 21	62	61	ANDA 071454 withdrawn, FR effective 03/26/2018.
93.	Norcept-E 1/35 28	62	61	ANDA 071546 withdrawn, FR effective 03/26/2018.
94.	Renotec	62	N/A	Brand discontinued with no generic equivalents available. NDA 017045 withdrawn, FR effective 03/13/2009.
95.	Norisc	61	N/A	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
96.	Rantec	61	N/A	International product marketed in the UK.
97.	Macrotec	60	N/A	Brand discontinued with no generic equivalents available. NDA 017339 withdrawn, FR effective 03/13/2009.
98.	Nortrel 0.5/35-21	60	N/A	ANDA 072692 withdrawn, FR effective 11/03/2016.
99.	Ceretic	60	44	Name identified in external study. Unable to find product characteristics in commonly used drug databases.
100.	Renitec	60	N/A	International product marketed in multiple countries.
101.	Mooredec	60	N/A	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%) (b) (4)	POCA Score (%) Nurtec ODT	Failure preventions
102.	Neuromed	59	56	International product formerly marketed in Indonesia and India.
103.	Aller-tec	58	N/A	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
104.	Minitec	58	N/A	Brand discontinued with no generic equivalents available. NDA 017045 withdrawn FR effective 03/13/2009.
105.	Narcof	58	N/A	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
106.	Numotac	58	N/A	International product formerly marketed in the Netherlands and the UK.
107.	Rinatec	58	N/A	International product marketed in the UK and Ireland.
108.	Vortex	58	N/A	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
109.	Nortuss Ex	57	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
110.	(b) (4) ***	55	N/A	This name was previously found acceptable by DMEPA (OSE# 2016-7900743, dated July 27, 2016) under NDA 203697/S-002. However, the applicant withdrew the name (b) (4) *** on 12/21/17 due to the U.S. Patent and Trademark Office refusing to register the trademark. The proposed name Vazalore, was found conditionally acceptable by DMEPA (OSE# 2018-20579612, dated April 20, 2018) under NDA 203697/S-003. The product is now marketed under the proprietary name Vazalore.
111.	Maldec	52	N/A	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
112.	Endure 100	46	N/A	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
113.	Endure 200	46	N/A	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%) (b) (4)	POCA Score (%) Nurtec ODT	Failure preventions
114.	Endure 250	46	N/A	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
115.	Endure 300	46	N/A	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
116.	Endure 450	46	N/A	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
117.	Nortuss-Nx	N/A	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
118.	Cardiotec	N/A	55	Name identified in Drugs@FDA database. Unable to find product characteristics in commonly used drug databases.
119.	Neo-Cort-Dome	N/A	50	Brand discontinued with no generic equivalents available. NDA 050237 and NDA 050238 withdrawn, pending publication in FR notice.
120.	(b) (4) ***	N/A	56	Proposed proprietary name for NDA 212728 (subject of this review) found unacceptable by DMEPA (OSE# 2019-29620574, 2019-32766582, 2019-30833121 and 2019-32851235).
121.	Durabac Forte	N/A	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
122.	Dur-Tann Forte	N/A	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
123.	Nicomide-T	N/A	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
124.	Nucotuss	N/A	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
125.	Rondec-Tr	N/A	52	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
126.	Natrecor	N/A	57	Brand discontinued with no generic equivalents available.

No.	Name	POCA Score (%) (b) (4)	POCA Score (%) Nurtec ODT	Failure preventions
127.	Neo Tect Kit	N/A	56	Brand discontinued with no generic equivalents available. NDA 021102 withdrawn, FR effective 12/07/07.
128.	Nutropin Depot	N/A	56	Brand discontinued with no generic equivalents available. NDA 021075 withdrawn FR effective 12/07/2007.
129.	Coconut Extract	N/A	48	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
130.	Duro Cort	N/A	68	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
131.	Naldecon Cx	N/A	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
132.	Nandrocot	N/A	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
133.	Noctesed	N/A	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
134.	Nordox	N/A	55	International product marketed in Chile and formerly marketed in the United Kingdom.
135.	Norethin 1/50 M	N/A	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
136.	Norethin 1/50M-21	N/A	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
137.	Norethin 1/50M-28	N/A	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
138.	Noromectin	N/A	60	Veterinary product.
139.	Pro-tec Gold	N/A	60	Veterinary product.
140.	Tricodene	N/A	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
141.	Uro-Ject	N/A	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[9].

No.	Name	POCA Score (%) (b) (4)	POCA Score (%) Nurtec ODT
142.	Cardec	62	N/A
143.	Oretic	62	N/A
144.	Duract	60	56
145.	Mircette	60	N/A
146.	Tri-Dec	60	N/A
147.	Xuret	60	N/A
148.	Tenoretic	60	N/A
149.	Tenoretic 100	60	N/A
150.	Tenoretic 50	60	N/A
151.	Accuretic	60	N/A
152.	Duratest	59	63
153.	Uritact	58	56
154.	Inrebic	58	N/A
155.	Tretten	58	N/A
156.	Durophet	57	N/A
157.	Pro1tek	57	N/A
158.	Cort-K	56	N/A
159.	Durabac	56	N/A
160.	Lorcet	56	N/A
161.	Bar-Test	56	N/A
162.	Protac	56	N/A
163.	Sustac	56	N/A
164.	Duratan	56	N/A
165.	Duricef	56	N/A
166.	Xoten-C	56	N/A
167.	Turgex	56	N/A
168.	Teronac	56	N/A
169.	Moduretic	56	N/A
170.	Moduretic 5-50	56	N/A
171.	Curretab	56	N/A
172.	Cortane	56	N/A
173.	Retet	56	N/A
174.	Anuprep-Hc	56	N/A
175.	Tencet	56	N/A
176.	Anusert	56	N/A

[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

No.	Name	POCA Score (%) (b) (4)	POCA Score (%) Nurtec ODT
177.	Cortan	55	N/A
178.	Certuss	55	N/A
179.	Muricin	55	N/A
180.	Sulten-10	55	N/A
181.	Berkatens	N/A	56
182.	Dermacort	N/A	64
183.	Cortidex	N/A	60
184.	Dupixent	N/A	56
185.	Dur-Tann Dm	N/A	60
186.	Dormonoct	N/A	60
187.	Mastic Dent	N/A	57
188.	Instacort	N/A	60
189.	Instacort 10	N/A	60
190.	Uritact Ds	N/A	60
191.	Cardec Dm	N/A	56
192.	Durapatite	N/A	56
193.	Predacort 50	N/A	62
194.	Predicort-50	N/A	62
195.	Articadent	N/A	60
196.	Medicort	N/A	60
197.	Surgident	N/A	58
198.	Mentadent	N/A	57
199.	Topicort	N/A	57
200.	Duratuss Cs	N/A	56
201.	Carbacot	N/A	55
202.	Duratuss Pe	N/A	55
203.	Pulmicort	N/A	55
204.	Torphaject	N/A	55
205.	Corticool	N/A	56
206.	Methacort 40	N/A	56
207.	Methacort 80	N/A	56
208.	Dome-Cort	N/A	60
209.	Dricort	N/A	58
210.	Dura-Vent	N/A	58
211.	Cotacort	N/A	57
212.	Protex D	N/A	57
213.	Ortho-Cept	N/A	56
214.	Anestacon	N/A	56
215.	Dermtex Hc	N/A	56
216.	Endacof Dc	N/A	56
217.	Dexacort	N/A	58

No.	Name	POCA Score (%) (b) (4)	POCA Score (%) Nurtec ODT
218.	Darvocet-N 100	N/A	56
219.	Darvocet-N 50	N/A	56
220.	Contac Cold	N/A	58
221.	Duranest	N/A	58
222.	Pseudocot-C	N/A	57
223.	Cortinide	N/A	56
224.	Butacote	N/A	58
225.	Duration	N/A	57
226.	Uticort	N/A	60
227.	Duramectin	N/A	58
228.	Resicort	N/A	58
229.	Cetacort	N/A	56
230.	Cortimed	N/A	56
231.	Duraclon	N/A	55
232.	Mertodol	N/A	55
233.	Texacort	N/A	58
234.	Theracort	N/A	57
235.	Proctocort	N/A	56
236.	Doramectin	N/A	56
237.	Prednicot	N/A	59
238.	All-Nite Cold	N/A	56
239.	Cardec Tr	N/A	56
240.	Emete-Con	N/A	56
241.	Superdent	N/A	55
242.	Furocot	N/A	58
243.	Cordcyte***	N/A	56
244.	Butedronate	N/A	56
245.	Sure Comfort	N/A	56
246.	Curatoderm	N/A	55

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

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Date of This Review:	December 19, 2019
Application Type and Number:	NDA (b) (4) NDA 212728
Product Name and Strength:	(b) (4) (rimegepant) tablet, 75 mg (b) (4) (rimegepant) orally disintegrating tablet, 75 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Biohaven Pharmaceutical Holding Company Ltd (Biohaven)
Panorama #:	2019-34863029 & 2019-34863111
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Team Leader:	Briana Rider, PharmD, CPPS
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

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PROPRIETARY NAME REVIEW

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Office of Medication Error Prevention and Risk Management (OMEPRM)
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Date of This Review:	August 19, 2019
Application Type and Number:	IND 109886 & NDA (b) (4) IND 109886 & NDA 212728
Product Name and Strength:	(b) (4) (rimegepant) tablet, 75 mg (b) (4) (rimegepant), orally disintegrating tablet, 75 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Biohaven Pharmaceutical Holding Company Limited (Biohaven)
Panorama #:	2019-29620574 & 2019-32766582 2019-30833121 & 2019-32851235
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Team Leader (Acting):	Briana Rider, PharmD
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

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