CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216774Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	February 24, 2022
Application Type and Number:	NDA 216774
Product Name and Strength:	Alvaiz (eltrombopag) Tablet, 9 mg, 18 mg, 36 mg and 54 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Teva Pharmaceuticals USA, Inc. (Teva)
PNR ID #:	2021-1044724317
DMEPA 2 Safety Evaluator:	Maximilian Straka, PharmD, FISMP
DMEPA 2 Team Leader:	Hina Mehta, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD, FISMP

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Alvaiz, 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. Teva submitted an external name study, conducted by (b) (4) for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 3, 2021.

- Intended Pronunciation: al-VAYZ
- Active Ingredient: eltrombopag
- Indication of Use: Treatment of thrombopoietin in adults and pediatric patients (b) (4) and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglubulins, or splenectomy. Treatment of thrombocytopenia in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. Treatment of patients with severe aplastic anemia who have had an insufficient response to immunosupppresssive therapy.
- Route of Administration: Oral
- Dosage Form: Tablet
- Strength: 9 mg, 18 mg, 36 mg and 54 mg
- Dose and Frequency:
    - Persistent or chronic ITP: Initiate at 36 mg once daily for most adult and pediatric patients 6 years and older (b) (4) (b) (4) Dose reductions are needed for patients with hepatic impairment and some patients of Asian ancestry. Adjust to maintain platelet count greater than or equal to 50 x 10^9/L. Do not exceed 54 mg per day.
    - Chronic Hepatitis C-associated Thrombocytopenia: Initiate at 18 mg once daily for all patients. Adjust to achieve target platelet count required to initiate antiviral therapy. Do not exceed a daily dose of 72 mg.
    - Refractory Severe Aplastic Anemia: Initiate at 36 mg once daily. Reduce initial dose in patients with hepatic impairment or patients of Asian ancestry. Adjust to maintain platelet count greater than 50 x 10^9/L. Do not exceed (b) (4) mg per day.
- How Supplied: Bottles of 14 count and 180 count
- Storage: Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F)
- Reference Listed Drug/Reference Product: Promacta (NDA 022291)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Alvaiz would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) and the Division of Non-Malignant Hematology (DNH) concurred with the findings of OPDP's assessment for Alvaiz.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Teva did not provide a derivation or intended meaning for the proposed proprietary name, Alvaiz, in their submission. This proprietary name 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.

2.2.3 Comments from Other Review Disciplines at Initial Review

On January 31, 2022 the Division of Non-Malignant Hematology (DNH) did not forward any comments or concerns relating to Alvaiz at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One Hundred Sixteen (116) practitioners participated in DMEPA's prescription studies for Alvaiz.

In the Computerized Physician Order Entry (CPOE) study, one participant entered an incorrect sequence of letters, 'alvi' instead of 'alva', when searching for the study name, which generated a pick list that did not contain the proposed study name Alvaiz. After 18 seconds passed, the participant incorrectly selected the name 'Lybalvi', suggesting that the participant selected a random name in order to proceed with the simulation study. Thus, in this case, the study response is unlikely to be representative of a plausible CPOE based risk. Nonetheless, we evaluate this name pair below:

Alvaiz vs. Lybalvi

[a] USAN stem search conducted on December 8, 2021.

Orthographically, there is an upstroke letter 'l' in the second position of Alvaiz which is absent from Lybalvi. The infixes and suffixes (vaiz vs. balvi) of the name pair also have sufficient orthographic differences. Phonetically, the first ('Al' vs. 'Li') and second (' -vayz-' vs. ' -bal-') syllables sound different. In addition, Alvaiz has 2 syllables whereas Lybalvi has 3 syllables. FDA's Phonetic and Orthographic Computer Analysis (POCA) program, which calculates a combined orthographic and phonetic score of 54%, suggesting that there is low similarity between these names.

Additionally, the products differ in strengths (9 mg, 18 mg, 36 mg and 54 mg vs. 5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg, 20 mg/10 mg) where the strength must be included on a prescription. Thus, the risk of name confusion between the name pair is minimized. We evaluate this name pair in Appendix E.

The remaining responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline.

Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[b] identified 63 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, FDA Prescription Simulation Study, 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%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	60
Low similarity name pair: combined match percentage score ≤54%	4

[b] POCA search conducted on December 8, 2021 in version 4.4.

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

Our analysis of the 66 names contained in Table 1 determined none of the names will pose a risk for confusion with Alvaiz as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On February 23, 2022, DMEPA 2 communicated our determination to the Division of Non-Malignant Hematology (DNH).

3 CONCLUSION

The proposed proprietary name, Alvaiz, is acceptable.

If you have any questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0949.

3.1 COMMENTS TO TEVA PHARMACEUTICALS USA, INC.

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

If any of the proposed product characteristics as stated in your submission, received on December 3, 2021, 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. [c]

[c] 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, 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[d]. 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

[d] 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.

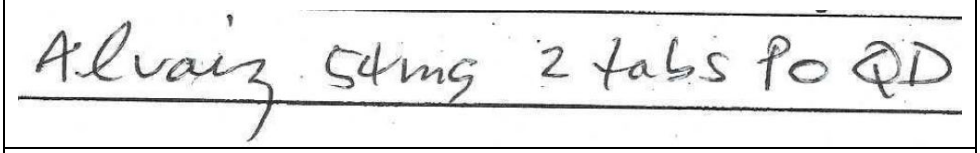
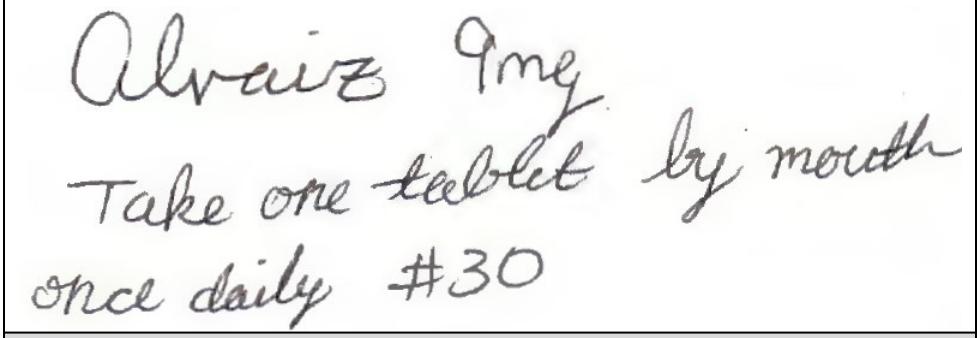
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Figure 1. Alvaiz Study (Conducted on December 17, 2021)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Alvaiz Take one tablet by mouth once daily # 30
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Alvaiz	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Alvaiz

262 People Received Study

116 People Responded

Study Name: Alvaiz

Total	**27**	**26**	**33**	**30**	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
ALBAYZ	0	0	1	0	1
ALBEIZ	0	0	1	0	1
ALDAZE	0	0	1	0	1

ALFAZE	0	0	1	0	1
ALVAIR	1	0	0	0	1
ALVAISE	0	0	1	0	1
ALVAIZ	26	25	0	30	81
ALVAIZE	0	0	1	0	1
ALVASE	0	0	2	0	2
ALVAYZ	0	0	3	0	3
ALVAYZE	0	0	1	0	1
ALVAZ	0	0	1	0	1
ALVAZE	0	0	15	0	15
ALVAZE 9 MG	0	0	1	0	1
ALVEAZ	0	0	1	0	1
ALVEYS	0	0	1	0	1
ALVEZ	0	0	1	0	1
HALVAZE	0	0	1	0	1
LYBALVI	0	1	0	0	1

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

No.	**Proposed name:** Alvaiz **Established name:** eltrombopag **Dosage form:** Tablet **Strength(s):** 9 mg, 18 mg, 36 mg and 54 mg **Usual Dose:** One to two tablets once daily	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Alvaiz***	100	This name is the subject of this review.
2.	Alpain	70	Name identified in RxNorm database. Product discontinued with no generics available. Also, international product marketed in Indonesia.

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.	(b) (4)***	64
2.	Alevazol	62
3.	(b) (4)***	56
4.	(b) (4)***	56
5.	Akovaz	55
6.	(b) (4)***	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:** Alvaiz **Established name:** eltrombopag **Dosage form:** Tablet **Strength(s):** 9 mg, 18 mg, 36 mg and 54 mg **Usual Dose:** One to two tablets once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Advair	66	Orthographically, Alvaiz contains the downstroke letter 'z' in the last position which is absent from Advair providing some differences. Phonetically, the ending sounds of the first and last syllables (ad' vs. al) and

No.	**Proposed name:** Alvaiz **Established name:** eltrombopag **Dosage form:** Tablet **Strength(s):** 9 mg, 18 mg, 36 mg and 54 mg **Usual Dose:** One to two tablets once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			(vair vs. VAYZ) provide sufficient phonetic differences. Although the name pair overlap in dose (one to two) however, there is no overlap in strength (9 mg, 18 mg, 36 mg and 54 mg vs. 100 mcg/50 mcg, 250 mcg /50 mcg and 500 mcg /50 mcg or 45 mcg /21 mcg, 115 mcg /21 mcg and 230 mcg /21 mcg*), frequency (once daily vs. twice daily), route (oral vs. inhalation), or dosage form ((b) (4) vs. powder). In addition, Advair comes as a Diskus and an HFA inhaler; thus, the product characteristic differences provide additional differentiation if included on a prescription. *Depending on product (Diskus vs. HFA)
2.	Balziva	66	This name pair has sufficient orthographic and phonetic differences.
3.	Balziva-21	66	This name pair has sufficient orthographic and phonetic differences.
4.	Balziva-28	66	This name pair has sufficient orthographic and phonetic differences.
5.	Lovaza	64	Orthographically, Alvaiz contains the upstroke letter ‘l’ which is absent from Lovaza which provides some orthographic difference. In addition, the letter ‘a’ follows the downstroke letter ‘z’ in Lovaza which is not present in Alvaiz. Phonetically, there are three syllables in Lozava (loh-VAH-zah) vs. two in Alvaiz*** (al-VAYZ) with the first

No.	**Proposed name:** Alvaiz **Established name:** eltrombopag **Dosage form:** Tablet **Strength(s):** 9 mg, 18 mg, 36 mg and 54 mg **Usual Dose:** One to two tablets once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			and last syllable providing sufficient phonetic differences. Although the name pair overlap in route (oral) and frequency (once daily), there is no overlap in dose (9 mg to (b) (4) mg vs. 4 grams), dosage form (b) (4) vs. tablet), or strength (9 mg, 18 mg, 36 mg and 54 mg vs. 1 gram); thus, the product characteristic differences provide additional differentiation if included on a prescription.
6.	Aleve-D	61	This name pair has sufficient orthographic and phonetic differences.
7.	Allzital	61	This name pair has sufficient orthographic and phonetic differences.
8.	Aluvea	61	This name pair has sufficient orthographic and phonetic differences.
9.	Alvesco	60	Orthographically, the suffix ("-esco" vs. "-aiz") of the name pair provides some orthographic difference. Phonetically, there are three syllables in Alvesco (al-VES-co) vs. two in Alvaiz*** (al-VAYZ) where Alvesco contains an extra 3rd syllable "co" that's not heard in Alvaiz. Although Alvaiz and Alvesco overlap in route (oral), there is no overlap in strength (9 mg, 18 mg, 36 mg and 54 mg vs. 80 mcg and 160 mcg), dose (9 mg to (b) (4) mg vs. 80 mcg and 320 mcg), dosage form ((b) (4) vs. inhalation) or frequency (once daily vs. twice daily); thus, the product characteristic differences provide

No.	**Proposed name:** Alvaiz **Established name:** eltrombopag **Dosage form:** Tablet **Strength(s):** 9 mg, 18 mg, 36 mg and 54 mg **Usual Dose:** One to two tablets once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			additional differentiation if included on a prescription.
10.	Altace	60	Orthographically, the second half of the name (“-tace“ vs. “-vaiz“) provides sufficient orthographic difference. Phonetically, the second syllable (-ACE) vs. -VAYZ) does not sound similar Although Alvaiz and Altace overlap in route (oral), (b) (4) and frequency (once daily), there is no overlap in strength (9 mg, 18 mg, 36 mg and 54 mg vs. 1.25 mg, 2.5 mg, 5 mg and 10 mg) or dose (9 mg to (b) (4) mg vs. 2.5 mg, 5 mg, 10 mg, and 20 mg per day administered as a single dose or in two equally divided doses); thus, the product characteristic differences provide additional differentiation if included on a prescription.
11.	Advil	59	This name pair has sufficient orthographic and phonetic differences.
12.	Aleve	59	This name pair has sufficient orthographic and phonetic differences.
13.	Avinza	58	Orthographically, there is an upstroke letter ‘l’ in the 2nd position and a down stroke letter ‘z’ in the 6th position which provides some orthographic differentiation from the name “Avinza” Phonetically, there are three syllables in Avinza vs. two syllables in Alvaiz (a-VIN-za) vs. (al-VAYZ). The first syllable (al- vs. a) and second syllable (-vin- vs. -vayz) sound different.

No.	**Proposed name:** Alvaiz **Established name:** eltrombopag **Dosage form:** Tablet **Strength(s):** 9 mg, 18 mg, 36 mg and 54 mg **Usual Dose:** One to two tablets once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			Although Alvaiz and Avinza overlap in route (oral), (b) (4) frequency (once daily) and numeric similarity in strength (9 mg vs. 90 mg) there is no overlap in the other listed strengths (18 mg, 36 mg and 54 mg vs. 30 mg, 45 mg, 60 mg, 75 mg and 120 mg) or dose (9 mg to (b) (4) mg vs. Individualized according to patients medical history); thus, the product characteristic differences provide additional differentiation if included on a prescription.
14.	Avycaz	58	This name pair has sufficient orthographic and phonetic differences.
15.	Ablavar	56	This name pair has sufficient orthographic and phonetic differences.
16.	Acuvail	56	This name pair has sufficient orthographic and phonetic differences.
17.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
18.	Algal-900	56	This name pair has sufficient orthographic and phonetic differences.
19.	Advate	55	Orthographically, there is an upstroke letter ‘t’ in the 5th position, a downstroke letter ‘z’ in the 6th position which provides some orthographic difference. The second letter ‘d’ vs. ‘l’ also provides some orthographic difference. Phonetically, the second syllable (‘VATE’ vs. ‘VAYZ) provides some differentiation. In addition, there is no overlap in strength (9 mg, 18 mg, 36 mg and 54 mg vs. 250, 500, 1,000, 1,500, 2,000,

No.	**Proposed name:** Alvaiz **Established name:** eltrombopag **Dosage form:** Tablet **Strength(s):** 9 mg, 18 mg, 36 mg and 54 mg **Usual Dose:** One to two tablets once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			3,000 and 4,000 International Units), dose (9 mg to (b) (4) mg vs. individualized per the patient's needs*), dosage form (b) (4) vs. for injection), route (oral vs. intravenous) and frequency (once daily vs. once to four times daily depending on bleeding episode); thus, the product characteristic differences provide additional differentiation if included on a prescription. *Dose calculated as: Required dose (International Units) = body weight (kg) × desired factor VIII rise (IU/dL or % of normal) × 0.5 (IU/kg per IU/dL)
20.	Ayvakit	55	This name pair has sufficient orthographic and phonetic differences.
21.	Lybalvi	54	Orthographically, there is an upstroke letter 'l' in the second position of Alvaiz which is absent from Lybalvi. The infixes and suffixes (vaiz vs. balvi) of the name pair also have sufficient orthographic differences. Phonetically, the first ('Al' vs. 'Li') and second (' -vayz-' vs. ' -bal-') syllables sound different. In addition, Alvaiz has 2 syllables whereas Lybalvi has 3 syllables. Additionally, the products differ in strengths (9 mg, 18 mg, 36 mg and 54 mg vs. 5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg, 20 mg/10 mg) where the strength must be included on a prescription. Thus, the risk of name

No.	**Proposed name:** Alvaiz **Established name:** eltrombopag **Dosage form:** Tablet **Strength(s):** 9 mg, 18 mg, 36 mg and 54 mg **Usual Dose:** One to two tablets once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			confusion between the name pair is minimized.

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

No.	Name	POCA Score (%)
1.	Alrex	48
2.	Alli	46
3.	Alteplase	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.	Malvin	67	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	Laviv	65	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Amvaz	63	This product is withdrawn FR effective as of July 8, 2011 under NDA 21435. Brand discontinued with no generic equivalent available.
4.	Alphalin	62	This product is withdrawn FR effective as of June 9, 1993 under ANDA 080883. Brand discontinued with no generic available.
5.	Livial	62	International product marketed in numerous international countries.
6.	(b) (4) ***	59	Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA (OSE# (b) (4) No new names have been submitted.
7.	(b) (4) ***	58	Proposed CBER proprietary name found unacceptable by APLB on (b) (4) and was then found acceptable by the Review Division on (b) (4) IND (b) (4) was inactivated on (b) (4) and withdrawn on (b) (4)
8.	Alnide	58	International product formerly marketed in the United Kingdom.
9.	(b) (4) **	56	Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA (OSE# (b) (4) dated (b) (4) . IND (b) (4) is active and no new names have been submitted.
10.	Alpha E	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
11.	Alphavase	56	International product marketed in the United Kingdom.
12.	Albucid	55	International product marketed in South Africa, Germany, Indonesia and many other countries.
13.	Aluzine	55	This is a formerly marketed international drug product.
14.	alv-001	55	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[e].

No.	Name	POCA Score (%)
1.	Elavil	64
2.	Calm-Aid	62
3.	Galzin	62
4.	(b) (4)***	60
5.	Salvax	60
6.	Wal-Zan	60
7.	(b) (4)***	60
8.	Calcid	58
9.	Valmid	58
10.	Zolvit	58
11.	Solvadi	57
12.	Del-Vi-A	56
13.	Salzone	56
14.	Terlivaz***	56
15.	Ultiva	56
16.	Valbazen	56
17.	Valoid	56
18.	Valpin 50	56
19.	Valclair	55
20.	Wal-Zyr	55

[e] 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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MAXIMILIAN STRAKA
02/24/2022 09:58:03 AM

HINA S MEHTA
02/24/2022 11:41:49 AM

CHI-MING TU
02/24/2022 02:42:15 PM