

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761369Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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

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

Date of This Review:	6/3/2024
Responsible OND Division:	Division of Non-Malignant Hematology (DNH)
Application Type and Number:	BLA 761369
Product Name and Strength:	Hypavzi (marstacimab-hncq) injection, 150 mg/mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Pfizer, Inc. (Pfizer)
Nexus NPNS ID #:	2023-208
DMEPA 2 Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffix for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761369.

1.1 Regulatory History

Pfizer requested that FDA designate an appropriate suffix for their BLA^a.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

marstacimab-hncq

FDA generated a four-letter suffix, -hncq. This suffix was evaluated using the principles described in the applicable guidance^b.

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

3 COMMUNICATION OF DMEPA 2 ANALYSIS

These findings were shared with OPDP. On May 30, 2024, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Non-Malignant Hematology (DNH) on June 3, 2024.

^a Proprietary Names BLA 761369. New York (NY): Pfizer, Inc.; 2023 Dec 11. Available from:

<\\CDSESUB1\EVSPROD\bla761369\0001\m1\us\proprietary-name.pdf>

^b Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf>

4 CONCLUSION

We find the suffix -hncq acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to marstacimab-hncq. DMEPA 2 will communicate our findings to the Applicant via letter.

4.1 Recommendation for Pfizer, Inc.

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

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

/s/

CARLOS M MENA-GRILLASCA
06/03/2024 01:43:14 PM

CHI-MING TU
06/03/2024 01:56:17 PM

PROPRIETARY NAME REVIEW

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

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Date of This Review:	March 29, 2024
Application Type and Number:	BLA 761369
Product Name, Dosage Form, and Strength:	Hympavzi (marstacimab-xxxx) ^a Injection, 150 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Pfizer, Inc. (Pfizer)
PNR ID #:	2024-1044725562
DMEPA 2 Safety Evaluator:	Christina Topper, PharmD, BCPS
DMEPA 2 Team Leader (Acting):	Nicole Iverson, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature & Labeling:	Hina Mehta, PharmD

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

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Pfizer previously submitted the proposed proprietary name, (b) (4) *** under BLA 761369 on October 11, 2023. However, on December 20, 2023, we found the name, (b) (4) *** unacceptable due to orthographic similarities and shared product characteristics with the proprietary name, (b) (4) .^b

Thus, Pfizer submitted the proposed proprietary name, Hympavzi, for review on January 12, 2024 under BLA 761369.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 12, 2024^c and proposed Prescribed Information^d received on October 11, 2023

Table 1. Relevant Product Information for Hympavzi	
Intended pronunciation:	him-PAV-zee
Nonproprietary name:	marstacimab-xxxx
Indication:	Indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and pediatric patients 12 years of age and older with: <ul style="list-style-type: none">• Hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors, or• Hemophilia B (congenital factor IX deficiency) without factor XI inhibitors.
Dosage Form:	Injection
Strength:	150 mg/mL

^b Black, S. Proprietary Name Review for (b) (4) *** (BLA 761369). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2023 DEC 20. PNR ID No. 2023-1044725402.

^c Request for Proprietary Name Review (BLA 761369 Hympavzi (marstacimab-xxxx). Collegeville (PA): Pfizer, Inc.; 2024 JAN 12. Available from: <\\CDSESUB1\EVSPROD\bla761369\0015\m1\us\proprietary-name.pdf>.

^d Draft Prescribing Information (BLA 761369 and Hympavzi). New York (NY): Pfizer, Inc.; 2023 OCT 11. Available from: <\\CDSESUB1\EVSPROD\bla761369\0001\m1\us\uspi-lab-1556-0-1-clean.pdf>.

Table 1. Relevant Product Information for Hympavzi							
Route of administration:	subcutaneously						
Usual dosage and frequency:	<p>Administer marstacimab-xxxx by subcutaneous injection, once weekly, at any time of the day in the abdomen or thigh. Other injection sites are acceptable if required.</p> <p>The recommended dosage of marstacimab-xxxx for patients 12 years and older, weighing (b) (4) is as follows:</p> <ul style="list-style-type: none"> • Day 1: Administer 300 mg (two 150 mg injections) by subcutaneous injection (loading dose) • Day 8 and thereafter: Administer 150 mg every week by subcutaneous injection. <p><u>Dose Adjustment During Treatment</u></p> <p>A dose adjustment to 300 mg subcutaneous injection weekly can be considered in patients weighing ≥ 50 kg when control of bleeding events is judged to be inadequate by the healthcare provider.</p>						
How Supplied:	<p>Marstacimab-xxxx injection is a sterile, preservative-free, clear and colorless to light yellow solution for subcutaneous administration supplied in the following strengths and package configurations:</p> <table border="1"> <thead> <tr> <th>Unit of Sale</th> <th>Concentration</th> </tr> </thead> <tbody> <tr> <td>NDC 0069-1510-01 Carton of 1 single-dose prefilled syringe</td> <td>150 mg/mL</td> </tr> <tr> <td>NDC 0069-2151-01 Carton of 1 single-dose prefilled pen</td> <td>150 mg/mL</td> </tr> </tbody> </table> <p><u>Prefilled Syringe Carton – 150 mg/mL</u></p> <p>Each carton contains one single-dose prefilled syringe (Type I glass) with a plunger stopper (chlorobutyl elastomer) and a stainless steel 27 gauge, ½ inch, staked needle with a needle shield (thermoplastic elastomer).</p> <p>Each prefilled syringe contains 1 mL solution for injection.</p> <p><u>Prefilled Pen Carton – 150 mg/mL</u></p> <p>Each carton contains one single-dose prefilled pen. The syringe inside the pen is made from Type I glass with a plunger stopper (chlorobutyl elastomer) and a stainless steel 27 gauge, ½ inch, staked needle with a needle shield (thermoplastic elastomer).</p> <p>Each prefilled pen contains 1 mL solution for injection.</p> <p>Not made with natural rubber latex.</p>	Unit of Sale	Concentration	NDC 0069-1510-01 Carton of 1 single-dose prefilled syringe	150 mg/mL	NDC 0069-2151-01 Carton of 1 single-dose prefilled pen	150 mg/mL
Unit of Sale	Concentration						
NDC 0069-1510-01 Carton of 1 single-dose prefilled syringe	150 mg/mL						
NDC 0069-2151-01 Carton of 1 single-dose prefilled pen	150 mg/mL						

Table 1. Relevant Product Information for Hympavzi

Storage:	Store refrigerated between 36°F to 46°F (2°C to 8°C) in the original carton to protect from light. Product may be removed from refrigerated storage and may be stored in its original carton for one single period of maximum 7 days at room temperature [up to 86°F (30°C)]. The product must not be returned to refrigerated storage. Prior to end of this period of room temperature storage, the product must be used or discarded. Do not freeze. Do not shake.
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2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

There is no USAN stem present in the proposed proprietary name.^e

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Pfizer did not provide a derivation or intended meaning for the proposed proprietary name, Hympavzi, 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 can contribute to medication error.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

On February 14, 2024, the Division of Non-Malignant Hematology (DNH) did not forward any comments or concerns relating to Hympavzi at the initial phase of the review.

^e USAN stem search conducted on January 25, 2024.

2.2.4 FDA NAME SIMULATION STUDIES

Eighty-three (n=83) practitioners participated in DMEPA's prescription studies for Hympavzi.

The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search^f identified 13 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 lists the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	12
Low similarity name pair: combined match percentage score $\leq 54\%$	0

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

Our analysis of the 13 names contained in Table 2 determined none of the names will pose a risk for confusion with Hympavzi as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On March 29, 2024, DMEPA 2 communicated our determination to the Division of Non-Malignant Hematology (DNH).

3 CONCLUSION

The proposed proprietary name, Hympavzi, is conditionally acceptable.

If you have any questions or need clarifications, please contact Carol Corbie, OSE project manager, at 240-402-1124.

^f POCA search conducted on January 25, 2024 in version 5.5.

3.1 COMMENTS TO PFIZER, INC.

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

If any of the proposed product characteristics as stated in your submission, received on January 12, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems, available at <https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-stems>.

2. *Phonetic and Orthographic Computer Analysis (POCA)*

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved brand name and generic drugs; therapeutic biological products, prescription and over-the-counter human drugs; and discontinued drugs (see Drugs@FDA Glossary of Terms, available at <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms>).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (<http://www.nlm.nih.gov/research/umls/rxnorm/overview.html>).

Purple Book

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

Division of Medication Errors Prevention and Analysis pending proprietary name requests

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

5 APPENDICES

APPENDIX A. FDA'S PROPRIETARY NAME RISK ASSESSMENT EVALUATES PROPOSED PROPRIETARY NAMES FOR MISBRANDING AND SAFETY CONCERNS

1. **Misbranding Assessment:** For prescription drug products, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or ONPD provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. **Preliminary Assessment:** We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 3*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.⁹

*Table 3. Prescreening Checklist for Proposed Proprietary Name	
Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.	
Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.

⁹ National Coordinating Council for Medication Error Reporting and Prevention. <https://www.nccmerp.org/about-medication-errors>. Last accessed 10/05/2020.

*Table 3. Prescreening Checklist for Proposed Proprietary Name	
Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.	
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

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

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

Using the criteria outlined in the check list (Table 4-6) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 4).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
 - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in

the confusion of drug names^h. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.

- Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 5).
 - Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.
- c. FDA Prescription Simulation Studies: DMEPA also conducts prescription simulation studies using FDA health care professionals.
- Four separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions, verbal pronunciation of the drug name or during computerized provider order entry. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.
- In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.
- d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review.

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

Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the Safety Evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name.

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

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

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

Table 4. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is \geq 70%).			
Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such 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?		
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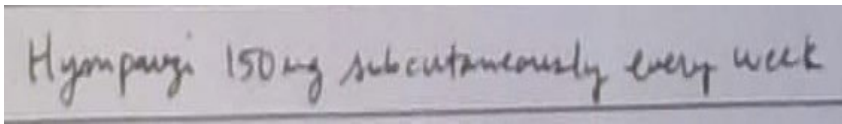
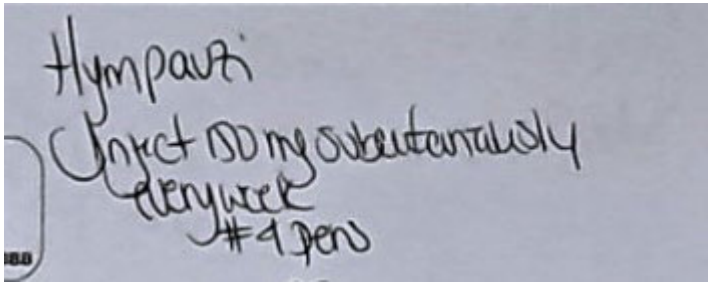
Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).			
Step 1	<p>Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths 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.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>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.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> • 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	<p>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.</p>		
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; vertical-align: top;"> <p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • 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 </td> <td style="width: 50%; vertical-align: top;"> <p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • 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? </td> </tr> </table>	<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • 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 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • 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?
<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • 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 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently? 		

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).		
	<p>there a different number or placement of upstroke/downstroke letters present in the names?</p> <ul style="list-style-type: none"> • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted? 	

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

APPENDIX B. PRESCRIPTION SIMULATION SAMPLES AND RESULTS

Figure 1. Hympavzi Study (Conducted on 1/26/2024)

Handwritten Medication Order Prescription	Verbal Prescription
<p>Medication Order:</p> 	<p>Hympavzi Inject 150 mg subcutaneously every week Dispense 4 pens</p>
<p>Outpatient Prescription:</p> 	
<p>CPOE Study Sample (displayed as sans-serif, 12-point, bold font)</p> <p>Hympavzi</p>	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Hympavzi					
People Received Study: 165					
People Responded: 83					
Total	22	18	23	20	83
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
HEMPAVSY	0	0	1	0	1
HEMPAVZI	0	0	1	0	1
HIMPABSY	0	0	1	0	1
HIMPAVSI	0	0	4	0	4
HIMPAVSY	0	0	1	0	1
HIMPAVZEE	0	0	2	0	2
HIMPAVZI	0	0	11	0	11
HYAMPAVZI	1	0	0	0	1
HYMPACZI	0	0	1	0	1
HYMPAUGI	1	0	0	0	1
HYMPAUZ	0	1	0	0	1

HYMPAUZI	2	0	0	0	2
HYMPAVJI	1	0	0	0	1
HYMPAVON	0	1	0	0	1
HYMPAVR	0	1	0	0	1
HYMPAVTI	0	1	0	0	1
HYMPAVX	0	1	0	0	1
HYMPAVZ	0	3	0	0	3
HYMPAVZI	15	8	0	20	43
HYMPAZI	0	1	0	0	1
HYMPAZVI	0	1	0	0	1
HYONPAVZI	1	0	0	0	1
HYVNPAUQI	1	0	0	0	1
IMPAVSI	0	0	1	0	1

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

No.	Proposed name: Hympavzi Established name: marstacimab-xxxx Dosage form: Injection Strength(s): 150 mg/mL Usual dose: Day 1: 300 mg subcutaneously once; Day 8 and thereafter: 150 mg or 300 mg subcutaneously every week	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.	Hympavzi	100	This name is the subject of this review.

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

No.	Name	POCA Score (%)
1.	Sympazan	63

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

No.	Proposed name: Hympavzi Established name: marstacimab-xxxx Dosage form: Injection Strength(s): 150 mg/mL Usual dose: Day 1: 300 mg subcutaneously once; Day 8 and thereafter: 150 mg or 300 mg subcutaneously every week	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.	Impavido	64	Orthographically, the prefix (Hym- vs. Im) and suffix ('-zi' vs. '-ido') provides some orthographic differences when scripted. Additionally, Hympavzi ends in the dotted letter 'i' and Impavido contains an upstroke letter 'd' in the seventh position of the name providing additional differentiation.

No.	Proposed name: Hympavzi Established name: marstacimab-xxxx Dosage form: Injection Strength(s): 150 mg/mL Usual dose: Day 1: 300 mg subcutaneously once; Day 8 and thereafter: 150 mg or 300 mg subcutaneously every week	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
			<p>We acknowledge 1 participant in the voice simulation study misinterpreted the name as Impavsi (the first letter 'H' was omitted).</p> <p>Phonetically, the ending of the second syllable (-pav- vs. -pah-) and the last syllables ('-zee' vs. '-doh') provide sufficient differences when spoken. Impavido contains an extra syllable.</p> <p>Although both products are single strength (150 mg/mL vs. 50 mg), where the strength may be omitted on a prescription, they differ in dose (150 mg and 300 mg vs. 50 mg), dosage form (injection vs. capsule), route of administration (subcutaneous vs. oral), and frequency (once and every week vs. twice daily and three times daily).</p> <p>Thus the risk of name confusion between the name pair is minimized.</p>
2.	Empaveli	62	This name pair has sufficient orthographic and phonetic differences.
3.	Hymovis	61	This name pair has sufficient orthographic and phonetic differences.

APPENDIX F: LOW SIMILARITY NAMES (e.g., combined POCA score is **≤54%**) -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 (%)	Failure preventions
1.	(b) (4) ***	67	Proposed proprietary name for BLA 761369 found unacceptable, due to a conflict with a marketed product, by DMEPA (OSE# 2023-1044725402 dated 12/20/2023). Proposed name Hympavzi, which is the subject of this review, was submitted for BLA 761369.
2.	Hypapril	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Hyospaz	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
4.	Hemavite F	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	(b) (4) ***	55	(b) (4)
6.	Hypaneze	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 confusionⁱ.

No.	Name	POCA Score (%)
1.	(b) (4) ***	58
2.	Lynparza	55

ⁱ Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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03/29/2024 11:06:55 AM

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	December 20, 2023
Application Type and Number:	BLA 761369
Product Name and Strength:	(b) (4) (marstacimab-xxxx) ^a injection, 150 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Pfizer, Inc. (Pfizer)
PNR ID #:	2023-1044725402
DMEPA 2 Safety Evaluator:	Sue Black, PharmD
DMEPA 2 Team Leader (Acting):	Nicole Iverson, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature and Labeling (Acting):	Hina Mehta, PharmD

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

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