CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761179Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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:	5/19/2021
Responsible OND Division:	Division of Hematologic Malignancies 1 (DHM 1)
Application Type and Number:	BLA 761179
Product Name and Strength:	Rylaze (asparaginase erwinia chrysanthemi (recombinant)-rywn) injection, 10 mg/0.5 mL
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Jazz Pharmaceuticals Ireland Limited (Jazz)
FDA Received Date:	April 30, 2021
Nexus NPNS ID #:	2021-26
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Division Director (Acting):	Lubna Merchant, MS, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Jazz for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761179.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On April 30, 2021, Jazz submitted a list of 9 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Jazz also provided findings from an external study conducted by (b) (4) evaluating the proposed four-letter suffixes in conjunction with the proprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Jazz.

Table 1. Suffixes submitted by Jazz***

1.	(b) (4)
2.	rywn
3.	(b) (4)
4.	
5.	
6.	
7.	
8.	
9.	

[a] Nonproprietary Name Suffix Review BLA 761179. Dublin (Ireland): Jazz Pharmaceutical Ireland Limited; 2021 Apr 30. Available from: \\CDSESUB1\evsprod\bla761179\0025\m1\us\118 nonproprietarynamesuffix-review_bla.pdf

(b) (4)

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

2.1 (b) (4)

(b) (4)

2.2 asparaginase erwinia chrysanthemi (recombinant)-rywn

Jazz's second proposed suffix, -rywn, is comprised of 4 distinct letters.

We determined that the proposed suffix -rywn, 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'S ANALYSIS

These findings were shared with OPDP. On May 18, 2021, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA also communicated our findings to the Division of Hematologic Malignancies 1 (DHM 1) on May 19, 2021.

[a] See Section VI which describes that any suffixes should be devoid of meaning in 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 Jazz's proposed suffix -rywn acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to asparaginase erwinia chrysanthemi (recombinant)-rywn. DMEPA will communicate our findings to the Applicant via letter.

4.1 Recommendations for Jazz Pharmaceuticals Ireland Limited

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

We also note that the first proposed suffix is unacceptable for the following reasons:

1. (b) (4)

[redacted]

[a] See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

We acknowledge that our evaluation differs from that of the external study performed by the [redacted] (b) (4) However, the external study did not evaluate whether the proposed suffix [redacted] (b) (4)

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/s/

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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)

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Date of This Review:	March 10, 2021
Application Type and Number:	BLA 761179
Product Name and Strength:	Rylaze (asparaginase Erwinia chrysanthemi (Recombinant)-xxxx)[a] injection, 20 mg/mL
Total Product Strength:	10 mg/0.5 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Jazz Pharmaceuticals Ireland Limited (Jazz)
Panorama or PNR ID #:	2020-1044425334
DMEPA Safety Evaluator:	Mariette Aidoo, PharmD, MPH
DMEPA Team Leader:	Hina Mehta, PharmD
DMEPA Associate Director of Nomenclature and Labeling:	Chi-Ming Tu, PharmD, BCPS

[a] The proposed nonproprietary name for this product at the time of this review is pending. We therefore refer to the proposed product as "asparaginase Erwinia chrysanthemi (Recombinant)-xxxx" throughout this review in place of the nonproprietary name for this product.

Contents

1 INTRODUCTION

This review responds to a December 18, 2020 request from Jazz to re-evaluate the proposed proprietary name, Rylaze. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively. Jazz re-submitted the external name study, conducted by [redacted] which was previously reviewed under the IND.

1.1 REGULATORY HISTORY

Jazz previously submitted the proposed proprietary name, Rylaze, on March 5, 2020. However, we found the name, Rylaze, unacceptable due to orthographic similarities and overlapping product characteristics with the another pending proposed proprietary name, [redacted].

Following the unacceptable decision for the proposed proprietary name, Jazz submitted this request for proposed proprietary name review on December 18, 2020.

We note that the conflicting proposed proprietary name, [redacted], has been withdrawn by the Applicant [redacted].***

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 18, 2020.

- Intended Pronunciation: rye layz'
- Nonproprietary Name: asparaginase Erwinia chrysanthemi (Recombinant)-xxxx
- Indication of Use: Indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of pediatric and adult patients with ALL or LBL who have developed hypersensitivity to *E. coli* derived L-asparaginase
- Route of Administration: intramuscular (IM)
- Dosage Form: injection
- Strength: 10 mg/0.5 mL
- Dose and Frequency: The two proposed dosing regimen are:
    - Regimen 1: The recommended dose is 25 mg/m^2 administered intramuscularly Monday and Wednesday and 50 mg/m^2 on Friday for a total of six doses every two weeks to replace each planned dose of long-acting *E.coli* asparaginase.
    - Regimen 2: The recommended dose is 25 mg/m^2 administered intramuscularly every 48 hours for two weeks for a total 7 doses for each scheduled dose of long-acting *E.coli* asparaginase.
- How Supplied: Single vial per packs; commercial pack size: 3 vials per carton.

[b] Iverson, N. Proprietary Name Review for Ryalaze (IND 129622). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 AUG 27. Panorama No. 2020-38295886.

- Storage: Store at 2°C to 8°C (36°F to 46°F). Unopened vials may be stored at room temperature (15°C to 25°C [59°F to 77°F]) for (b) (4)

1.3 RATIONALE FROM JAZZ

(b) (4)

Jazz submitted their evaluation of the name pair's orthographic and phonetic differences, product characteristics, indication, prescribers, setting of use, and other factors.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Rylaze would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Cardiology and Nephrology (DCN) concurred with the findings of OPDP's assessment for Rylaze.

2.2 SAFETY ASSESSMENT

The following aspects were re-evaluated in the safety evaluation of the proposed proprietary name, Rylaze.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Comments from Other Review Disciplines at Initial Review

On January 21, 2021, the Division of Cardiology and Nephrology (DCN) did not forward any comments or concerns relating to Rylaze at the initial phase of the review.

2.2.3 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified sixty-three names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that other than the change in the recommended product dosing (from 25 mg/ m^2 in our previous review to the currently proposed 25 mg/m^2 and 50 mg/m^2), no other product characteristics have changed. We re-evaluated previously identified names taking into account the change in dose and we agree

[c] USAN stem search conducted on February 23, 2021.

[d] POCA search conducted on February 23, 2021 in version 4.4.

with the findings from our previous review for the names evaluated previously with the exception of [redacted]***. Therefore, we identified three names not previously analyzed, and included [redacted]*** for re-evaluation. These names are included in Table 1 below.

2.2.4 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search, [redacted]***, and [redacted] 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%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	4
Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the 4 names contained in Table 1 determined none of the names will pose a risk for confusion with Rylaze as described in Appendices C through H.

2.3 EVALUATION OF RATIONALE FROM JAZZ

The conflicting proposed proprietary name, [redacted], has been withdrawn by the Applicant [redacted]*** Thus, we did not consider the information Jazz submitted for Rylaze in light of the fact that the conflict is resolved (See [redacted]*** in Appendix G).

2.4 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to Division of Cardiology and Nephrology (DCN). At that time we also requested additional information or concerns that could inform our review. On March 10, 2021, the Division of Cardiology and Nephrology (DCN) stated no additional concerns with the proposed proprietary name, Rylaze.

3 CONCLUSION

The proposed proprietary name, Rylaze, is acceptable.

If you have any questions or need clarifications, please contact Neil Vora, OSE project manager, at 240-402-4845.

3.1 COMMENTS TO JAZZ PHARMACEUTICALS IRELAND LIMITED

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

If any of the proposed product characteristics as stated in your submission, received on December 18, 2020, 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. 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.[e]

[e] 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 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.

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[f]. We evaluate all moderately similar names retrieved from

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

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

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

No.	**Proposed name:** Rylaze **Established name:** asparaginase Erwinia chrysanthemi (Recombinant)-xxxx **Dosage form:** injection **Strength(s):** 10 mg/0.5 mL **Usual Dose:** - 25 mg/m2 administered intramuscularly Monday and Wednesday and 50 mg/m2 on Friday for a total of six doses every two weeks. - 25 mg/m2 administered intramuscularly every 48 hours for two weeks for a total 7 doses.	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.	N/A		

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)***	60

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:** Rylaze **Established name:** asparaginase Erwinia chrysanthemi (Recombinant)-xxxx **Dosage form:** injection **Strength(s):** 10 mg/0.5 mL **Usual Dose:** - 25 mg/m2 administered intramuscularly Monday and Wednesday and 50 mg/m2 on Friday for a total of six doses every two weeks. - 25 mg/m2 administered intramuscularly every 48 hours for two weeks for a total 7 doses.	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.	(b) (4) **	58	(b) (4)

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.	Amylase	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
2.	(b) (4) ***	70	(b) (4) Proposed proprietary name withdrawn by the Applicant (b) (4)

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[g]. – N/A

[g] 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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