CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214383Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	September 11, 2020
Application Type and Number:	IND 116362 and NDA 214383
Product Name and Strength:	Pepaxto (melphalan flufenamide) for Injection, 20 mg/vial
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Oncopeptides AB
Panorama #:	2020-38682071 and 2020-41896821
DMEPA Safety Evaluator:	Nicole Iverson, PharmD, BCPS
DMEPA Team Leader:	Hina Mehta, PharmD

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Oncopeptides AB previously submitted the proposed proprietary name, Ygalo*** on June 18, 2019. However, we found the name, Ygalo *** unacceptable due to orthographic similarities and shared product characteristics with the proprietary name, Zyflo under NDA 020471 on December 10, 2019.[a]

Thus, Oncopeptides AB submitted the name, Pepaxto, for review on March 20, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 20, 2020.

- Intended Pronunciation: peh-PAX-toe
- Active Ingredient: melphalan flufenamide
- Indication of Use: For the treatment of relapsed-refractory multiple myeloma (RRMM)
- Route of Administration: intravenous infusion
- Dosage Form: for Injection
- Strength: 20 mg/vial
- Dose and Frequency: 40 mg administered by intravenous infusion every 28 days until disease progression or unacceptable toxicity.
- How Supplied: Single 20 mg vial unit per carton
- Storage: Store refrigerated at 2 to 8°C. Protect from light.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Pepaxto would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and

[a] DeGraw, S. Proprietary Name Review for Ygalo (IND 116362). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 DEC 10. Panorama No. 2019-32522514.

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the Division of Hematologic Malignancies 2 (DHM 2) concurred with the findings of OPDP's assessment for Pepaxto.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

Additionally, we note the three-letter string 'Pep-' is present in the proposed proprietary name and the Sponsor's name. Our draft Guidance for Industry Best Practices in Developing Proprietary Names for Drugs, states "proprietary names should not incorporate the sponsor's name across multiple products (e.g., "ABCName1," "ABCName2," "ABCName3"). This practice can result in creating multiple similar proprietary names, which might increase the risk of confusion among the products. The practice can be problematic when products are stored alphabetically in distributor or pharmacy locations or when products are ordered from alphabetized lists."[c] We note that there are multiple products that contain the letter string 'Pep-' across multiple sponsors (Pepcid, Pepcid AC, Pepcid Complete, and Zenpep). We conducted a FAERS search and did not identify any cases of drug name confusion between the currently marketed products containing the letter string 'Pep-' (see Section 2.2.5). Therefore, in this case, we find the use of the letters 'Pep-' in the name acceptable.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, April 10, 2020 e-mail, the Division of Hematologic Malignancies 2 (DHM 2) did not forward any comments or concerns relating to Pepaxto at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-two (92) practitioners participated in DMEPA's prescription studies for Pepaxto. 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.

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[b] USAN stem search conducted on August 3, 2020.

[c] Draft Guidance for Industry: Best Practices in Developing Proprietary Names for Drugs. 2014. Available from: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm398997.pdf.

2.2.5 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 1 (see Appendix A1 for a description of FAERS database) for name confusion errors involving Pepaxto that would be relevant for this review.

Table 1. FAERS Search Strategy	
Search Date	August 7, 2020
Drug Name	Pepcid, Pepcid AC, Pepcid Complete and Zenpep [product name]
Event (MedDRA Terms)	**DMEPA Official PNR Name Confusion Search Terms Event List:** **Preferred terms:** Circumstance or information capable of leading to medication error Drug administration error Drug dispensing error Drug prescribing error Intercepted drug dispensing error Intercepted drug prescribing error Intercepted medication error Medication error Product name confusion Transcription medication error **Lower level terms:** Intercepted product selection error Intercepted wrong drug product selected Intercepted wrong drug selected Product selection error Wrong device dispensed Wrong drug administered Wrong drug dispensed Wrong drug prescribed Wrong drug product selected Wrong drug selected Wrong product selected
Date Limits	Approval date to June 1, 2020

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

After individual review, three reports were not included in the final analysis as they were not relevant to drug name confusion.

Following exclusions, the search did not yield any relevant cases.

2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 119 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.7 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and (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%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	124
Low similarity name pair: combined match percentage score ≤54%	2

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

Our analysis of the 127 names contained in Table 1 determined none of the names will pose a risk for confusion with Pepaxto as described in Appendices C through H.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Hematologic Malignancies 2 (DHM 2) via e-mail on September 4, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Hematologic Malignancies 2 (DHM 2) on September 11, 2020, they stated no additional concerns with the proposed proprietary name, Pepaxto.

3 CONCLUSION

The proposed proprietary name, Pepaxto, is acceptable.

[d] POCA search conducted on May 22, 2020 in version 4.2.

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

3.1 COMMENTS TO ONCOPEPTIDES AB

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

If any of the proposed product characteristics as stated in your submission, received on March 20, 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 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. [e]

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

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***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%.

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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 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.

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

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?		

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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.

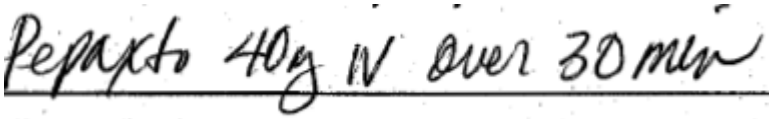
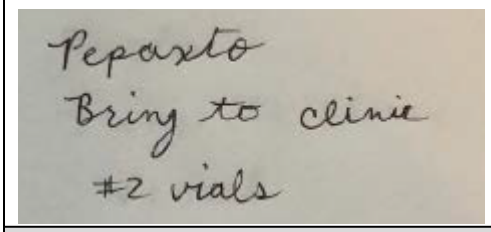
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Pepaxto Study (Conducted on April 7, 2020)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Pepaxto Bring to clinic Dispense #2 vials
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Pepaxto	

FDA Prescription Simulation Responses (Aggregate Report)

209 People Received Study

92 People Responded

Study Name: Pepaxto

Total	**23**	**20**	**31**	**18**	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
PAPACTO	0	0	1	0	1
PAPAKTO	0	0	1	0	1
PAPAXTO	0	0	1	0	1
PAPAXTONE	0	0	1	0	1
PAYPACKTO	0	0	3	0	3
PAYPACTO	0	0	3	0	3

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PAYPAKTO	0	0	1	0	1
PAYPAXTO	0	0	19	0	19
PAYPAXTOE	0	0	1	0	1
PEPAXTO	22	20	0	17	59
PEPAXTO IV	0	0	0	1	1
PEPAXTO OR PEPOXTO	1	0	0	0	1

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

No.	**Proposed name:** Pepaxto **Established name:** melphalan flufenamide **Dosage form:** for Injection **Strength(s):** 20 mg/vial **Usual Dose:** 40 mg administered by intravenous infusion every 28 days until disease progression or unacceptable toxicity.	**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.	Pepaxto***	100	Subject of this review

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

No.	Name	POCA Score (%)
2.	Depakote Er	56
3.	Picato	58
4.	Pradaxa	58
5.	(b) (4)***	56

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:** Pepaxto **Established name:** melphalan flufenamide **Dosage form:** for Injection **Strength(s):** 20 mg/vial **Usual Dose:** 40 mg administered by intravenous infusion every 28 days until disease progression or unacceptable toxicity.	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
6.	Adipex-P	64	This name pair has sufficient orthographic and phonetic differences.
7.	Copaxone	60	This name pair has sufficient orthographic and phonetic differences.
8.	Depakote	62	This name pair has sufficient orthographic and phonetic differences. Orthographically, this name pair begins with different letters (‘D’ vs. ‘P’) and

No.	**Proposed name:** Pepaxto **Established name:** melphalan flufenamide **Dosage form:** for Injection **Strength(s):** 20 mg/vial **Usual Dose:** 40 mg administered by intravenous infusion every 28 days until disease progression or unacceptable toxicity.	**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**
			suffixes (‘-kote’ vs. ‘-toe’) look different. Phonetically, the 2nd syllables (‘a’ in ‘ax’), and 3rd syllables (‘kote’ vs. ‘toe’) provide phonetic difference. In addition to the orthographic and phonetic differences, the following nonoverlapping product characteristics would help mitigate the error when written/ordered on a prescription: dosage form (injection vs. delayed-release tablet), route of administration (intravenous vs. oral), strength (20 mg vs. 125 mg, 250 mg, and 500 mg), frequency of administration (every 28 days until disease progression or unacceptable toxicity vs. once daily OR twice daily), dose (40 mg vs. 10 mg/kg to 60 mg/kg/day OR 250 mg to 1,500 mg) and indication (relapsed refractory multiple myeloma vs. complex partial seizures and complex absence seizures). Additionally, because injectable oncology drugs administered by healthcare professionals typically undergo independent double checks by two pharmacists in the usual clinical setting, the likelihood of both pharmacists overlooking the difference in dosage form, routes of administration, and frequency of administration is minimized. When the

No.	**Proposed name:** Pepaxto **Established name:** melphalan flufenamide **Dosage form:** for Injection **Strength(s):** 20 mg/vial **Usual Dose:** 40 mg administered by intravenous infusion every 28 days until disease progression or unacceptable toxicity.	**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**
			above is considered in totality, we find low the potential for name confusion with this name pair to be minimal.
9.	Hepzato***	56	This name pair has sufficient orthographic and phonetic differences. Orthographically, this name pair begins with different letters (‘H’ vs. ‘P’) and the infixes (‘-za-’ vs. ‘-ax-‘) look different. In addition, the modifier ‘Kit’ provides orthographic differentiation when included. Phonetically, the beginning sounds in the 1st syllables (‘H’ in Hep vs. ‘P’ in Pep) and the in the 2nd syllables (‘za’ in ‘ax’) provide slight phonetic difference. In addition, Hepzato Kit has 4 syllables when the modifier ‘Kit’ is included for a prescription, whereas Pepaxto has 3 syllables. (b) (4)

No.	**Proposed name:** Pepaxto **Established name:** melphalan flufenamide **Dosage form:** for Injection **Strength(s):** 20 mg/vial **Usual Dose:** 40 mg administered by intravenous infusion every 28 days until disease progression or unacceptable toxicity.	**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** (b) (4)
10.	Onexton	58	This name pair has sufficient orthographic and phonetic differences.
11.	Pacnex	55	This name pair has sufficient orthographic and phonetic differences.
12.	Panex	57	This name pair has sufficient orthographic and phonetic differences.
13.	Panex 500	57	This name pair has sufficient orthographic and phonetic differences.
14.	Pediatex Ct	58	This name pair has sufficient orthographic and phonetic differences.
15.	Pentetate	55	This name pair has sufficient orthographic and phonetic differences.
16.	Pentoxil	57	This name pair has sufficient orthographic and phonetic differences.
17.	Pentrax	62	This name pair has sufficient orthographic and phonetic differences.
18.	Pexeva	55	This name pair has sufficient orthographic and phonetic differences.
19.	Photrexa	59	This name pair has sufficient orthographic and phonetic differences.
20.	Predator	56	This name pair has sufficient orthographic and phonetic differences.
21.	Prenexa	56	This name pair has sufficient orthographic and phonetic differences.
22.	Promacta	55	This name pair has sufficient orthographic and phonetic differences.
23.	Pytest	57	This name pair has sufficient orthographic and phonetic differences.
24.	Topex	65	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Pepaxto **Established name:** melphalan flufenamide **Dosage form:** for Injection **Strength(s):** 20 mg/vial **Usual Dose:** 40 mg administered by intravenous infusion every 28 days until disease progression or unacceptable toxicity.	**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**
25.	Zotex Pe	64	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
26.	Pepcid	50
27.	Refacto	54
28.	Zipantol	52

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
29.	Cepastat	63	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
30.	Comixco	52	International product formerly marketed in the UK.
31.	Depakota	65	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
32.	Depakote Cp	55	Brand discontinued with no generic equivalents available. NDA 019794 withdrawn FR effective 06/18/2009.
33.	(b) (4) ***	60	Proposed proprietary name for CBER IND 14171 and found unacceptable on September 11, 2017 by the Advertising and Promotional Labeling Branch (APLB). However, the corresponding BLA 125701 was approved under the name Menquadfi.
34.	Mepact	62	International product marketed in Italy, Poland, Argentina, Austria, Germany, Greece, Ireland, Netherlands, Norway, Sweden, Switzerland, and the UK.

No.	Name	POCA Score (%)	Failure preventions
35.	(b) (4) ***	57	Proposed proprietary name for CBER IND 15463 was found acceptable on August 15, 2018 by the Advertising and Promotional Labeling Branch (APLB). However, the corresponding BLA 125696 was approved under the name Palforzia.
36.	Pandex	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
37.	Papacon	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
38.	Papulex	56	International product marketed in France, Malaysia, Philippines, Hong Kong, and Indonesia.
39.	Pattotic	55	Veterinary product.
40.	Paxofen	58	International product marketed formerly in the UK.
41.	Paxtin	62	International product marketed in Poland and Australia.
42.	Pediatex	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
43.	Pediatex 12	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
44.	Pediatex 12D	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
45.	Pediatex D	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
46.	Pediatex Td	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
47.	Pediox	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
48.	Peditex	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
49.	Pen-G Max	58	Veterinary product.
50.	Pentasol	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
51.	Pentaspan	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
52.	Pentostam	57	International product marketed in the UK and Israel.
53.	Pentoxyl	56	International product marketed in Hungary.
54.	Pentrax Gold	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
55.	Peptac	56	International product marketed in the UK.

No.	Name	POCA Score (%)	Failure preventions
56.	Peptavlon	57	Brand discontinued with no generic equivalents available. NDA 017048 withdrawn FR effective 09/17/2003.
57.	Peptazol	62	International product marketed in Malaysia, Singapore, Argentina, Russia, Italy, and Hong Kong.
58.	Peptimax 200	60	International product formerly marketed in the UK.
59.	Peptimax 400	60	International product formerly marketed in the UK.
60.	Peptimax 800	60	International product formerly marketed in the UK.
61.	Peptones	58	This product is not a drug. It is a soluble protein formed in the early of protein breakdown during digestion.
62.	Permax	60	Brand discontinued with no generic equivalents available. NDA 019385 withdrawn FR effective 04/08/2009.
63.	Phentex La	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
64.	Pipexus	63	International product marketed in the UK.
65.	Plenaxis	56	Brand discontinued with no generic equivalents available. NDA 021320 withdrawn FR effective 08/19/2013.
66.	Poly Pact	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
67.	Posatex	61	Veterinary product.
68.	Predacort 50	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
69.	Pri-Dextra	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
70.	Pritox	56	Veterinary product.
71.	Probax	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
72.	Propacet	61	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
73.	Propacet 100	61	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
74.	Propacet 100	61	Brand discontinued with no generic equivalents available. ANDA 070107 withdrawn FR effective 01/22/1999.
75.	Propagest	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
76.	Protectol	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
77.	Protex	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
78.	Protex D	66	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
79.	Sepasoothe	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
80.	Xpect-At	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
81.	Zenapax	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

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

No.	Name	POCA Score (%)
82.	Apexicon	59
83.	Atenixco	59
84.	Atti Plex P	61
85.	Bepotastine	56
86.	Betasept	58
87.	Betastat	56
88.	Betaxolol	56
89.	Betaxon	66
90.	Capacet	56
91.	Capastat	57
92.	Capex	59
93.	Carba Xp	55
94.	Cetacort	55
95.	Cypex	56
96.	Depixol	62
97.	Depotest	62
98.	Entex T	56
99.	Epermax	57
100.	(b) (4) ***	56
101.	(b) (4) ***	55

[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

No.	Name	POCA Score (%)
102.	Kaopectate	56
103.	Keppra Xr	59
104.	Medi-Paste	56
105.	Mentax-Tc	58
106.	Natesto	57
107.	Nuedexta	56
108.	(b) (4)***	57
109.	Optimax	55
110.	Siennaxp***	56
111.	Sivextro	60
112.	Tapentadol	56
113.	Taztia Xt	57
114.	Tepmetko***	62
115.	Tetraxetan	58
116.	Tetroxy	56
117.	Tezacaftor	56
118.	Theraplex T	55
119.	Ti-Plex	58
120.	Topamax	58
121.	Topex Apf	64
122.	Tpoxx	60
123.	Trepoxen-250	58
124.	Triple Paste	56
125.	Xpect Hc	56
126.	Xpect Pe	62
127.	Zotex-Gp	57

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/s/

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