# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 761102Orig1s000

# 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:** | March 22, 2018 |
| **Application Type and Number:** | BLA 761102 |
| **Product Name and Strength:** | Asparlas (calaspargase pegol) Injection<br>3,750 units/5 mL (750 units/mL) |
| **Total Product Strength:** | 750 units/mL |
| **Product Type:** | Single-Ingredient |
| **Rx or OTC:** | Rx |
| **Applicant/Sponsor Name:** | Baxalta |
| **Panorama #:** | 2017- 20079824 |
| **DMEPA Safety Evaluator:** | Leeza Rahimi, Pharm.D. |
| **DMEPA Team Leader:** | Hina Mehta, Pharm.D. |

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# 1 INTRODUCTION

This review evaluates the proposed proprietary name, Asparlas, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A, respectively. The Applicant submitted an external name study, conducted by [redacted] (b) (4) for this proposed proprietary name.

## 1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 22, 2017.

- Intended Pronunciation: N/A
- Active Ingredient: calaspargase pegol
- Indication of Use: a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia (ALL)
- Route of Administration: intravenous infusion
- Dosage Form: Injection
- Strength: 3,750 units/5 mL (750 units/mL)
- Dose and Frequency: 2,500 units/$m^2$ administered intravenously [redacted] (b) (4) in 100 mL of 0.9% sodium chloride or 5% dextrose injection every 21 days.
- How Supplied: single-dose vial
- Storage: [redacted] (b) (4) Do not shake or freeze product [redacted] (b) (4)

# 2 RESULTS

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

## 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Hematology Products (DHP) concurred with the findings of OPDP's assessment of the proposed name.

## 2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

### *2.2.1 United States Adopted Names (USAN) Search*

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

### *2.2.2 Components of the Proposed Proprietary Name*

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

### *2.2.3 Comments from Other Review Disciplines at Initial Review*

In response to the OSE, January 18, 2018 e-mail, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

### *2.2.4 FDA Name Simulation Studies*

Seventy-two (n=72) practitioners participated in DMEPA's prescription studies. 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 verbal and written prescription studies.

### *2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Our POCA search[b] identified 138 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%**.** These names are included in Table 1 below.

### *2.2.6 Names with Strength Overlap and Potential Orthographic, Spelling, and Phonetic Similarities*

The proposed product, Asparlas will be available in 3,750 units/5 mL (750 units/mL) strength. Since this is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify names with strength overlap. Our search did not retrieve any results.

### *2.2.7 Names Retrieved for Review Organized by Name Pair Similarity*

Table 1 lists the number of names retrieved from our POCA search and the (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

[a] USAN stem search conducted on January 23, 2018

[b] POCA search conducted on January 23, 2018 in version 4.2.

| Table 1. Similarity Category | Number of Names |
|---|---|
| Highly similar name pair:<br>combined match percentage score ≥70% | 4 |
| Moderately similar name pair:<br>combined match percentage score ≥55% to ≤ 69% | 136 |
| Low similarity name pair:<br>combined match percentage score ≤54% | 37 |

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

Our analysis of the 177 names contained in Table 1 determined none of the names will pose a risk for confusion 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 Hematology Products (DHP) via e-mail on March 20, 2018. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DHP on March 21, 2018, they stated no additional concerns with the proposed proprietary name, Asparlas.

## 3 CONCLUSION

The proposed proprietary name 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 THE APPLICANT

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

A request for proprietary name review for Asparlas should be submitted once the BLA is submitted.

If any of the proposed product characteristics as stated in your submission, received on December 22, 2017, are altered prior to approval of the marketing application, the name must be resubmitted for review.

## 4 REFERENCES


1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   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.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

## APPENDICES

### Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [c]

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

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

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

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

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[d]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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[d] 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.

   Three 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 or verbal pronunciation of the drug name. 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 orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

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?<br>*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?<br>**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.<br><br>For single strength products, also consider circumstances where the strength may not be expressed.<br><br>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.<br><br>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:<br><br>• 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.<br><br>• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.<br><br>• 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. |

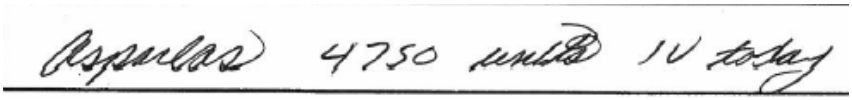
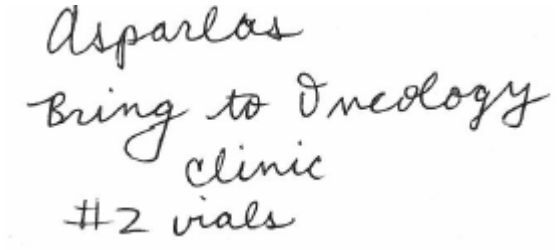
| | | |
|---|---|---|
| | Orthographic Checklist (Y/N to each question)<br>• Do the names begin with different first letters?<br>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br>• Are the lengths of the names dissimilar* when scripted?<br>*FDA considers the length of names different if the names differ by two or more letters.<br>• 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?<br>• Is there different number or placement of cross-stroke or dotted letters present in the names?<br>• Do the infixes of the name appear dissimilar when scripted?<br>• Do the suffixes of the names appear dissimilar when scripted? | Phonetic Checklist (Y/N to each question)<br>• Do the names have different number of syllables?<br>• Do the names have different syllabic stresses?<br>• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?<br>• 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. Asparlas Study (Conducted on January 26, 2018)**

| Handwritten Medication Order/Prescription | Verbal Prescription |
|---|---|
| Medication Order:<br>  <br> | Asparlas<br>Bring to oncology clinic<br># 2 vials |
| Outpatient Prescription:<br>  <br> | |

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

## Study Name: Asparlas

As of Date 2/26/2018

301 People Received Study
72 People Responded

Study Name: Asparlas

| Total | 20 | 19 | 33 | |
|---|---|---|---|---|
| **INTERPRETATION** | **OUTPATIENT** | **VOICE** | **INPATIENT** | **TOTAL** |
| ASPARALAS | 0 | 0 | 1 | 1 |
| ASPARLA | 0 | 1 | 0 | 1 |
| ASPARLACE | 0 | 1 | 0 | 1 |
| ASPARLAS | 20 | 1 | 27 | 48 |
| ASPARLES | 0 | 1 | 0 | 1 |
| ASPARLESS | 0 | 1 | 0 | 1 |
| ASPARLIS | 0 | 4 | 0 | 4 |
| ASPARLOS | 0 | 0 | 1 | 1 |
| ASPARLUS | 0 | 4 | 0 | 4 |
| ASPARLYS | 0 | 1 | 0 | 1 |
| ASPERLAS | 0 | 0 | 2 | 2 |
| ASPERLOS | 0 | 0 | 1 | 1 |
| ASPHARLUS | 0 | 1 | 0 | 1 |
| ASPRALAS | 0 | 0 | 1 | 1 |
| ASSBARLIS | 0 | 1 | 0 | 1 |
| HASPARLAS | 0 | 1 | 0 | 1 |
| HASPARLIS | 0 | 2 | 0 | 2 |

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

| No. | **Proposed name:** Asparlas<br>**Established name:** calaspargase<br>**Dosage form:** injection<br>**Strength(s):** 3,750 units/5 mL (750 units/mL)<br>**Usual Dose:** 2,500 units/$m^2$ intravenously every 21 days over 1 hour | POCA Score (%) | **Orthographic and/or phonetic differences in the names sufficient to prevent confusion**<br><br>**Other prevention of failure mode expected to minimize the risk of confusion between these two names.** |
|---|---|---|---|
| 1. | Asparlas | 100 | Subject of the study |
| 2. | Aspir-Low | 72 | Orthographic differences: Aspir Low has a dotted letter 'i' in the 4th position whereas Asparlas has a rounded letter 'a'. Aspir Low has a letter ‘w’ in the last position, whereas Asparlas has the letter ‘s’. This provides some orthographic differences.<br><br>Phonetic differences: The third syllables (low vs. las) of the name pair sound different.<br><br>Aspir-Low vs. Asparlas:<br>Route of Administration: oral vs. intravenous infusion<br>Dosage form: tablet vs. for injection<br>Dose and frequency: 4 to 8 tablets every 4 hours (not to exceed 48 tablets in 24 hours) vs. 2,500 units/$m^2$ over 1 hour infusion, every 21 days |

| No. | **Proposed name:** Asparlas<br>**Established name:** calaspargase<br>**Dosage form:** injection<br>**Strength(s):** 3,750 units/5 mL (750 units/mL)<br>**Usual Dose:** 2,500 units/$m^2$ intravenously every 21 days over 1 hour | **POCA Score (%)** | **Orthographic and/or phonetic differences in the names sufficient to prevent confusion**<br><br>**Other prevention of failure mode expected to minimize the risk of confusion between these two names.** |
|---|---|---|---|
| 3. | Aspircaf | 70 | Orthographic differences: Aspircaf has a dotted letter 'i' in the 4th position and an upstroke letter 'f' in the 8th position, whereas Asparlas has a rounded letter ‘a’ in the 4th position and an upstroke letter ‘l’ in the 6th position. This provides some orthographic differences.<br>Phonetic differences: The last syllables of the name pair (caf vs. las) sound different.<br><br>Aspircaf vs. Asparlas:<br>Route of administration: oral vs. intravenous infusion<br>Dosage Form: tablets vs. for injection<br>Dosing and frequency: 2 tablets every 6 hours (do not exceed 8 tablets in 24 hours) vs. 2,500 units/$m^2$ over 1 hour infusion, every 21 days |
| 4. | Starlix | 70 | The prefixes (St vs. Asp) and suffixes (ix vs. as) provide sufficient orthographic differences.<br>Asparlas contains an additional syllable compared to Starlix. The first (Star vs. As) and second (lix vs. par) syllable of this name pair sound different.<br><br>Starlix vs. Asparlas:<br>Route of administration: oral vs. intravenous infusion<br>Dosage form: tablets vs. for injection<br>Strength: 60 mg and 120 mg vs. 3,750 units/5 mL (750 units/mL)<br>Dosing frequency: three times daily before meals vs. every 21 days |

**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 (%) |
|---|---|---|
| 5. | Estarylla | 69 |
| 6. | Astagraf | 68 |
| 7. | Yosprala | 65 |
| 8. | Spirapril | 59 |
| 9. | Alteplase | 58 |
| 10. | Aralast | 58 |
| 11. | Exparel | 58 |
| 12. | Marlissa | 58 |
| 13. | Natpara | 58 |
| 14. | Abstral | 57 |
| 15. | Alphavase | 56 |
| 16. | Antispas | 56 |
| 17. | Asclera | 56 |
| 18. | Nasarel | 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:** Asparlas<br>**Established name:** calaspargase<br>**Dosage form:** injection<br>**Strength(s):** 3750 units/5 mL **(**750 units/mL)<br>**Usual Dose:** 2,500 units/$m^2$ intravenously every 21 days over 1 hour | POCA Score (%) | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 19. | Asper-Flex | 68 | The suffixes (las vs. flex) provide sufficient orthographic differences. The last syllables (las vs. flex) provide sufficient phonetic differences.<br><br>Asper-Flex vs. Asparlas<br>Dosage form: Topical gel vs. injection<br>Dose and frequency: Apply in to affected area, until thoroughly absorbed. Repeat as necessary, but no more than 4 times daily vs. 2,500 units/$m^2$ over 1 hour infusion, every 21 days |

| No. | **Proposed name:** Asparlas<br>**Established name:** calaspargase<br>**Dosage form:** injection<br>**Strength(s):** 3750 units/5 mL **(**750 units/mL)<br>**Usual Dose:** 2,500 units/$m^2$ intravenously every 21 days over 1 hour | **POCA Score (%)** | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 20. | Aspirtab | 68 | The suffixes (las vs. tab) provide sufficient orthographic differences. The last syllables (las vs. tab) provide sufficient phonetic differences.<br><br>Aspirtab vs. Asparlas<br>Dosage form: Oral caplet vs. injection<br>Dose and frequency: 1-2 caplets every 4 hours NTE 12 caplets in 24 hours unless directed by a doctor vs. 2,500 units/$m^2$ over 1 hour infusion, every 21 days |
| 21. | A-spas S/L | 67 | The name pair has sufficient orthographic and phonetic differences. |
| 22. | A-spas | 66 | The name pair has sufficient orthographic and phonetic differences. |
| 23. | Aspertec*** | 64 | The name pair has sufficient orthographic and phonetic differences.<br><br>Aspertec vs. Asparlas<br>Dosage form: Oral capsule vs. injection<br>Dose and frequency: 1-2 capsule every 4 hours NTE 12 capsule in 24 hours unless directed by a doctor vs. 2,500 units/$m^2$ over 1 hour infusion, every 21 days |
| 24. | Ascarel | 64 | The name pair has sufficient orthographic and phonetic differences. |
| 25. | Acular LS | 63 | This name pair has sufficient orthographic and phonetic differences. |
| 26. | Aspirin | 61 | This name pair has sufficient orthographic and phonetic differences.<br><br>Aspirin vs. Asparlas<br>Dosage form: oral tablet vs. injection<br>Dose and frequency: 81 mg, 325 mg vs. 2,500 units/$m^2$ over 1 hour infusion, every 21 days |
| 27. | Asmalix | 61 | This name pair has sufficient orthographic and phonetic differences. |

| No. | **Proposed name:** Asparlas<br>**Established name:** calaspargase<br>**Dosage form:** injection<br>**Strength(s):** 3750 units/5 mL **(**750 units/mL)<br>**Usual Dose:** 2,500 units/$m^2$ intravenously every 21 days over 1 hour | **POCA Score (%)** | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 28. | Aspi-Rub | 61 | This name pair has sufficient orthographic and phonetic differences.<br><br>Aspi-Rub vs. Asparlas<br>Dosage form: Topical oil vs. injection<br>Dose and frequency: apply to painful area 3-4 times daily vs. 2,500 units/$m^2$ over 1 hour infusion, every 21 days |
| 29. | (b) (4) *** | 61 | The name pair has sufficient orthographic and phonetic differences. |
| 30. | Serpalan | 60 | The name pair has sufficient orthographic and phonetic differences. |
| 31. | Ascor L 500 | 62 | The name pair has sufficient orthographic and phonetic differences. |
| 32. | Alcare Plus | 60 | This name pair has sufficient orthographic and phonetic differences. |
| 33. | spacol T/S | 59 | The name pair has sufficient orthographic and phonetic differences. |
| 34. | Vanspar | 59 | This name pair has sufficient orthographic and phonetic differences. |
| 35. | Acerola C | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 36. | Aralast | 58 | The name pair has sufficient orthographic and phonetic differences. |
| 37. | Aspir-Trin | 58 | This name pair has sufficient orthographic and phonetic differences.<br><br>Aspir-Trin vs. Asparlas<br>Dosage form: tablet vs. injection<br>Dose and frequency; 1-2 tab po every 4 hours vs. 2,500 units/$m^2$ over 1 hour infusion, every 21 days |
| 38. | Basaglar | 58 | This name pair has sufficient orthographic and phonetic differences. |

| No. | **Proposed name:** Asparlas<br>**Established name:** calaspargase<br>**Dosage form:** injection<br>**Strength(s):** 3750 units/5 mL **(**750 units/mL)<br>**Usual Dose:** 2,500 units/$m^2$ intravenously every 21 days over 1 hour | POCA Score (%) | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 39. | Elspar | 58 | This name pair has sufficient orthographic and phonetic differences.<br>The beginning sounds (El vs. A) and the additional syllable 'las' in Asparlas provide some phonetic differences.<br><br>Elspar vs. Asparlas<br>Dose: 2,500 units/m2 vs. 6,000 units/m2<br>Frequency of administration: every 21 days vs. three times a week |
| 40. | Respaire-120 Sr | 58 | The name pair has sufficient orthographic and phonetic differences. |
| 41. | Respaire-60 Sr | 58 | The name pair has sufficient orthographic and phonetic differences. |
| 42. | Elaprase | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 43. | Ala-Scalp | 57 | The name pair has sufficient orthographic and phonetic differences. |
| 44. | Alprolix | 57 | The name pair has sufficient orthographic and phonetic differences. |
| 45. | Apremilast | 56 | The name pair has sufficient orthographic and phonetic differences. |
| 46. | Asparaginase | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 47. | Carlesta | 56 | The name pair has sufficient orthographic and phonetic differences. |
| 48. | sparklefresh | 56 | The name pair has sufficient orthographic and phonetic differences. |
| 49. | Pegaspargase | 56 | The name pair has sufficient orthographic and phonetic differences. |
| 50. | spasdel | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 51. | Supartz | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 52. | Asmasal | 55 | This name pair has sufficient orthographic and phonetic differences. |
| 53. | Casporyn*** | 55 | The name pair has sufficient orthographic and phonetic differences. |

| No. | **Proposed name:** Asparlas<br>**Established name:** calaspargase<br>**Dosage form:** injection<br>**Strength(s):** 3750 units/5 mL **(**750 units/mL)<br>**Usual Dose:** 2,500 units/$m^2$ intravenously every 21 days over 1 hour | POCA Score (%) | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 54. | Respa-1St | 55 | The name pair has sufficient orthographic and phonetic differences. |
| 55. | Salonpas | 53 | The name pair has sufficient orthographic and phonetic differences. |
| 56. | Apra | 49 | The name pair has sufficient orthographic and phonetic differences. |
| 57. | Panasal | 45 | This name pair has sufficient orthographic and phonetic differences. |
| 58. | Nasal LA | 54 | This name pair has sufficient orthographic and phonetic differences. |
| 59. | Masporin | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 60. | Aspergum | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 61. | Caprelsa | 59 | The name pair has sufficient orthographic and phonetic differences. |
| 62. | Aspercreme | 54 | The name pair has sufficient orthographic and phonetic differences.<br><br>Aspercreme vs. Asparlas<br>Dosage form: topical patch vs. injection<br>Dosing and frequency: 1 patch on affected area per week vs. 2,500 units/$m^2$ over 1 hour infusion, every 21 days |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 63. | A+D DIAPER RASH | 53 |
| 64. | ABARELIX | 54 |
| 65. | ACARBOSE | 54 |
| 66. | ACEROLA | 54 |
| 67. | ADALAT | 52 |
| 68. | ADCETRIS | 40 |
| 69. | ALCALAK | 27 |
| 70. | AMOXICILLIN | 48 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 71. | ANASPAZ | 42 |
| 72. | APRESOLINE | 54 |
| 73. | APRISO | 29 |
| 74. | ARICEPT | 46 |
| 75. | ASMANEX | 52 |
| 76. | ASTAGRAF XL | 54 |
| 77. | ASTELIN | 54 |
| 78. | ASTEPRO | 60 |
| 79. | ASTRAGALUS | 54 |
| 80. | ATARAX | 53 |
| 81. | AVITEARS | 52 |
| 82. | DISPAS | 50 |
| 83. | E.E.S. GRANULES | 52 |
| 84. | ENVARSUS | 54 |
| 85. | EPERBEL-S | 53 |
| 86. | ESPOTABS | 54 |
| 87. | ESTRA-C | 53 |
| 88. | ESTRACE | 54 |
| 89. | ESTRA-D | 50 |
| 90. | ESTRATAB | 52 |
| 91. | ESTROVIS | 20 |
| 92. | FUROSEMIDE | 54 |
| 93. | HISTALET | 50 |
| 94. | HIST-PLUS | 40 |
| 95. | INSULIN ASPART | 54 |
| 96. | KYPROLIS | 52 |
| 97. | ONCASPAR | 43 |
| 98. | ONSOLIS | 54 |
| 99. | SPHERULIN | 49 |
| 100. | STERIL-EYES | 53 |

**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 |
|---|---|---|---|
| 101. | Carles | 64 | Product is not a drug. It is a toothpaste. |
| 102. | Aspartame | 63 | Product is not a drug. It is a sweetener. |
| 103. | Nova Pearls | 62 | Veterinary product. |
| 104. | Ascalix | 62 | International product formerly marketed in the United Kingdom |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 105. | Parasal | 61 | Product discontinued with no generic equivalent available. NDA 06811 withdrawn FR effective 08/13/1990. |
| 106. | (b) (4) *** | 59 | Proposed proprietary name for NDA2087941 found unacceptable by DMEPA (OSE# 2017-13156423). NDA 208791 approved under new proprietary name Clorotekal. |
| 107. | Apap Sleep | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 108. | Apara | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 109. | Arco-lase | 58 | Product discontinued with no generic equivalent available per Redbook. |
| 110. | Aspidrox | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 111. | Optilast | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 112. | Palcaps | 58 | Product discontinued with no generic equivalent available. |
| 113. | Paltrase | 58 | Product discontinued with no generic equivalent available. |
| 114. | (b) (4) *** | 57 | Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA (OSE# 2016-783541). BLA 761061 is approved under new proprietary name Tremfya. |
| 115. | (b) (4) | 56 | This is a secondary proposed proprietary name for IND (b) (4) and NDA # (b) (4) was approved under proprietary name (b) (4) |
| 116. | Asparagine | 56 | Product is not a drug. Product is an amino acid that is used in the biosynthesis of proteins. |
| 117. | Catalase | 56 | Product is not a drug. It is an enzyme that catalyzes the reduction of hydrogen peroxide. |
| 118. | Paracets | 56 | International product marketed in United Kingdom. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 119. | Partuss-La | 56 | Name identified in RxNorm database. Discontinued with no generics available per REDBOOK. |
| 120. | Surpass | 56 | Veterinary product. |
| 121. | Sulparex | 56 | International product marketed in the United Kingdom. |
| 122. | Pharmasal | 55 | Veterinary product. |
| 123. | Paral | 54 | Discontinued with no generics available Per REDBOOK. |
| 124. | Respa-SA | 54 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 125. | Rispas | 53 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 126. | Saralasin | 53 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 127. | Air Salonpas | 52 | Formerly marketed international product. |
| 128. | (b) (4) *** | 52 | Proposed proprietary name for BLA 761070 found unacceptable by DMEPA (OSE# 2017-13059521). BLA 761070 is approved under new proprietary name, Fasenra. |
| 129. | Bellaspas | 52 | Product discontinued with no generic equivalent available per Redbook. |
| 130. | Nasal Asalt | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 131. | Palipase | 52 | Product discontinued with no generic equivalent available per Redbook. |
| 132. | Kerasal AL | 50 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 133. | Plaretase | 50 | Product discontinued with no generic equivalent available per Redbook. |
| 134. | Lapase | 48 | Product discontinued with no generic equivalent available per Redbook. |
| 135. | Aspartate | 68 | Product is not a drug. It is a salt used in established name nomenclature. |
| 136. | Asperdrink | 54 | Brand discontinued per Redbook with no generic equivalent available. |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 137. | Resporal | 62 |
| 138. | Septra Ds | 58 |
| 139. | Spirulina | 60 |
| 140. | Suprax | 58 |
| 141. | Marpres | 57 |
| 142. | Saphris | 55 |
| 143. | Stelara | 56 |
| 144. | Trelstar La | 58 |
| 145. | Catarase | 56 |
| 146. | Lax-Pills | 60 |
| 147. | Naprelan | 56 |
| 148. | Xatral Sr | 56 |
| 149. | Ferraplus | 57 |
| 150. | Nasatab La | 55 |
| 151. | Risperdal | 60 |
| 152. | (b) (4) *** | 58 |
| 153. | Spiriva | 56 |
| 154. | Surelac | 56 |
| 155. | Sur-Q-Lax | 58 |
| 156. | Catapres | 57 |
| 157. | Enaprilat | 58 |
| 158. | Estroplan | 58 |
| 159. | Fatal-Plus | 58 |
| 160. | Icar-C Plus | 55 |
| 161. | Respiram | 58 |
| 162. | Spinraza | 56 |
| 163. | (b) (4) *** | 58 |
| 164. | (b) (4) *** | 56 |
| 165. | Purelax | 56 |
| 166. | Ceta Plus | 56 |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 167. | (b) (4) *** | 55 |
| 168. | Nostrilla | 56 |
| 169. | Starflex | 62 |
| 170. | Testro-L.A. | 56 |
| 171. | Vistaril | 56 |
| 172. | Cystaran | 56 |
| 173. | Estra-V 40 | 56 |
| 174. | Estazolam | 55 |
| 175. | Staflex | 56 |
| 176. | Xtra-Lax | 56 |
| 177. | Eskalith | 56 |

**Appendix I**: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences. – N/A

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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LEEZA RAHIMI
03/22/2018

HINA S MEHTA
03/22/2018