# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 216686Orig1s000

# PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)

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***

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|---|---|
| Date of This Review: | April 10, 2023 |
| Application Type and Number: | NDA 216686 |
| Product Name and Strength: | Focinvez (fosaprepitant injection), 150 mg/50 mL (3 mg/mL) |
| Product Type: | Single Ingredient Product |
| Rx or OTC: | Prescription (Rx) |
| Applicant/Sponsor Name: | Spes Pharmaceuticals Inc (SPES) |
| PNR ID #: | 2023-1044725018 |
| DMEPA 1 Safety Evaluator: | Sarah K. Vee, PharmD |
| DMEPA 1 Team Leader: | Idalia E. Rychlik, PharmD |
| DMEPA 1 Director: | Mishale Mistry, PharmD, MPH |

Contents

# 1 INTRODUCTION

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

## 1.1 REGULATORY HISTORY

SPES previously submitted the proposed proprietary name, Focinvez*** on January 21, 2022 and we found the name conditionally acceptable.[a] However, NDA 216686 received a complete response on October 19, 2022.

Thus, SPES submitted the name, Focinvez, for review on February 28, 2023.

## 1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on February 28, 2023.

- Intended Pronunciation: ˈfɒsin-vɛz
- Active Ingredient: fosaprepitant injection
- Indication of Use: in adults and pediatric patients 6 months of age and older, in combination with other antiemetic agents, for the prevention of:
    - acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin.
    - delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).
- Route of Administration: intravenous infusion
- Dosage Form: injection
- Strength: 150 mg/50 mL (3 mg/mL)
- Dose and Frequency:
  Recommended Adult Dosing for the Prevention of Nausea and Vomiting Associated with HEC

| | Day 1 | Day 2 | Day 3 | Day 4 |
|---|---|---|---|---|

[a] Abraham, Sherly. Proprietary Name Review for Focinvez (NDA 216686). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 APR 13. PNR ID No. 2022-1044724404.

| | | | | |
|---|---|---|---|---|
| FOCINVEZ | 150 mg intravenously over 20 to 30 minutes | none | none | none |
| Dexamethasone | 12 mg orally | 8 mg orally | 8 mg orally twice daily | 8 mg orally twice daily |
| 5-$HT_3$ antagonist | See selected 5-$HT_3$ antagonist prescribing information for the recommended dosage | none | none | none |

Recommended Adult Dosing for the Prevention of Nausea and Vomiting Associated with MEC

| | Day 1 |
|---|---|
| FOCINVEZ[a] | 150 mg intravenously over 20 to 30 minutes |
| Dexamethasone | 12 mg orally |
| 5-$HT_3$ antagonist | See selected 5-$HT_3$ antagonist prescribing information for the recommended dosage |

Single Dose Regimen for the Prevention of Nausea and Vomiting Associated with Single-Day Regimens of HEC or MEC in Pediatric Patients 6 Months to 17 Years

| Drug | Age | Regimen |
|---|---|---|
| FOCINVEZ | 12 Years to 17 Years | 150 mg intravenously over 30 minutes |
| | 2 Years to less than 12 Years | 4 mg/kg (maximum dose 150 mg) intravenously over 60 minutes |
| | 6 Months to less than 2 Years | 5 mg/kg (maximum dose 150 mg) intravenously over 60 minutes |
| Dexamethasone | 6 Months to 17 Years | If a corticosteroid, such as dexamethasone, is co-administered, administer 50% of the recommended corticosteroid dose on Days 1 and 2. |
| 5-$HT_3$ antagonist | 6 Months to 17 Years | See selected 5-$HT_3$ antagonist prescribing information for the recommended dosage |

3-Day Fosaprepitant/Aprepitant Dosage Regimen for Prevention of Nausea and Vomiting Associated with Single or Multi-day Regimens of HEC or MEC in Pediatric Patients 6 Months to 17 Years

| Age Group | Drug | Day 1 | Day 2 | Day 3 |
|---|---|---|---|---|
| 12 Years to 17 Years | FOCINVEZ | 115 mg intravenously over 30 minutes | -- | -- |

| | | | | |
|---|---|---|---|---|
| | Aprepitant capsules[c] | -- | 80 mg orally | 80 mg orally |
| 6 Months to Less than 12 Years | FOCINVEZ | 3 mg/kg<br>(maximum dose 115 mg) intravenously over 60 minutes | -- | -- |
| | Aprepitant for oral suspension | -- | 2 mg/kg orally (maximum 80 mg) | 2 mg/kg orally (maximum 80 mg) |
| 6 Months to 17 Years | Dexamethasone | If a corticosteroid, such as dexamethasone, is co-administered, administer 50% of the recommended corticosteroid dose on Days 1 through 4 | | |
| 6 Months to 17 Years | 5-$HT_3$ antagonist | See selected 5-$HT_3$ antagonist prescribing information for the recommended dosage | | |

- How Supplied: 1 vial per carton
- Storage: Refrigerate at 2°C to 8°C (36°F to 46°F). FOCINVEZ vials, when kept in original carton, can remain at room temperature 20°C to 25°C (68°F to 77°F) for up to 90 days.
- Reference Listed Drug: Emend (fosaprepitant) NDA 022023.

## 2 RESULTS

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

### 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Focinvez would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Focinvez. The Division of Gastroenterology (DG) did not comment on the findings of OPDP's assessment for Focinvez.

### 2.2 SAFETY ASSESSMENT

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

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

The proposed proprietary name, Focinvez, contains the United States Adopted Name (USAN) stem, 'Fo-', in the prefix position used by the USAN Council to indicate phosphoro-derivatives

products[b]. We did not object to the inclusion of the two-letter USAN stem "fo-", incorporated into the proposed proprietary name, Focinvez, in our previous review[c]. We maintain our non-objection.

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

SPES indicated in their submission that the proposed proprietary name, Focinvez, is derived from: "Fo(c)-" as for fosaprepitant, "cinv" as for chemotherapy induced nausea and vomiting; "-ez" as for easing (on cinv) and easy (for drug dosing). We also noted that Focinvez includes the letter string '-in-,' a medical abbreviation for "intranasal" route of administration. We determined that the location of the abbreviation, '-in-', in the infix of the name, is unlikely to be separated from the surrounding letters in a manner that would lead to confusion in this case.

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

As of April 6, 2023, the Division of Gastroenterology (DG) did not forward any comments or concerns relating to Focinvez at the initial phase of the review.

### *2.2.4 FDA Name Simulation Studies*

Ninety-three (n=93) practitioners participated in DMEPA's prescription studies for Focinvez. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

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

Our POCA search[d] identified 53 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 none of the product characteristics have changed, and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified one name not previously analyzed. This name is included in Table 1 below.

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

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

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[b] USAN stem search conducted on March 15, 2023

[c] Abraham, Sherly. Proprietary Name Review for Focinvez (NDA 216686). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 APR 13. PNR ID No. 2022-1044724404.

[d] POCA search conducted on March 15, 2023 in version 5.2.

| Table 1. Names Retrieved for Review Organized by Name Pair Similarity | |
|---|---|
| Similarity Category | Number of Names |
| Highly similar name pair:<br>combined match percentage score ≥70% | 0 |
| Moderately similar name pair:<br>combined match percentage score ≥55% to ≤ 69% | 1 |
| Low similarity name pair:<br>combined match percentage score ≤54% | 0 |

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

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

#### *2.2.8 Communication of DMEPA's Determination*

On April 7, 2023, DMEPA 1 communicated our determination to the Division of Gastroenterology (DG).

## 3 CONCLUSION

The proposed proprietary name, Focinvez, is conditionally acceptable.

If you have any questions or need clarifications, please contact Alvis Dunson, OSE project manager, at 301-796-6400.

### 3.1 COMMENTS TO SPES PHARMACEUTICALS INC

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

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. https://www.nccmerp.org/about-medication-errors Last accessed 10/05/2020.

*Table 2- Prescreening Checklist for Proposed Proprietary Name

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

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@FDA, Cerner RxNorm, 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 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

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

likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA 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.

   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. | | | |
|---|---|---|---|
| <u>Orthographic Checklist</u> | | <u>Phonetic Checklist</u> | |
| 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 <u>with</u> overlapping or similar strengths or doses. |

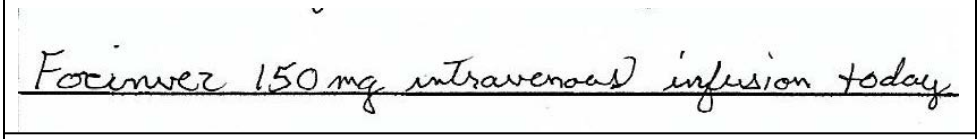
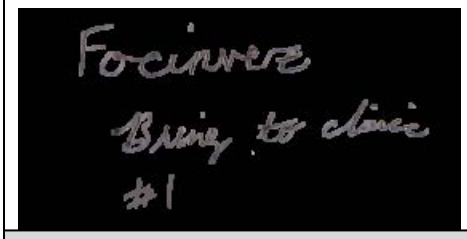
| | | |
|---|---|---|
| | Orthographic Checklist (Y/N to each question)<br>• Do the names begin with different first letters?<br>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br>• Are the lengths of the names dissimilar* when 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. Focinvez Study (Conducted on March 10, 2023)

| Handwritten Medication Order/Prescription | Verbal Prescription |
|---|---|
| Medication Order:<br>  <br> | Focinvez<br>Bring to clinic<br>#1 |
| Outpatient Prescription:<br>  <br> | |
| CPOE Study Sample (displayed as sans-serif, 12-point, bold font) | |
| Focinvez | |

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Focinvez

258 People Received Study

93 People Responded

Total 23 25 20 25

| INTERPRETATION | INPATIENT | CPOE | VOICE | OUTPATIENT | TOTAL |
|---|---|---|---|---|---|
| FOCINEZ | 0 | 0 | 0 | 2 | 2 |
| FOCINUEZ | 1 | 0 | 0 | 0 | 1 |
| FOCINVER | 1 | 0 | 0 | 0 | 1 |
| FOCINVERZ | 0 | 0 | 0 | 8 | 8 |
| FOCINVEZ | 20 | 25 | 0 | 13 | 58 |
| FOCIVEREZ | 0 | 0 | 0 | 1 | 1 |
| FORINVEZ | 1 | 0 | 0 | 0 | 1 |
| FOSENBEZ | 0 | 0 | 1 | 0 | 1 |
| FOSENVES | 0 | 0 | 1 | 0 | 1 |
| FOSENVEZ | 0 | 0 | 5 | 0 | 5 |
| FOSIMBEZ | 0 | 0 | 1 | 0 | 1 |
| FOSIMVEZ | 0 | 0 | 1 | 0 | 1 |
| FOSINVES | 0 | 0 | 1 | 0 | 1 |
| FOSINVEZ | 0 | 0 | 6 | 0 | 6 |

| | | | | | |
|---|---|---|---|---|---|
| FOSIVENZ | 0 | 0 | 1 | 0 | 1 |
| FOXIRVEZ | 0 | 0 | 0 | 1 | 1 |
| PHOSIMBEZ | 0 | 0 | 1 | 0 | 1 |
| PHOSINVEZ | 0 | 0 | 1 | 0 | 1 |
| VOSAVEZ | 0 | 0 | 1 | 0 | 1 |

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

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose – N/A

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. – N/A

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 (%) |
|---|---|---|
| 1. | Tofidence*** | 56 |

[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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/s/

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SARAH K VEE
04/10/2023 10:14:58 AM

IDALIA E RYCHLIK
04/10/2023 12:42:23 PM

MISHALE P MISTRY
04/11/2023 01:32:51 PM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)

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: | April 13, 2022 |
| Application Type and Number: | NDA 216686 |
| Product Name and Strength: | Focinvez (fosaprepitant) injection, 150 mg/50 mL (3 mg/mL) |
| Product Type: | Single Ingredient Product |
| Rx or OTC: | Prescription (Rx) |
| Applicant/Sponsor Name: | Spes Pharmaceuticals, Inc. (SPES) |
| PNR ID #: | 2022-1044724404 |
| DMEPA 1 Safety Evaluator: | Sherly Abraham, R.Ph. |
| DMEPA 1 Team Leader: | Idalia E. Rychlik, Pharm.D. |
| DMEPA 1 Associate Director for Nomenclature and Labeling: | Mishale Mistry, Pharm.D., MPH |

Contents

# 1 INTRODUCTION

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

## 1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 21, 2022.

- Intended Pronunciation: 'fosin-vez
- Active Ingredient: fosaprepitant
- Indication of Use: Fosaprepitant Injection is indicated in adults and pediatric patients 6 months of age and older, in combination with other antiemetic agents, for the prevention of:
    - acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin.
    - delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).
- Route of Administration: intravenous
- Dosage Form: injection
- Strength: 150 mg/50 mL (3 mg/mL)
- Dose and Frequency: Adults: 150 mg on Day 1.

**Single Dose Regimen of FOCINVEZ for Pediatric Patients 6 Months* to 17 Years for the Prevention of Nausea and Vomiting Associated with Single-Day Regimens of HEC or MEC**

| Drug | Age | Regimen |
|---|---|---|
| FOCINVEZ | 12 Years to 17 Years | 150 mg intravenously over 30 minutes |
| | 2 Years to less than 12 Years | 4 mg/kg (maximum dose 150 mg) intravenously over 60 minutes |
| | 6 Months to less than 2 Years | 5 mg/kg (maximum dose 150 mg) intravenously over 60 minutes |
| Dexamethasone† | 6 Months to 17 Years | If a corticosteroid, such as dexamethasone, is co-administered, administer 50% of the recommended corticosteroid dose on Days 1 and 2. |
| 5-$HT_3$ antagonist | 6 Months to 17 Years | See selected 5-$HT_3$ antagonist prescribing information for the recommended dosage |

**Table 4. Pediatric Patients 6 Months* to 17 Years Recommended 3-Day Fosaprepitant/Aprepitant Dosage Regimen for Prevention of Nausea and Vomiting Associated with Single or Multi-day Regimens of HEC or MEC**

| Age Group | Drug | Day 1 | Day 2 | Day 3 |
|---|---|---|---|---|
| 12 Years to 17 Years | FOCINVEZ | 115 mg intravenously over 30 minutes | -- | -- |

| | | | | |
|---|---|---|---|---|
| | Aprepitant capsules† | -- | 80 mg orally | 80 mg orally |
| 6 Months to Less than 12 Years | FOCINVEZ | 3 mg/kg (maximum dose 115 mg) intravenously over 60 minutes | -- | -- |
| | Aprepitant for oral suspension | -- | 2 mg/kg orally (maximum 80 mg) | 2 mg/kg orally (maximum 80 mg) |
| 6 Months to 17 Years | Dexamethasone‡ | If a corticosteroid, such as dexamethasone, is co-administered, administer 50% of the recommended corticosteroid dose on Days 1 through 4 | | |
| 6 Months to 17 Years | 5-$HT_3$ antagonist | See selected 5-$HT_3$ antagonist prescribing information for the recommended dosage | | |

* Dosing in pediatric patients less than 6 kg is not recommended.

- How Supplied: Single-dose vial containing 150 mg of fosaprepitant as a clear and colorless ready-to-use injection. 1 vial per carton.
- Storage: Store Fosaprepitant Injection vials in the refrigerator at 2°C to 8°C (36°F to 46°F). Fosaprepitant Injection vials, in its original carton, can be kept at room temperature, (b) (4) for a total of 90 days.
- Reference Listed Drug/Reference Product: Emend for injection (NDA 22023)

## 2 RESULTS

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

### 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Focinvez would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) and the Division of Gastroenterology (DG) concurred with the findings of OPDP's assessment for Focinvez.

### 2.2 SAFETY ASSESSMENT

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

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

The proposed proprietary name, Focinvez, contains the United States Adopted Name (USAN) stem, 'Fo-', in the prefix position used by the USAN Council to indicate phosphoro-derivatives products.[a] Proprietary names should usually not incorporate USAN stems in the position that

[a] USAN stem search conducted on February 18, 2022

USAN designates for the stem.[b] The use of an USAN stem within proprietary names, even when used consistently with the USAN meaning, can result in multiple similar proprietary names and proprietary names that are similar to established names, thus increasing the chance of confusion among those drugs, which may compromise patient safety. To reduce the potential for confusion, USAN stems should usually not be incorporated into proprietary names.

However, we determined that the two-letter stem 'fo-' is often not distinct enough to be recognized as an USAN stem. We also note that USAN has used the stem 'fo-' in established names (e.g., fosphenytoin) as well as in other USAN stems (-cerfont). This has resulted in conflicting stems, and therefore in those instances, the stem does not support the USAN Council naming system or accurately indicate the pharmacological or chemical trait of the drug. Additionally, based on our post marketing experience, we do not have the same safety concerns with the two-letter stems, including 'fo-', that we have identified with three or more letter USAN stems.[c,d]

Therefore, we do not object to the inclusion of the two-letter USAN stem 'Fo-', incorporated into the proposed proprietary name Focinvez.

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

SPES indicated in their submission that in the proposed proprietary name, Focinvez, 'Foc' stands for fosaprepitant, 'cinv', stands for chemotherapy induced nausea and vomiting, and 'ez' stands for easing (on cinv) and easy (for drug dosing) [fosaprepitant injection for easing on chemotherapy induced nausea and vomiting in an easy dosing format].

This proprietary name is comprised of a single word. We note that Focinvez includes the letter string '-in-,' a medical abbreviation for "intranasal" route of administration, and '-cinv-' which is an abbreviation for the proposed product's indication 'chemotherapy induced nausea and vomiting'. Although we typically discourage the inclusion of medical abbreviation in proprietary names, we determined that the location of the abbreviation, '-in-', in the infix of the name, is unlikely to be separated from the surrounding letters in a manner that would lead to confusion in this case. With respect to the letter string '-cinv-', we note that the product is indicated for the prevention of chemotherapy induced nausea and vomiting in adults and pediatric patients 6 months of age and older and thus would not lead to confusion in this case. Beyond these abbreviations, we note that Focinvez does not contain any additional components (i.e., modifier, route of administration, dosage form etc.) that are misleading or can contribute to medication error.

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[b] Guidance for industry: Best practices in developing proprietary names for drugs. Draft Guidance May 2014. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM39899

[c] Institute for Safe Medication Practices. Safety briefs: Aripiprazole or rabeprazole? ISMP Med Saf Alert Acute Care. 2003;8(8):1-3.

[d] Institute for Safe Medication Practices. Safety Briefs. ISMP Med Saf Alert Acute Care. 2002;7(17):1-2.

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

As of February 22, 2022, the Division of Gastroenterology (DG) did not forward any comments or concerns relating to Focinvez at the initial phase of the review.

### *2.2.4 FDA Name Simulation Studies*

One-hundred and two (n=102) practitioners participated in DMEPA's prescription studies for Focinvez. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

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

Our POCA search[e] identified 51 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

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

Table 1 lists the number of names retrieved from our POCA search. 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:<br>combined match percentage score ≥70% | 1 |
| Moderately similar name pair:<br>combined match percentage score ≥55% to ≤ 69% | 46 |
| Low similarity name pair:<br>combined match percentage score ≤54% | 4 |

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

Our analysis of the 51 names contained in Table 1 determined none of the names will pose a risk for confusion with Focinvez as described in Appendices C through H.

### *2.2.8 Communication of DMEPA's Determination*

On April 12, 2022, DMEPA 1 communicated our determination to the Division of Gastroenterology (DG).

[e] POCA search conducted on February 18, 2022 in version 4.4.

# 3 CONCLUSION

The proposed proprietary name, Focinvez, is acceptable.

If you have further questions or need clarifications, please contact Alvis Dunson, OSE project manager, at 301-796-6400.

## 3.1 COMMENTS TO SPES PHARMACEUTICALS, INC.

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

## 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. 6F[f]

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

*Table 2- Prescreening Checklist for Proposed Proprietary Name

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

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

DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

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

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names7F[g]. 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).

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

- 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. 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.

   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 <u>with</u> overlapping or similar strengths or doses. |

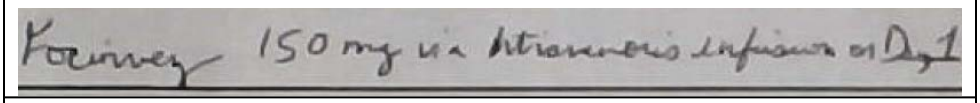
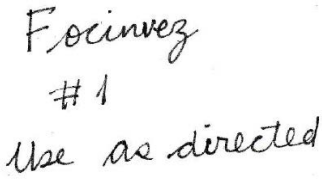
| | | |
|---|---|---|
| | Orthographic Checklist (Y/N to each question)<br>• Do the names begin with different first letters?<br>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br>• Are the lengths of the names dissimilar* when 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. Focinvez Study (Conducted on February 4, 2022)

| Handwritten Medication Order/Prescription | Verbal Prescription |
|---|---|
| Medication Order:<br>  <br> | Focinvez<br>#1<br>Use as directed |
| Outpatient Prescription:<br>  <br> | |
| CPOE Study Sample (displayed as sans-serif, 12-point, bold font) | |
| Focinvez | |

FDA Prescription Simulation Responses (Aggregate Report)

262 People Received Study

102 People Responded

Study Name: Focinvez

| Total | 24 | 32 | 23 | 23 | |
|---|---|---|---|---|---|
| INTERPRETATION | OUTPATIENT | CPOE | VOICE | INPATIENT | TOTAL |
| FOCINEZ | 1 | 0 | 0 | 1 | 2 |
| FOCINVEY | 0 | 0 | 0 | 3 | 3 |
| FOCINVEZ | 22 | 32 | 0 | 4 | 58 |
| FOCIRVEZ | 0 | 0 | 0 | 1 | 1 |
| FOCIRVVEG | 0 | 0 | 0 | 1 | 1 |
| FOCIVEY | 0 | 0 | 0 | 1 | 1 |

| | | | | | |
|---|---|---|---|---|---|
| FOCIVVEZ | 0 | 0 | 0 | 1 | 1 |
| FORCIONVEZ | 0 | 0 | 0 | 1 | 1 |
| FORINVEZ | 1 | 0 | 0 | 0 | 1 |
| FORIVEZ | 0 | 0 | 0 | 1 | 1 |
| FOSCINVAS | 0 | 0 | 1 | 0 | 1 |
| FOSENVAZE | 0 | 0 | 1 | 0 | 1 |
| FOSENVEZ | 0 | 0 | 1 | 0 | 1 |
| FOSIMVAZ | 0 | 0 | 1 | 0 | 1 |
| FOSINMOZ | 0 | 0 | 1 | 0 | 1 |
| FOSINVAZ | 0 | 0 | 3 | 0 | 3 |
| FOSINVEZ | 0 | 0 | 10 | 0 | 10 |
| FOSSINVEZ | 0 | 0 | 1 | 0 | 1 |
| FOSYMBAZ | 0 | 0 | 1 | 0 | 1 |
| KOCINVEY | 0 | 0 | 0 | 2 | 2 |
| KOCINVEZ | 0 | 0 | 0 | 1 | 1 |
| KOCIRVEZ | 0 | 0 | 0 | 1 | 1 |
| KOCIVEY | 0 | 0 | 0 | 1 | 1 |
| KOCIVEZ | 0 | 0 | 0 | 3 | 3 |
| KORIVEZ | 0 | 0 | 0 | 1 | 1 |
| PHOSIMVEZ | 0 | 0 | 1 | 0 | 1 |
| PHOSINVEB | 0 | 0 | 1 | 0 | 1 |
| PHOSINVEZ | 0 | 0 | 1 | 0 | 1 |

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

| No. | Proposed name: Focinvez<br>Established name: fosaprepitant<br>Dosage form: injection<br>Strength(s): 150 mg/50 mL (3 mg/mL)<br>Usual Dose: Dose varied, 150 mg, 115 mg, 3 mg/kg, 4 mg/kg, 5 mg/kg | 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. | Focinvez | 100 | Name subject of 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-N/A

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: Focinvez<br>Established name: fosaprepitant<br>Dosage form: injection<br>Strength(s): 150 mg/50 mL (3 mg/mL)<br>Usual Dose: Dose varied, 150 mg, 115 mg, 3 mg/kg, 4 mg/kg, 5 mg/kg | 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 |
|---|---|---|---|
| 1. | (b) (4) *** | 64 (orthographic alone score =75) | This name pair has sufficient orthographic and phonetic differences. |
| 2. | (b) (4) *** | 64 | This name pair has sufficient orthographic and phonetic differences. |
| 3. | Finevin | 60 | This name pair has sufficient orthographic and phonetic differences. |
| 4. | Zokinvy | 60 | This name pair has sufficient orthographic and phonetic differences. |

| No. | Proposed name: Focinvez<br>Established name: fosaprepitant<br>Dosage form: injection<br>Strength(s): 150 mg/50 mL (3 mg/mL)<br>Usual Dose: Dose varied, 150 mg, 115 mg, 3 mg/kg, 4 mg/kg, 5 mg/kg | 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 |
|---|---|---|---|
| 5. | Foscavir | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 6. | Vonvendi | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 7. | Folivane-F | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 8. | Fosfomycin | 57 | This name pair has sufficient orthographic and phonetic differences. |
| 9. | (b) (4) *** | 56 (phonetic alone score =73) | This name pair has sufficient orthographic and phonetic differences. |
| 10. | Focalin | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 11. | Fusilev | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 12. | (b) (4) *** | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 13. | Femcon Fe | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 14. | Fer-In-Sol | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 15. | Fe-Tinic 150 | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 16. | Folicet | 55 | This name pair has sufficient orthographic and phonetic differences. |

| No. | Proposed name: Focinvez<br>Established name: fosaprepitant<br>Dosage form: injection<br>Strength(s): 150 mg/50 mL (3 mg/mL)<br>Usual Dose: Dose varied, 150 mg, 115 mg, 3 mg/kg, 4 mg/kg, 5 mg/kg | 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 |
|---|---|---|---|
| 17. | Otocidin | 55 | This name pair has sufficient orthographic and phonetic differences. |
| 18. | Foscarnet | 55 | This name pair has sufficient orthographic and phonetic differences. |
| 19. | Ferrocite F | 55 | 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 (%) |
|---|---|---|
| 1. | Dezocine | 50 |
| 2. | Efodine | 48 |
| 3. | Cocaine | 44 |
| 4. | Novocaine | 44 |

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. | Floxin I.V. | 63 | Product is deactivated per Redbook and no generic equivalents are available. |
| 2. | Cefovecin | 62 | Veterinary drug. |
| 3. | Fominoben | 61 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 4. | Fucidin | 60 | International product marketed in many countries including Canada. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 5. | Florinef | 60 | Brand discontinued with no generic equivalents available. NDA 10060 withdrawn pending FR effective as of 06/18/2009. |
| 6. | Fonazine | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 7. | Solfenacin | 57 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 8. | Folacin | 56 | International product marketed in Ukraine, Sweden, and Brazil. |
| 9. | Fe-Tinic | 56 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 10. | Fosveset | 56 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 11. | Clocinizine | 56 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 12. | Femseven 50 | 55 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 13. | Femseven 75 | 55 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 14. | Femseven 100 | 55 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | Cefonicid | 64 |

[h] 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 (%) |
|---|---|---|
| 2. | (b) (4) *** | 60 |
| 3. | (b) (4) *** | 60 |
| 4. | Docefrez | 60 |
| 5. | Cefizox | 58 |
| 6. | Stingeze | 58 |
| 7. | (b) (4) *** | 58 |
| 8. | Cifenline | 58 |
| 9. | Zolinza | 56 |
| 10. | (b) (4) *** | 56 |
| 11. | Cefazolin | 56 |
| 12. | Cefenil | 55 |
| 13. | (b) (4) *** | 55 |

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/s/

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SHERLY ABRAHAM
04/13/2022 11:02:10 AM

IDALIA E RYCHLIK
04/13/2022 04:54:03 PM

MISHALE P MISTRY
04/19/2022 02:44:53 PM