

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

216203Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	April 26, 2023
Application Type and Number:	NDA 216203
Product Name and Strength:	Inpefa (sotagliflozin) tablet, 200 mg and 400 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Lexicon Pharmaceuticals, Inc. (Lexicon)
PNR ID #:	2023-1044725021
DMEPA 2 Safety Evaluator:	Christina Topper, PharmD, BCPS
DMEPA 2 Team Leader:	Hina Mehta, PharmD
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1 INTRODUCTION

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

The submitted external name study was previously reviewed under IND 135095 and NDA 216203 (see section 1.1 below).

1.1 REGULATORY HISTORY

The proposed name, Inpefa, was found unacceptable under IND 135095 and NDA 216203 on January 28, 2022.^a The proposed proprietary name, Inpefa, was found to be vulnerable to medication errors due to confusion with another product, Onprefa***, under review at the time. Therefore, the ultimate acceptability of the proposed name, Inpefa, was dependent upon which underlying application was approved first. Subsequently, the proposed name (b) (4) was submitted on June 13, 2022 and found conditionally acceptable on September 6, 2022 under NDA 216203.^b

We note the underlying application for Onprefa*** (b) (4).^c Therefore, the goal date for NDA 216203 precedes the approval of the application with the conflicting proposed name, Onprefa***.

Thus, Lexicon withdrew the conditionally acceptable name (b) (4) and resubmitted the proposed proprietary name, Inpefa, for review on March 1, 2023.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 1, 2023.

- Intended Pronunciation: in peh' fah
- Active Ingredient: sotagliflozin
- Indication of Use:
 - Reduce the risk of cardiovascular death, hospitalization for heart failure, urgent heart failure visit, (b) (4) in adults with type 2 diabetes mellitus and chronic kidney disease with other cardiovascular risk factors, including those with a history of heart failure (b) (4)

^aKarpow, C. Proprietary Name Review for Inpefa (NDA 216203 and IND 135095). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2022 JAN 28. PNR ID No. 2022-1044724372 and 2021-1044724114.

^bStewart, J. Proprietary Name Review for (b) (4) (NDA 216203). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2022 SEP 06. PNR ID No. 2022-1044724626.

^cNDA 213231*** (b) (4) as of 6/11/2021.

- Reduce the risk of cardiovascular death, hospitalization for heart failure, urgent heart failure visit in adults with type 2 diabetes mellitus (b) (4) for worsening heart failure regardless of left ventricular ejection fraction
- Route of Administration: oral
- Dosage Form: tablet
- Strength: 200 mg and 400 mg
- Dose and Frequency: one 200 mg tablet once daily titrated to 400 mg tablet once daily as tolerated.
- How Supplied:
 - Bottles containing 30 or 90 tablets per bottle
 - Blister packages containing seven 200 mg or 400 mg tablets per package
- Storage: Store at 68°F to 77°F (20°C to 25°C); excursions permitted between 59°F and 86°F (15°C and 30°C).

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Inpefa would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Inpefa. The Division of Cardiology and Nephrology (DCN) provided the following concern for consideration: *"INPEFA can be construed as treatment for heart failure with preserved ejection fraction (HFpEF), a term that we have stayed away from. While sotagliflozin will benefit this population, the approval applies to the broader HF population and there are other SGLT2 inhibitors that are approved for similar indication. The name suggests an edge over other SGLT2 inhibitors (falsely)."*

Therefore, we requested that OPDP reassess the proposed proprietary name, Inpefa. On April 5, 2023, OPDP responded that they reassessed the proposed proprietary name and provided their rationale for maintaining their position that the name is not false or misleading:

"According to the Request for Proprietary Name Review submitted by Lexicon Pharmaceuticals, the proposed indications are to reduce the risk of cardiovascular death, hospitalization for heart failure, urgent heart failure visit, nonfatal myocardial infarction, and nonfatal stroke in adults with type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors, including a history of heart failure and to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure, including those with acute or worsening heart failure. The OPDP PNR team discussed that the proposed proprietary name could potentially evoke "in" and "pef," which is part of the medical abbreviation for heart failure with preserved ejection fraction

(HFpEF). However, the team concluded that if a promotional connection is made with the term “pef” and this product, such a connection would not be false or misleading regarding the safety or efficacy of the proposed drug as the product is intended for use in heart failure patients, including those with preserved ejection fraction. Therefore, OPDP has determined that the proposed name is not false or misleading from a promotional perspective.”

On April 10, 2023, OPDP’s reassessment was communicated to the Division of Cardiology and Nephrology and no further concerns were expressed.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

The proposed proprietary name, Inpefa, contains the United States Adopted Name (USAN) stem “-ef-” in the infix position is used by the USAN council to indicate Fc fusion protein containing products.^d Proprietary names should usually not incorporate USAN stems in the position that USAN designates for the stem.^{ce} 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 ‘ef’ is often not distinct enough to be recognized as an USAN stem. We also note that USAN has used the stem ‘ef’ in established names (e.g., cefaclor, cefdinir, deferasirox, deflazacort, mefloquine, nefazodone, etc.) as well as in other USAN stems (e.g., cef- and -kef-). 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 ‘ef’, that we have identified with three or more letter USAN stems.^{f,g}

Therefore, we do not object to the proposed proprietary name based on the presence of a USAN stem in this instance.

^d USAN stem search conducted on January 8, 2020.

^e Guidance for industry: Best practices in developing proprietary names for drugs. Draft Guidance May 2014. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM39899>.

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

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

^h POCA search conducted on February 17, 2023 in version 5.2.

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

On March 23, 2023, the Division of Cardiology and Nephrology (DCN) forwarded concerns relating to the proposed proprietary name, Inpefa, at the initial phase of the review (see section 2.1).

2.2.4 FDA Name Simulation Studies

Eighty-nine (N=89) practitioners participated in DMEPA's prescription studies for Inpefa. 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^h identified 61 names with the combined score of $\geq 55\%$ or individual orthographic or phonetic score of $\geq 70\%$. 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 2 names not previously analyzed. 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: combined match percentage score $\geq 70\%$	0
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	2
Low similarity name pair: combined match percentage score $\leq 54\%$	0

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

Our analysis of the 2 names contained in Table 1 determined none of the names will pose a risk for confusion with Inpefa as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On April 26, 2023, DMEPA 2 communicated our determination to the Division of Cardiology and Nephrology (DCN).

3 CONCLUSION

The proposed proprietary name, Inpefa, is conditionally acceptable.

If you have any questions or need clarifications, please contact Monique Killen, OSE project manager, at 240-429-3715.

3.1 COMMENTS TO LEXICON PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on March 1, 2023 are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. **USAN Stems** (<https://www.ama-assn.org/about/united-states-adopted-names-approved-stems>)

USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

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

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

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm

(<http://www.nlm.nih.gov/research/umls/rxnorm/overview.html>).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

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

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

ⁱ 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.

- Low similarity: combined match percentage score $\leq 54\%$.

Using the criteria outlined in the check list (Table 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^j. 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

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

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 $\geq 70\%$).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such as 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 $\geq 55\%$ to $\leq 69\%$).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e., drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.

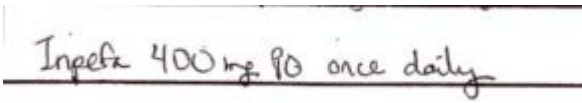
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

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. Inpefa Study (Conducted on March 24, 2023)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u>  Inpefa 400 mg po once daily	Inpefa Take 200 mg by mouth once daily Dispense #30
<u>Outpatient Prescription:</u>  Inpefa Take 200 mg po once daily #30	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Inpefa	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Inpefa

257 People Received Study

89 People Responded

Total	20	25	21	23	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
ANPEFA	0	0	0	1	1
EMPEFA	0	0	1	0	1
ENPEFA	0	0	1	0	1
ENPREFA	0	0	1	0	1
IMPEFA	0	0	4	7	11
IMPEFFA	0	0	3	0	3
IMPETHA	0	0	2	0	2
IMTEFFA	0	0	1	0	1
INPATHA	0	0	1	0	1
INPEFA	20	25	3	15	63
INPEFFA	0	0	2	0	2
INPETHA	0	0	2	0	2

Appendix C: Highly Similar Names (e.g., combined POCA score is $\geq 70\%$)-N/A

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

No.	Name	POCA Score (%)
1.	(b) (4) ***	61

Appendix E: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Inpefa Established name: sotagliflozin Dosage form: tablet Strength(s): 200 mg and 400 mg Usual Dose: 200 mg once daily or 400 mg once daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	Entadfi	61	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is $\leq 54\%$)-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^k.-N/A

^k 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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