CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215960Orig1s000

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***

Date of This Review:	February 24, 2026
Application Type and Number:	NDA 215960
Product Name, Dosage Form, and Strength:	Utebzi (tebipenem pivoxil) Tablets, 300 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	GlaxoSmithKline, LLC (GSK)
PNR ID #:	2025-1044726910
DMEPA 1 Safety Evaluator:	Deborah Myers, RPh, MBA
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Table of Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Utebzi, 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. GSK submitted an external name study, conducted by [redacted],[a] for this proposed proprietary name. The submitted external name study was previously reviewed under IND 132744 (see Section 1.1 below).

1.1 REGULATORY HISTORY

Spero previously submitted the proposed proprietary name, [redacted]*** under IND 132744 on December 4, 2020. We found the name, [redacted]*** conditionally acceptable under IND 132744.[b]

Subsequently, on October 27, 2021, Spero submitted the proposed proprietary name, [redacted]*** under NDA 215960. We found the name, [redacted]***, conditionally acceptable under NDA 215960.[c]

On June 24, 2022, NDA 215960 received a Complete Response Letter (CRL).[d]

On December 18, 2024, Spero submitted a Proprietary Name Withdraw Request for the proposed proprietary name, [redacted], under IND 132744.[e] Concurrently, Spero submitted the proposed proprietary name, Utebzi, for review on December 18, 2024 under IND 132744. Subsequently, on March 31, 2025, we found the name, Utebzi, conditionally acceptable under IND 132744.[f]

On October 30, 2025, the Agency was informed that the ownership for NDA 215960 is being transferred from Spero Therapeutics, Inc. to GlaxoSmithKline, LLC.[g] Additionally, on October 30, 2025, GlaxoSmithKline, LLC informed the Agency of their acceptance of this transfer of

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[a] Proprietary Name Safety Summary for Utebzi. [redacted] 2024 DEC 05. Available from: \\CDSESUB1\EVSPROD\nda215960\0046\m1\us\118-proprietary-names\proprietary-name-pivoxil.pdf.

[b] Myers, D. Proprietary Name Review for [redacted]*** (IND 132744). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 APR 27. PNR ID No. 2020-1044191079.

[c] Myers, D. Proprietary Name Review for [redacted]*** (NDA 215960). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 JAN 10. PNR ID No. 2021-1044724255.

[d] Rosenberger, J. Communication: Complete Response Letter for tebipenem pivoxil tablets. Silver Spring (MD): FDA, CDER, OND, OID, DAI (US); 2022 JUN 24. NDA 215960. Available from: https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af8066d1a3.

[e] Cover Letter: Request for Proprietary Name for Tebipenem Pivoxil Hydrobromide Oral Tablet (IND 132744). Cambridge (MA): Spero Therapeutics, Inc.; 2024 DEC 18. Available from: \\CDSESUB1\EVSPROD\ind132744\0178\m1\us\cover-letter.pdf.

[f] Myers, D. Proprietary Name Review for Utebzi (IND 132744). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2025 MAR 31. PNR ID No. 2024-1044726171.

[g] Cover Letter: Transfer of NDA Ownership for tebipenem pivoxil (NDA 215960). Cambridge (MA): Spero Therapeutics, Inc.; 2025 OCT 30. Available at: \\CDSESUB1\EVSPROD\nda215960\0044\m1\us\cover-letter.pdf.

ownership and assumes all responsibility for NDA 215960.[h] Subsequently, on December 19, 2025, the Agency sent an Acknowledgement Letter regarding the Transfer of NDA Ownership for NDA 215960 from Spero Therapeutics, Inc. to GlaxoSmithKline, LLC.[i]

On December 18, 2025, GSK submitted their Class 2 Resubmission for NDA 215960, which includes a complete response to the deficiencies included in the Agency's CRL dated June 24, 2022, as well as their request for review of the proposed proprietary name, Utebzi, under NDA 215960, which is the subject of this review.[j]

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 18, 2025[k] and the prescribing information received on December 18, 2025.[l]

Table 1. Relevant Product Information for Utebzi	
Intended Pronunciation:	yoo teb' zee
Active ingredient:	tebipenem pivoxil
Indication:	Complicated urinary tract infection (cUTI) & pyelonephritis, caused by the following susceptible microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, (b) (4) *Enterobacter cloacae* species complex, (b) (4) *Klebsiella oxytoca*, and *Enterococcus faecalis* in adult patients (b) (4) who have limited or no alternative oral treatment options.
Dosage Form:	Tablets
Strength:	300 mg
Route of Administration:	oral

[h] Cover Letter: Transfer of NDA Ownership for tebipenem pivoxil (NDA 215960). Philadelphia (PA): GlaxoSmithKline, LLC; 2025 OCT 30. Available at: \\CDSESUB1\EVSPROD\nda215960\0045\m1\us\102-cover-letters\cover.pdf.

[i] Kim, D. FDA Correspondence: Acknowledgement – Transfer of NDA Ownership for tebipenem pivoxil (NDA 215960). Silver Spring (MD): FDA, CDER, OND, OAP, DAI (US); 2025 DEC 19. Available at: https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af807f63aa&sourceSys=DARRTS.

[j] Cover Letter: Resubmission: Complete Response to Deficiencies for Utebzi (tebipenem pivoxil) NDA 215960. Philadelphia (PA): GlaxoSmithKline, LLC; 2025 DEC 18. Available at: \\CDSESUB1\EVSPROD\nda215960\0046\m1\us\102-cover-letters\cover.pdf.

[k] Request for Proprietary Name Review for tebipenem (NDA 215960). Philadelphia (PA): GlaxoSmithKline, LLC; 2025 DEC 18. Available from: \\CDSESUB1\EVSPROD\nda215960\0046\m1\us\118-proprietary-names\request-review-utebzi.pdf.

[l] Proposed prescribing information for Utebzi. Philadelphia (PA): GlaxoSmithKline, LLC; 2025 DEC 18. Available from: \\CDSESUB1\EVSPROD\nda215960\0046\m1\us\114-labeling\1141-draft\draft-clean.docx.

Table 1. Relevant Product Information for Utebzi	
Dose and Frequency:	600 mg (two 300 mg tablets) [redacted] (b) (4) (every 6 hours) for 7 to 10 days. The recommended dosage for patients with renal impairment: [redacted] (b) (4)
How Supplied:	Blister pack of 80 tablets: 8 tablets per blister strip, 10 strips per pack
Storage:	Store at 68° to 77°F (20° to 25°C), excursions permitted between 59° to 86°F (15° to 30°C). *[See USP controlled room temperature].*

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Utebzi 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 Utebzi. The Division of Anti-Infectives (DAI) concurred with the findings of OPDP's assessment for Utebzi.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

GSK did not provide a derivation or intended meaning for the proposed proprietary name, Utebzi, in their submission. However, we note that the proposed proprietary name, Utebzi, includes the letter string, 'teb,' which may suggest the active ingredient, tebipenem pivoxil. As the letter string 'teb' is consistent with the product's active ingredient, tebipenem pivoxil, we find the inclusion in the proposed proprietary name, Utebzi, acceptable from a medication error perspective.

[m] USAN stem search conducted on December 19, 2025.

Additionally, 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 errors.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Anti-Infectives (DAI) did not forward any comments or concerns relating to Utebzi at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-seven (87) practitioners participated in FDA's prescription simulation studies for Utebzi. 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[n] identified thirty-one (31) names with a combined phonetic and orthographic score of ≥55% or an 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.

We identified four (4) names not previously analyzed. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides 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 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	4
Low similarity name pair: combined match percentage score ≤54%	0

[n] POCA search conducted on December 19, 2025 in version 5.16.3.

2.2.7 SAFETY ANALYSIS OF NAMES IDENTIFIED

Our analysis of the four (4) names contained in Table 2 determined none of the names will pose a risk for confusion with Utebzi as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On February 24, 2026, DMEPA 1 communicated our determination to the Division of Anti-Infectives (DAI).

3 CONCLUSION

The proposed proprietary name, Utebzi, is conditionally acceptable.

3.1 COMMENTS TO GLAXOSMITHKLINE, LLC

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

If any of the proposed product characteristics as stated in your submission, received on December 18, 2025, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. United States Adopted Names (USAN) Stems

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-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 https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms).

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).

Purple Book

The Purple Book is an online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service (PHS) Act. See Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or.

Division of Medication Errors Prevention and Analysis pending proprietary name requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis.

5 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, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD 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 ONPD 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 3. 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.[o]

Table 3. 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.

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

Table 3. 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 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, Purple Book, 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 (Tables 4-6) 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 that 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 4).
- 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[p]. 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 5).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) 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 also conducts 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), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) for their comments or concerns with the proposed proprietary name and ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review.

[p] 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

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 OPQ 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 Safety Evaluator 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 4. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.

Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such 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 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e., drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg	
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses.	
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? • Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as z and f), is	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 as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	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 names appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	

Table 6. 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. Utebzi Study (Conducted on 1/5/2026)

Handwritten Medication Order Prescription	Verbal Prescription
Inpatient: Utebzi 600 mg po q6hrs	Utebzi 2 tablets by mouth four times daily for 10 days. Dispense 80
Outpatient: Utebzi 2 tablets po QID x 10 days Dispense #80	
Computerized Prescription Order Entry (CPOE) Study Sample (displayed as sans-serif, 12-point, bold font)	
Utebzi	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Utebzi People Received Study: 158 People Responded: 87					
Total	25	21	19	22	87
INTERPRETATION	INPATIENT WRITTEN	OUTPATIENT WRITTEN	VERBAL	CPOE	TOTAL
EUTEBZY	0	0	1	0	1
UTEBYI	2	0	0	0	2
UTEBZEE	0	0	1	0	1
UTEBZI	6	21	6	22	54
UTEBZY	0	0	7	0	7
UTELRYI	1	0	0	0	1
UTELZI	5	0	0	0	5
UTEMPZEE	0	0	1	0	1
UTEMPZY	0	0	1	0	1
UTEPBZY	0	0	1	0	1
VTEBZI	3	0	0	0	3
VTEBZY	1	0	0	0	1
VTELBYI	1	0	0	0	1
VTELZI	6	0	0	0	6
YOUTEPYI	0	0	1	0	1

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is **≥70%)**

No.	Proposed name: Utebzi Pronunciation: yoo teb' zee Established name: tebipenem pivoxil Dosage form: Tablets Strength(s): 300 mg Dosage: 600 mg (two 300 mg tablets) 4 times a day (every 6 hours) for 7 to 10 days.	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	N/A		

APPENDIX D. MODERATELY SIMILAR NAMES (e.g., combined POCA score is **≥55%** to **≤69%)** with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	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: Utebzi Pronunciation: yoo teb' zee Established name: tebipenem pivoxil Dosage form: Tablets Strength(s): 300 mg Dosage: 600 mg (two 300 mg tablets) 4 times a day (every 6 hours) for 7 to 10 days.	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.	N/A		

APPENDIX F: LOW SIMILARITY NAMES (e.g., combined POCA score is **≤54%)**

No.	Name	POCA Score (%)
1.	N/A	

APPENDIX G. Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4) ***	56	Proposed proprietary name for NDA (b) (4) found to be unacceptable due to a conflict with a marketed product (PNR ID # (b) (4)). NDA (b) (4) is pending, and no new names have been submitted.

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

No.	Name	POCA Score (%)
1.	(b) (4) ***	66
2.	(b) (4) ***	57
3.	(b) (4) ***	56

[q] 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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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)

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Date of This Review:	January 10, 2022
Application Type and Number:	NDA 215960
Product Name and Strength:	(b) (4) (tebipenem pivoxil) Tablets, 300 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Spero Therapeutics, Inc. (Spero)
PNR ID #:	2021-1044724255
DMEPA 1 Safety Evaluator:	Deborah Myers, RPh, MBA
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

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