CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215423Orig1s000

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:	October 4, 2021
Application Type and Number:	NDA 215423
Product Name and Strength:	Entadfi (finasteride and tadalafil) capsule, 5 mg/5 mg
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Veru Inc. (Veru)
PNR ID #:	2021-1044724080
DMEPA 2 Safety Evaluator:	Justine Kalonia, PharmD
DMEPA 2 Acting Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2 Acting Director:	Danielle Harris, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Entadfi, 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. Veru submitted an external name study, conducted by [redacted], for this proposed proprietary name.

1.1 REGULATORY HISTORY

Veru previously submitted the proposed proprietary name, [redacted]*** on February 24, 2021. However, we found the name, [redacted]*** unacceptable due to orthographic similarities and shared product characteristics with the proposed proprietary name, [redacted]*** under NDA 215423 on June 14, 2021.[a]

Thus, Veru submitted the name, Entadfi, for review on July 23, 2021.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on July 23, 2021.

- Intended Pronunciation: en-TAD-fee
- Active Ingredient: finasteride and tadalafil
- Indication of Use: treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) for up to 26 weeks.
- Route of Administration: oral
- Dosage Form: capsule
- Strength: 5 mg/5 mg
- Dose and Frequency: 1 capsule once daily for up to 26 weeks
- How Supplied: HDPE bottles with a low moisture polyester coil and sealed with a heat-sealed foil HDPE cap as 30-count per bottle or 90-count per bottle.
- Storage: Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

2 RESULTS

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

[a] Morris, C. Proprietary Name Review for [redacted] (tadalafil and finasteride). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 JUN 14. PNR ID No. 2021-1044723829.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Entadfi would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) and the Division of Urology, Obstetrics, and Gynecology (DUOG) concurred with the findings of OPDP's assessment for Entadfi.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Veru indicated in their submission that the proposed proprietary name, Entadfi, is "a variation on the first syllables of the two active ingredients in the product, tadalafil and finasteride." This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On August 16, 2021, the Division of Urology, Obstetrics, and Gynecology (DUOG) did not forward any comments or concerns relating to Entadfi at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One hundred thirty-seven practitioners participated in DMEPA's prescription studies for Entadfi.

One respondent in the Computerized Physician Order Entry (CPOE) study selected "Alfentanil" instead of Entadfi from the dynamic contains picklist, which is a direct hit to the marketed product Alfentanil. Upon further evaluation, we note that the participant typed the correct first four letters of Entadfi, however, they were randomized to a "Dynamic Contains" picklist, which instead of showing names beginning with those letters, shows any name containing that letter string. Thus, the respondent selected one of the first names in the picklist instead of scrolling down to the correct name. We evaluated the name pair, Entadfi and Alfentanil, further and find that there are sufficient orthographic, phonetic and product characteristic differences.

> Orthographically, the names begin with different first letters (E vs. A) and differ in length (7 vs. 10 letters). Additionally, Entadfi contains the cross-stroke letter "t" in the 3rd position, whereas the letter "t' appears in the 6th position in Alfentanil. Furthermore, Entadfi contains 2 upstroke letters (d and f) in the 5th and 6th positions, whereas Alfentanil contains 3 upstroke letters (l, f, and l) in the 2nd, 3rd, and 10th positions. These differences give the name pair different shapes when scripted.

[b] USAN stem search conducted on July 27, 2021.

Phonetically, Entadfi has one less syllable than Alfentanil and the names sound different when spoken (en-TAD-fee vs. al-fen-ta-nil).

Furthermore, FDA's Phonetic and Orthographic Computer Analysis (POCA) program calculates a combined score of 52% for this name pair suggesting there is low similarity between the names.

Additionally, there is no direct overlap in dosage form (capsule vs. injection), route of administration (oral vs. intravenous), and frequency of administration (once daily vs. as needed for anesthesia), which may provide additional differentiation if included. Furthermore, it is unlikely that Alfentanil will be available in the same use environment as Entadfi because Alfentanil is administered intravenously to a patient in an operating room.

When all of the aforementioned mitigations are considered in totality, we find the risk of name confusion is minimal (See **Appendix F**).

Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 146 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 and (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	6
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	122
Low similarity name pair: combined match percentage score ≤54%	20

[c] POCA search conducted on July 27, 2021 in version 4.4.

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

Our analysis of the 148 names contained in Table 1 determined none of the names will pose a risk for confusion with Entadfi as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA 2 communicated our findings to the Division of Urology, Obstetrics, and Gynecology (DUOG). At that time we also requested additional information or concerns that could inform our review. On October 4, 2021, the Division of Urology, Obstetrics, and Gynecology (DUOG) stated no additional concerns with the proposed proprietary name, Entadfi.

3 CONCLUSION

The proposed proprietary name, Entadfi, is acceptable.

If you have any questions or need clarifications, please contact Oyinlola Fashina, OSE project manager, at 301-796-4446.

3.1 COMMENTS TO VERU INC.

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

If any of the proposed product characteristics as stated in your submission, received on July 23, 2021, 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. [d]

[d] 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 names[e]. 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

[e] 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. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

   When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

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

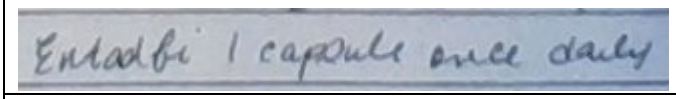
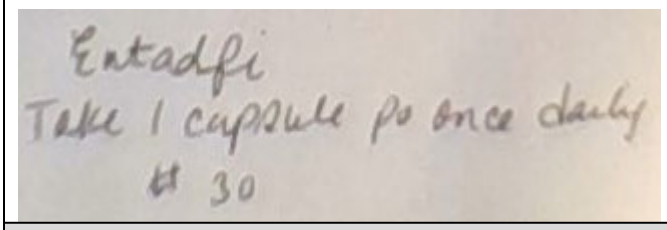
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Entadfi Study (Conducted on August 3, 2021)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Entadfi Take 1 capsule by mouth once daily. Dispense # 30
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Entadfi	

FDA Prescription Simulation Responses (Aggregate Report)

As of Date 8/17/2021

265 People Received Study

137 People Responded

Study Name: Entadfi

Total	**29**	**43**	**32**	**33**	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
ALFENTANIL	0	1	0	0	1
ANTADFEE	0	0	2	0	2
ANTADFI	0	0	2	0	2
ANTADFY	0	0	1	0	1
ANTADPHI	0	0	1	0	1
ANTADTHEE	0	0	1	0	1
EATADFI	1	0	0	0	1

ENLADBI	0	0	0	2	2
ENLADFI	0	0	0	2	2
ENLODBI	0	0	0	1	1
ENLODFI	0	0	0	2	2
ENRODFI	0	0	0	1	1
ENTABFI	0	0	1	0	1
ENTADBI	0	0	0	3	3
ENTADEE	0	0	1	0	1
ENTADFE	0	0	1	0	1
ENTADFEE	0	0	7	0	7
ENTADFI	25	42	7	10	84
ENTADFLI	1	0	0	0	1
ENTADFY	0	0	2	0	2
ENTADIFI	2	0	0	0	2
ENTADPHIE	0	0	1	0	1
ENTADTY	0	0	1	0	1
ENTADVEE	0	0	1	0	1
ENTADVI	0	0	1	0	1
ENTAFEE	0	0	1	0	1
ENTODBI	0	0	0	5	5
ENTODFI	0	0	0	5	5
ERLADBI	0	0	0	1	1
ERTODFI	0	0	0	1	1
INTADFEE	0	0	1	0	1

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

No.	**Proposed name:** Entadfi **Established name:** finasteride and tadalafil **Dosage form:** capsule **Strength(s):** 5 mg/5 mg **Usual Dose:** 1 capsule once daily	**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.	(b) (4) ***	71	Proposed proprietary name for NDA 215423 found unacceptable by DMEPA (OSE# 2021-1044723829). Subsequently, the Applicant submitted the proposed proprietary name, Entadfi, which is the subject of this review.
2.	Menquadfi	70	This name pair has sufficient orthographic and phonetic differences. Orthographically, the names begin with different first letters (E vs. M) and differ in length (7 vs. 9 letters). Additionally, Entadfi contains the cross-stroke letter 't' in the 3rd position, whereas Menquadfi does not contain any cross-stroke letters. Furthermore, Menquadfi contains the downstroke letter 'q' in the 4th position, whereas Entadfi does not contain any downstroke letters. These differences give the name pair different shapes when scripted. Phonetically, the onsets of the first two syllables (en-TAD vs. men-quad) sound different when spoken. Additionally, there is no direct overlap in dosage form (capsule vs. solution for injection), route of administration (oral vs. intramuscular injection), and frequency of administration (once daily vs. single dose), which may provide additional differentiation if included.
3.	Pentids '200'	70	Product discontinued with no generic equivalents available. ANDA 062149 and 062155 withdrawn FR effective 11/25/1992.
4.	Pentids '250'	70	Product discontinued with no generic equivalents available. ANDA 062155 withdrawn FR effective 11/25/1992.

No.	**Proposed name:** Entadfi **Established name:** finasteride and tadalafil **Dosage form:** capsule **Strength(s):** 5 mg/5 mg **Usual Dose:** 1 capsule once daily	**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.**
5.	Pentids '400'	70	Product discontinued with no generic equivalents available. ANDA 060392, 062149, and 062155 withdrawn FR effective 11/25/1992.
6.	Pentids '800'	70	Product discontinued with no generic equivalents available. ANDA 060392 and 062155 withdrawn FR effective 11/25/1992.

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.	Antacid I	66
2.	Antacid M	58

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:** Entadfi **Established name:** finasteride and tadalafil **Dosage form:** capsule **Strength(s):** 5 mg/5 mg **Usual Dose:** 1 capsule 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.	Tandem F	66	This name pair has sufficient orthographic and phonetic differences.
2.	Mentax	65	This name pair has sufficient orthographic and phonetic differences.
3.	End-Itch	64	This name pair has sufficient orthographic and phonetic differences.
4.	Pentacef	64	This name pair has sufficient orthographic and phonetic differences.
5.	Entex T	63	This name pair has sufficient orthographic and phonetic differences. Orthographically, Entadfi contains the upstroke letter ‘d’ in the 5th position and

No.	**Proposed name:** Entadfi **Established name:** finasteride and tadalafil **Dosage form:** capsule **Strength(s):** 5 mg/5 mg **Usual Dose:** 1 capsule 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**
			the dotted letter 'i' in the 7th position, whereas Entex T does not contain an upstroke letter in the 5th position nor any dotted letters, giving the names different shapes when scripted. Additionally, Entadfi contains the letter 'f' in the 6th position, which if scripted with a downstroke, could further differentiate the shapes of the names. Phonetically, Entadfi has an extra syllable than the root name Entex. Additionally, the second syllables (TAD vs. tex) sound different when spoken. Additionally, there is no direct overlap in strength (5 mg/5 mg vs. 375 mg-60 mg) and frequency of administration (once daily vs. every 4 to 6 hours as needed), which may provide additional differentiation if included. Furthermore, Entex is a root name for multiple products that each use a unique modifier; thus, a prescription for Entex T must include the modifier "T", which indicates the specific product and may provide further differentiation.
6.	Antabuse	62	This name pair has sufficient orthographic and phonetic differences.
7.	Centany	62	This name pair has sufficient orthographic and phonetic differences.
8.	Entyvio	62	This name pair has sufficient orthographic and phonetic differences. Orthographically, Entadfi contains the upstroke letters 'd' in the 5th position and 'f' in the 6th position, whereas Entyvio does not contain any upstroke letters in the suffix. Additionally, Entyvio contains the downstroke letter 'y' in the 4th position, whereas Entadfi does not contain

No.	**Proposed name:** Entadfi **Established name:** finasteride and tadalafil **Dosage form:** capsule **Strength(s):** 5 mg/5 mg **Usual Dose:** 1 capsule 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**
			any downstroke letters in the infix. These differences give the name pair different shapes when scripted. Phonetically, Entadfi contains one less syllable than Entyvio. Also, the ending of the second syllables (TAD vs. ti') sounds different when spoken. Additionally, there is no direct overlap in strength (5 mg/5 mg vs. 300 mg), dosage form (capsule vs. lyophilized powder for injection), route of administration (oral vs. intravenous infusion), and frequency of administration (once daily vs. administered at 0, 2, and 6 weeks then every 8 weeks thereafter), which may provide additional differentiation if included.
9.	Integra F	62	This name pair has sufficient orthographic and phonetic differences.
10.	Pentasa	62	This name pair has sufficient orthographic and phonetic differences.
11.	Ventavis	62	This name pair has sufficient orthographic and phonetic differences.
12.	Bentasil	61	This name pair has sufficient orthographic and phonetic differences.
13.	Endari	61	This name pair has sufficient orthographic and phonetic differences.
14.	Anti-Gas	60	This name pair has sufficient orthographic and phonetic differences.
15.	Anti-Gas-80	60	This name pair has sufficient orthographic and phonetic differences.
16.	Entecavir	60	This name pair has sufficient orthographic and phonetic differences. Orthographically, the names differ in length (7 vs. 9 letters). Additionally, Entadfi contains the upstroke letters 'd' and 'f', whereas Entecavir does not

No.	**Proposed name:** Entadfi **Established name:** finasteride and tadalafil **Dosage form:** capsule **Strength(s):** 5 mg/5 mg **Usual Dose:** 1 capsule 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**
			contain any upstroke letters, which give the names different shapes when scripted. Phonetically, the ending of the second syllables (TAD vs. tek') and the third syllables (fee vs. a) sound different when spoken. Additionally, Entadfi contains one less syllable than Entecavir.
17.	Gentafair	60	This name pair has sufficient orthographic and phonetic differences.
18.	End-Zit	59	This name pair has sufficient orthographic and phonetic differences.
19.	Alfenta	58	This name pair has sufficient orthographic and phonetic differences.
20.	Entex Lq	58	This name pair has sufficient orthographic and phonetic differences. Orthographically, Entadfi contains the upstroke letter 'd' in the 5th position and the dotted letter 'i' in the 7th position, whereas Entex Lq does not contain any dotted letters or upstroke letters in suffix of the root name, giving the names different shapes when scripted. Phonetically, Entadfi has an extra syllable than the root name Entex. Additionally, the second syllables (TAD vs. tex) sound different when spoken. Additionally, there is no direct overlap in strength (5 mg/5 mg vs. 100 mg-10 mg per 5 mL), dosage form (capsule vs. solution), and frequency of administration (once daily vs. every 4 hours as needed), which may provide additional differentiation if included. Furthermore, Entex is a root name for multiple products that each use a unique modifier; thus, a prescription for Entex Lq must include the modifier "Lq", which indicates the

No.	**Proposed name:** Entadfi **Established name:** finasteride and tadalafil **Dosage form:** capsule **Strength(s):** 5 mg/5 mg **Usual Dose:** 1 capsule 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**
			specific product and may provide further differentiation.
21.	Gentacidin	57	This name pair has sufficient orthographic and phonetic differences.
22.	Imfinzi	57	This name pair has sufficient orthographic and phonetic differences.
23.	[redacted]***	56	This name pair has sufficient orthographic and phonetic differences. Orthographically, the names begin with different first letters (E vs. A). Also, Entadfi contains the cross-stroke letter 't' in the 3rd position, whereas [redacted] contains the cross-stroke letter [redacted] in the 6th position, which give the names different shapes when scripted. Additionally, Entadfi contains the optional downstroke letter 'f', which may provide additional differentiation in shape if scripted with a downstroke because [redacted] does not contain any downstroke letters. Phonetically, the second and third syllables (TAD-fee vs. [redacted] sound different when spoken. Additionally, there is no direct overlap in strength (5 mg/ 5 mg vs. [redacted] dosage form (capsule vs. [redacted] route of administration (oral vs. [redacted]), and frequency of administration (once daily vs. [redacted] which may provide additional differentiation if included.
24.	Android-F	56	This name pair has sufficient orthographic and phonetic differences.
25.	Anktiva***	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Entadfi **Established name:** finasteride and tadalafil **Dosage form:** capsule **Strength(s):** 5 mg/5 mg **Usual Dose:** 1 capsule 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**
26.	Aptensio (root name for Aptensio XR)	56	This name pair has sufficient orthographic and phonetic differences.
27.	Endodan	56	This name pair has sufficient orthographic and phonetic differences.
28.	Entero Vu 24%	56	This name pair has sufficient orthographic and phonetic differences. Orthographically, Entadfi contains the upstroke letters 'd' in the 5th position and 'f' in the 6th position, and the dotted letter 'i' in the 7th position, whereas Entero Vu 24% does not contain any dotted letters or upstroke letters in the suffix. These differences give the name pair different shapes when scripted. Phonetically, the ending of the second syllables (TAD vs. (t)ə) and the third syllables (fee vs. rō) sound different when spoken. Additionally, there is no direct overlap in strength (5 mg/5 mg vs. 24% w/v), dosage form (capsule vs. suspension), and frequency of administration (once daily vs. for use in small bowel radiographic examinations), which may provide additional differentiation if included. Furthermore, Entero is a root name for two products, which each use a unique modifier; thus, a prescription for Entero Vu 24% must include the modifiers "Vu 24%", which indicates the specific product and may provide further differentiation.
29.	Entresto	56	This name pair has sufficient orthographic and phonetic differences. Orthographically, Entadfi contains the upstroke letters 'd' and 'f' in the 5th and 6th positions and a dotted letter 'i' in the 7th position, whereas Entresto does not

No.	**Proposed name:** Entadfi **Established name:** finasteride and tadalafil **Dosage form:** capsule **Strength(s):** 5 mg/5 mg **Usual Dose:** 1 capsule 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**
			contain any dotted letters nor any upstroke letters in the 5th and 6th positions. These differences give the name pair different shapes when scripted. Phonetically, the ending of the second syllables (TAD vs. TRESS) and the third syllables (fee vs. toh) sound different when spoken. Additionally, there is no direct overlap in strength (5 mg/5 mg vs. 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg) and since Entresto is available in multiple strengths, a strength must be provided on the prescription. Furthermore, there is no direct overlap in frequency of administration (once daily vs. twice daily), which may provide additional differentiation if included.
30.	Fentanyl	56	This name pair has sufficient orthographic and phonetic differences.
31.	Fentanyl-100	56	This name pair has sufficient orthographic and phonetic differences.
32.	Fentanyl-12	56	This name pair has sufficient orthographic and phonetic differences.
33.	Fentanyl-25	56	This name pair has sufficient orthographic and phonetic differences.
34.	Fentanyl-37	56	This name pair has sufficient orthographic and phonetic differences.
35.	Fentanyl-50	56	This name pair has sufficient orthographic and phonetic differences.
36.	Fentanyl-62	56	This name pair has sufficient orthographic and phonetic differences.
37.	Fentanyl-75	56	This name pair has sufficient orthographic and phonetic differences.
38.	Fentanyl-87	56	This name pair has sufficient orthographic and phonetic differences.
39.	Gentamicin	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Entadfi **Established name:** finasteride and tadalafil **Dosage form:** capsule **Strength(s):** 5 mg/5 mg **Usual Dose:** 1 capsule 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**
40.	Intuniv	56	This name pair has sufficient orthographic and phonetic differences.
41.	Mintab Dm	56	This name pair has sufficient orthographic and phonetic differences.
42.	Pentrax	56	This name pair has sufficient orthographic and phonetic differences.
43.	Endocet	55	This name pair has sufficient orthographic and phonetic differences.
44.	Pentacel	55	This name pair has sufficient orthographic and phonetic differences.
45.	Pentam	55	This name pair has sufficient orthographic and phonetic differences.
46.	Pentam 300	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.	Naftin	54
2.	Pentamidine	54
3.	Dent-O-Kain	53
4.	Alfentanil	52
5.	Amantadine	52
6.	Betadine	52
7.	Dentapaine	52
8.	Tepadina	52
9.	Butenafine	50
10.	Diet Aid	49
11.	Trandide	49
12.	Legend Teat Dip	48
13.	Naftifine	48
14.	EXCEDRIN	47
15.	Terfenadine	44
16.	Taladine	40
17.	Triadine	39
18.	ELIQUIS	25

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.	Entex	68	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
2.	(b) (4) ***	68	Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA (b) (4)). IND (b) (4) is pending and no new names have been submitted.
3.	Endafed	67	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
4.	Entex S	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Entaprin	64	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
6.	Fentazin	64	International product marketed in the United Kingdom and formerly marketed in Ireland.
7.	Antepsin	63	International product marketed in Italy, Turkey, the United Kingdom, Denmark, Finland, Norway; and formerly marketed in Argentina, Ireland, and Brazil.
8.	Entex La	63	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
9.	Entyce	63	Veterinary product.
10.	Antacid Ds	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
11.	Entex Er	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
12.	Mantadil	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
13.	(b) (4) ***	61	This was a proposed name for a CBER product. The name was withdrawn in CBER memorandum dated 11/13/2015. BLA 125586 was approved under the name Andexxa.

No.	Name	POCA Score (%)	Failure preventions
14.	Lentard	61	Brand discontinued with no generic equivalents available. NDA 018384 withdrawn FR effective 09/25/1997.
15.	Antacid Ii	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
16.	Anti Cle	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
17.	Antiben	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
18.	Enkaid	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
19.	Mentadent	60	Product is not a drug. It is a line of over-the-counter toothpastes.
20.	Antituss	58	International product formerly marketed in Hong Kong and South Africa.
21.	Anti-Tuss	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
22.	Bentex	58	International product formerly marketed in the United Kingdom
23.	Centex (root name for Centex PSE)	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
24.	Ed Cyte F	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
25.	(b) (4) ***	58	Proposed proprietary name for NDA 210566 found unacceptable by DMEPA (OSE# 2017-19081749). NDA 210566 approved under the proprietary name Lexette.
26.	Gentaved	58	Veterinary product.
27.	Gentaved 100	58	Veterinary product.
28.	Infestat	58	International product formerly marketed in the United Kingdom.
29.	(b) (4) ***	58	Proposed proprietary name for IND 120784 found unacceptable by DMEPA (OSE# 2019-34271035 dated 02/28/2020). Subsequently, the proposed proprietary name Tavneos*** was found conditionally acceptable for NDA 214487.

No.	Name	POCA Score (%)	Failure preventions
30.	Antatens	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
31.	Mantadine	57	International product formerly marketed in the United Kingdom.
32.	Andec-Tr	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
33.	Anti Bac	56	International product marketed in Canada.
34.	Centrax	56	Brand discontinued with no generic equivalents available. NDA 017415 and NDA 018144 withdrawn FR effective 03/02/1994 and 04/26/1996, respectively.
35.	Denti-Rinse	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
36.	(b) (4) ***	56	Proposed proprietary name for (b) (4) found to be conditionally acceptable on (b) (4) (b) (4) Entire application withdrawn by the Applicant.
37.	Endacof Ac	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
38.	Endacof C	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
39.	Endal Cd	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
40.	Endoxan	56	International product marketed and formerly marketed in multiple countries outside of the US.
41.	Entex Pse	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
42.	Entuss D	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
43.	Gentamed	56	Veterinary product.
44.	Kentace	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
45.	Adifax	55	International product formerly marketed in Australia, Ireland, South Africa, and the United Kingdom.
46.	Ancestim	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
47.	1,5-Pentanediol	55	Product is not a drug. It is an organic compound used as a plasticizer.
48.	Elantan	55	International product marketed and formerly marketed in multiple countries outside of the US.
49.	(b) (4) ***	55	Proposed proprietary name withdrawn by the Applicant. Product approved under the proprietary name, Qwo.
50.	Endotuss	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
51.	Entero (root name for Entero Vu 24% (b) (4)	55	Entero*** is a root name for the marketed products Entero Vu 24% (b) (4) The name Entero*** is not used alone to order a product without the suffix modifiers. Entero Vu 24% is evaluated in Appendix E above.
52.	Defend Ii	53	Veterinary product.
53.	Ventaire	49	Product discontinued with no generic equivalents available. ANDA 083459 withdrawn FR effective 07/07/1983.

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

No.	Name	POCA Score (%)
1.	Xtandi	63
2.	Uni-Tann D	62
3.	An-Dtpa	60
4.	Tannate 12D S	60
5.	(b) (4) ***	59
6.	Zenzedi	59
7.	Ben Tann	58
8.	(b) (4) ***	57

[f] 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 (%)
9.	Bendectin	56
10.	Cinvanti	56
11.	Ditate-Ds	56
12.	Femcon Fe	56
13.	Fintepla	56
14.	Masanti	56
15.	Nafrinse	56
16.	Nintedanib	56
17.	(b) (4) ***	56
18.	Tanafed	56
19.	Tanafed Dp	56
20.	Minitabs	55
21.	Mintex	55
22.	Natazia	55
23.	Pendex	55

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PROPRIETARY NAME REVIEW

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

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

Date of This Review:	June 14, 2021
Application Type and Number:	NDA 215423
Product Name and Strength:	(b) (4) (tadalafil and finasteride) capsule, 5 mg/ 5 mg
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Veru Inc. (Veru)
PNR ID #:	2021-1044723829
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Acting Team Leader:	Celeste Karpow, PharmD, MPH
DMEPA Deputy Director:	Danielle Harris, PharmD

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