CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210557Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	August 10, 2018
Application Type and Number:	NDA 210557
Product Name and Strength:	Vyleesi (bremelanotide) injection
Total Product Strength:	1.75 mg/0.3 mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Rx
Applicant/Sponsor Name:	AMAG Pharmaceuticals
Panorama #:	2018-2340393
DMEPA Safety Evaluator:	Denise V. Baugh, PharmD, BCPS
DMEPA Team Leader:	Lolita G. White, PharmD

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name [redacted], *** on September 8, 2017, and we found this name acceptable [redacted] dated March 6, 2018 for IND 064119). However, the Applicant withdrew the proposed proprietary name, [redacted] *** on June 8, 2018 and submitted the proposed proprietary name, Vyleesi, on May 30, 2018, to NDA 210557.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on May 30, 2018.

- Intended Pronunciation: vahy-lee-see
- Active Ingredient: bremelanotide
- Indication of Use: treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is not due to: a co-existing medical or psychiatric condition; problems with the relationship; or the effects of a medication or drug substance.
- Route of Administration: subcutaneous
- Dosage Form: injection
- Strength: 1.75 mg/0.3 mL
- Dose and Frequency: Inject 1.75 mg subcutaneously as desired at least 45 minutes before anticipated sexual activity.
- How Supplied: pre-packaged in a single use disposable prefilled autoinjector pen
- Storage: 25°C (77°F). Do not freeze. Protect from light.

2 RESULTS

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

*** This document contains proprietary and confidential information that should not be released to the public.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) concurred with the findings of OPDP's assessment of the proposed name. However, the Division of Bone, Reproductive and Urologic Products (DBRUP) expressed concerns that the name was promotional. See Section 2.2.3 for further details.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, June 19, 2018 e-mail, the Division of Bone, Reproductive and Urologic Products (DBRUP) forwarded the following comments relating to the proposed proprietary name at the initial phase of the review:

We believe that the proposed name could be considered promotional. There are overtones and undertones of strength, sexuality, and fertility with the name.

We will have objections based on the following language from the guidance. In addition to the safety review, FDA conducts a promotional review of proposed proprietary names. This promotional review considers whether the name functions to overstate the efficacy, minimize the risk, broaden the indication, or make unsubstantiated superiority claims for the product, or is overly "fanciful" by misleadingly implying unique effectiveness or composition, or is otherwise false or misleading. (See 21 U.S.C 321(n), 352(a) and (n); see also 21 CFR 201.10 (c)(3), 202.1(a)(3), (e)(5)(i), and (e)(6)(i).)

We communicated DBRUP's concerns to OPDP and they maintained their non-objection to the name. In our e-mail dated July 17, 2018 we acknowledged DBRUP's concerns and the DBRUP team deferred to OPDP's decision.

2.2.4 FDA Name Simulation Studies

Seventy-eight practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. We note one participant entered in

[a] USAN stem search conducted on June 4, 2018.

error the name (b) (4)***. This response was an error and not considered part of this name review. Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[b] identified 60 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 the (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	61
Low similarity name pair: combined match percentage score ≤54%	12

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

Our analysis of the 75 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Bone, Reproductive and Urologic Products (DBRUP) via e-mail on August 8, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DBRUP on August 9, 2018, they maintained their previous promotional concerns regarding the proposed proprietary name, Vyleesi, but deferred to OPDP and to DMEPA regarding the final decision about this name.

3 CONCLUSION

The proposed proprietary name is acceptable.

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

[b] POCA search conducted on July 19, 2018 in version 4.2.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on May 30, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

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

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

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

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

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

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

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

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

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

---

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

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

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

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

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

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

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

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

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *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.

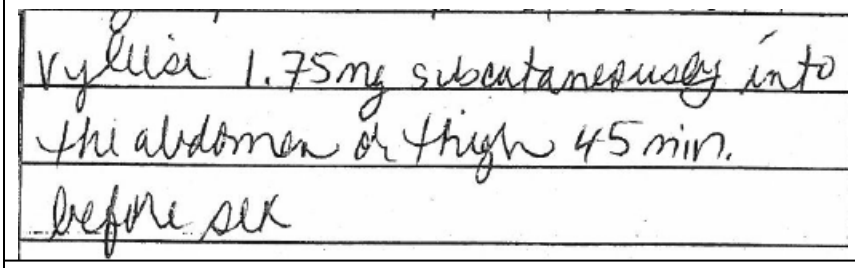
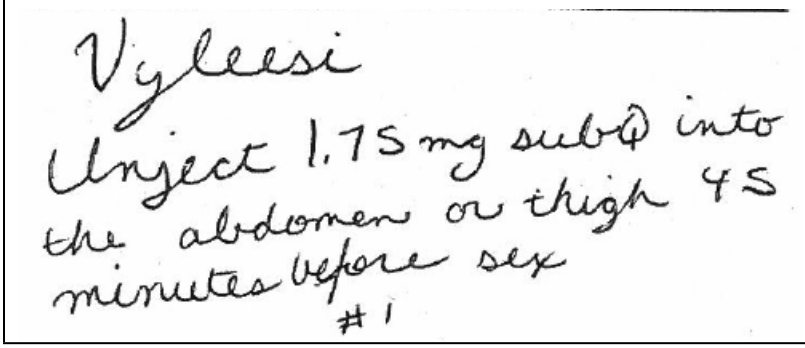
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Vyleesi Name Study (Conducted on June 8, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	"Vyleesi inject 1.75 mg subQ into the abdomen or thigh before sex; dispense # 1"
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Vyleesi

As of Date 7/19/2018

308 People Received
Study
78 People Responded

Study Name: Vyleesi

Total	**22**	**21**	**17**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
FALEESI	0	1	0	1
MAVENCLAD	0	0	1	1
VALEESE	0	1	0	1
VALEESI	0	1	0	1
VALEEVEE	0	1	0	1
VALEEZEE	0	1	0	1
VALEEZY	0	1	0	1
VALESEE	0	2	0	2
VALESY	0	1	0	1
VALEZEE	0	1	0	1
VALEZI	0	1	0	1
VALICI	0	1	0	1
VAYLEASY	0	1	0	1
VAYLEESEE	0	1	0	1
VAYLEESI	0	1	0	1
VAYLEZEE	0	1	0	1
VAYLIZEE	0	1	0	1
VELIZE	0	1	0	1
VEYLEESY	0	1	0	1
VLYUSI	0	0	1	1
VYLEESI	21	0	1	40
VYLESSI	1	0	0	1
VYLUSE	0	0	2	2
VYLUSI	0	0	12	12
ZALEESE	0	1	0	1
ZAYLISI	0	1	0	1

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

No.	**Proposed name:** Vyleesi **Established name:** bremelanotide **Dosage form:** injection **Strength(s):** 1.75 mg/0.03 mL **Usual Dose:** 1.75 mg subcutaneously into the thigh or abdomen 45 minutes before anticipated sexual activity	**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.	Vyleesi	100	Name is the focus of this review.
2.	(b) (4)***	70	DMEPA found this name unacceptable (OSE Review # 2016-7685005 dated July 14, 2016) due to its (b) (4) to Bevespi Aerosphere (NDA 208294). NDA 209195 was approved July 18, 2017 with the alternative proprietary name, Vosevi.

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 (%)
3.	Veetids	56
4.	Veetids '125'	56
5.	Veetids '250'	56
6.	Veetids '500'	56
7.	Veletri	66
8.	Veltassa	60
9.	Vivelle	60
10.	Vyvanse	59
11.	Levsin	56

*** This document contains proprietary and confidential information that should not be released to the public.

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:** Vyleesi **Established name:** bremelanotide **Dosage form:** injection **Strength(s):** 1.75 mg/0.03 mL **Usual Dose:** 1.75 mg subcutaneously into the thigh or abdomen 45 minutes before anticipated sexual activity	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**
12.	Mytesi	61	This name pair has sufficient orthographic and phonetic differences. Orthographically, the first letter (‘V’ vs. ‘M’) and third letter (‘l’ vs. ‘t’) differ when written. Additionally, the infix and suffix for Vyleesi (‘-eesi’) is longer in length than that for Mytesi (‘-esi’) further differentiating this name pair. Phonetically, the second syllables (‘ēē’ vs. ‘ĕ’) sound different. The dose does not overlap but would need to be specified on a prescription (1.75 mg or UD vs. 125 mg or one capsule) for Mytesi, which may help minimize the risk for medication error.
13.	Vosevi	60	This name pair has sufficient orthographic and phonetic differences.
14.	Philith	52	This name pair has sufficient orthographic and phonetic differences.
15.	Valisone	56	This name pair has sufficient orthographic and phonetic differences.
16.	Velivet	64	This name pair has sufficient orthographic and phonetic differences.
17.	Veltin	62	This name pair has sufficient orthographic and phonetic differences.
18.	Vemlidy	62	This name pair has sufficient orthographic and phonetic differences.
19.	Vepesid	60	This name pair has sufficient orthographic and phonetic differences.
20.	Verdeso	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Vyleesi **Established name:** bremelanotide **Dosage form:** injection **Strength(s):** 1.75 mg/0.03 mL **Usual Dose:** 1.75 mg subcutaneously into the thigh or abdomen 45 minutes before anticipated sexual activity	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**
21.	Xylose	64	This name pair has sufficient orthographic and phonetic differences. The applicant (Lyne Laboratories, Inc.) has stopped marketing the drug product and requested withdrawal of NDA 018856 on February 16, 2018***. The Agency has initiated withdrawal of this application.
22.	Zylet	63	This name pair has sufficient orthographic and phonetic differences.
23.	Beelith	60	This name pair has sufficient orthographic and phonetic differences.
24.	(b) (4)***	60	This name pair has sufficient orthographic and phonetic differences.
25.	(b) (4)***	59	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 (%)
26.	Vytorin	37
27.	Vyfemia	50
28.	Vilazodone	38
29.	EES (erythromycin ethylsuccinate)	34
30.	Wygesic	50
31.	Kyleena	54
32.	Valsartan	37
33.	Olysio	51
34.	Mvasi	48
35.	Varubi	35
36.	Verzenio	44
37.	Vyzulta	48

*** This document contains proprietary and confidential information that should not be released to the public.

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
38.	Velosef	62	Brand discontinued with no generic equivalents available. NDA 050530 withdrawn FR effective 11/05/1992.
39.	Velosef '125'	62	Brand discontinued with no generic equivalents available. ANDA 061673 withdrawn FR effective 05/15/2007.
40.	Velosef '250'	62	Brand discontinued with no generic equivalents available. NDA 050548 withdrawn FR effective 06/25/1993.
41.	Velosef '500'	62	Brand discontinued with no generic equivalents available. NDA 050548 withdrawn FR effective 06/25/1993.
42.	Zolyse	66	Brand discontinued with no generic equivalents available. NDA 011903 withdrawn FR effective 03/26/2018.
43.	Ceresin	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
44.	Sleepia	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
45.	Xylene	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
46.	(b) (4)***	59	DMEPA found this name unacceptable (OSE Review # 2016-8278936 dated August 22, 2016) due to its (b) (4) to another pending proprietary name, (b) (4)***. NDA 208743 was approved April 28, 2017 with the proprietary name, Tymlos.
47.	Belesse-21	60	Name identified in External Name Study ((b) (4)). Unable to find product characteristics in commonly used drug databases.
48.	Vyloma	62	International product marketed in Canada.
49.	Velbe	58	International product marketed in Europe.

No.	Name	POCA Score (%)	Failure preventions
50.	(b) (4)***	56	DMEPA found this name unacceptable (OSE Review # 2016-2924779 dated April 21, 2016) due to its (b) (4) with another pending proprietary name under review (b) (4)*** . NDA 208751 was approved September 29, 2017 with the proprietary names, Fiasp and Fiasp Flextouch.
51.	(b) (4)***	56	Name was found to be acceptable (OSE Review # (b) (4)
52.	(b) (4)***	55	DMEPA found this name unacceptable (OSE Review # 2016- 7928232 dated July 29, 2016) due to its (b) (4) with another pending proprietary name under review (b) (4)*** . NDA 208085 was approved April 25, 2018 with the non-proprietary name (hydrocodone and guaifenesin) and the alternative proprietary name Xtrelus*** was found to be acceptable (OSE Review# 2018-22767635 dated July 17, 2018).

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

No.	Name	POCA Score (%)
53.	Bevespi	59
54.	Cyclessa	62
55.	Dylix	58

*** This document contains proprietary and confidential information that should not be released to the public.

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

No.	Name	POCA Score (%)
56.	Elelyso	56
57.	Gelusil	56
58.	Gildess	56
59.	Gildess 1.5/30	56
60.	(b) (4)***	60
61.	Isolyte E	56
62.	Liletta	55
63.	Selseb	56
64.	Silace	56
65.	Sulzee	56
66.	(b) (4)***	58
67.	Tylosin	58
68.	Gildess 1/20	56
69.	(b) (4)***	56
70.	(b) (4)***	56
71.	(b) (4)***	56
72.	Xylitan	55
73.	Xylitol	56
74.	Zileze 3.75	59
75.	Zileze 7.5	59

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DENISE V BAUGH
08/10/2018

LOLITA G WHITE
08/10/2018