CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215244Orig1s000

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:	September 9, 2025
Application Type and Number:	NDA 215244
Product Name, Dosage Form, and Strength:	Forzinity (elamipretide) Injection, 280 mg/3.5 mL (80 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Stealth BioTherapeutics Inc. (Stealth)
PNR ID #:	2025-1044726656
DMEPA 2 Safety Evaluator:	Jody Kundreskas, PharmD
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Stealth previously submitted the proposed proprietary name, Forzinity, under IND 123553 on May 17, 2018 for elamipretide for the treatment of primary mitochondrial myopathy (PMM). On August 30, 2018, we found the name, Forzinity conditionally acceptable under IND 123553.[a]

On April 1, 2019, Stealth submitted the name, Forzinity, under IND 137429 for elamipretide for the treatment of Barth syndrome. On August 26, 2019, we found the name, Forzinity, conditionally acceptable under IND 137429.[b]

On January 29, 2024, Stealth submitted the name, Forzinity, under NDA 215244 for elamipretide for the treatment of Barth syndrome. On April 24, 2024, we found the name, Forzinity, conditionally acceptable under NDA 215244.[c] However, the Application received a Complete Response letter[d] on May 15, 2025.

Thus, Stealth resubmitted the proposed proprietary name, Forzinity, under NDA 215244 as part of the Class 2 Resubmission for review on August 15, 2025.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission[e] and the prescribing information[f] received on August 15, 2025.

Table 1. Relevant Product Information for Forzinity	
Intended Pronunciation:	for zin' i tee
Active Ingredient:	elamipretide
Indication:	For the treatment of patients with Barth syndrome (b) (4)
Dosage Form:	Injection

[a] Rider, B. Proprietary Name Review for Forzinity (IND 123553). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 AUG 30. PNR ID No. 2018-23121747.
[b] Little, C. Proprietary Name Review for Forzinity (IND 137429). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 AUG 26. PNR ID No. 2019-30479991.
[c] Black, S. Proprietary Name Review for Forzinity (NDA 215244). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 APR 24. PNR ID No. 2024-1044725597.
[d] Kane, B. Complete Response for Forzinity. Silver Spring (MD): FDA, CDER, DCN (US); 2025 MAY 15. NDA 215244. Available from: https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af807b944e.
[e] Proprietary Name Request for Forzinity (NDA 215244). Needham (MA): Stealth BioTherapeutics Inc.; 2025 AUG 15. Available from: \\CDSESUB1\EVSPROD\nda215244\0086\m1\us\proprietary-name-request.pdf.
[f] Proposed prescribing information for Forzinity. Needham (MA): Stealth BioTherapeutics Inc.; 2025 AUG 15. Available from: \\CDSESUB1\EVSPROD\nda215244\0086\m1\us\forzinity-elamipretide-uspi-tc.pdf.

Table 1. Relevant Product Information for Forzinity	
Strength:	280 mg/3.5 mL (80 mg/mL)
Route of Administration:	Subcutaneous
Dose and Frequency:	• Patients weighing at least 30 kg: o 40 mg (0.5 mL) once daily (b) (4) • Patients with severe renal impairment (GFR less than 30 mL/min): o 20 mg (0.25 mL) once daily
How Supplied:	FORZINITY (elamipretide) injection is a sterile, clear, colorless to yellow aqueous solution and contains preservative supplied as: Carton containing four 280 mg/3.5 mL (80 mg/mL) single-patient-use vials (NDC 72507-800-04)
Storage:	Store FORZINITY at 2°C to 8°C (36°F to 46°F). Do not freeze. Following the first dose, the in-use vial can be stored either refrigerated 2°C to 8°C (36°F to 46°F) or at room temperature between (b) (4) °C ((b) (4) °F). (b) (4)

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Forzinity would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Forzinity. The Division of Cardiology and Nephrology (DCN) concurred with the findings of OPDP's assessment for Forzinity.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

In our previous review,[c] we noted that the proposed proprietary name, Forzinity, contains the United States Adopted Name (USAN) stem "fo(s)-" in the prefix position of the name. We previously determined that this two-letter string is not distinct enough to be recognized as a

USAN stem and therefore we did not object to its inclusion in the proposed proprietary name. We agree with our previous assessment. Additionally, we searched the USAN stem list[g] and did not identify any other USAN stems contained within the proposed proprietary name.

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Stealth did not provide a derivation or intended meaning for the proposed proprietary name, Forzinity, in their submission. This proprietary name is comprised of a single word that contains the letter strings 'or' and 'in', which are medical abbreviations for 'operating room' and the route of administration 'intranasal', respectively. In our previous review,[c] we determined that the abbreviations "-or-" and "-in-" located within the proposed proprietary name are unlikely to be separated from the surrounding letters in a manner that could lead to confusion. Therefore, we did not object to their inclusion in the proposed proprietary name. We agree with our previous assessment.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Cardiology and Nephrology (DCN) did not forward any comments or concerns relating to Forzinity at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Seventy (70) practitioners participated in FDA's prescription simulation studies for Forzinity. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[h] identified 103 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 reviews. 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 also evaluated the previously identified names considering the change in product characteristics listed in Table 2.

Table 2. Changes in Product Characteristics for Forzinity

	Forzinity (Previous Submission)[c]	Forzinity (Current Submission)
Indication:	Treatment of patients with Barth syndrome	For the treatment of patients with Barth syndrome (b) (4)

[g] USAN stem search conducted on August 19, 2025.
[h] POCA search conducted on August 19, 2025 in version 5.14.3.

Table 2. Changes in Product Characteristics for Forzinity		
	Forzinity (Previous Submission)[c]	Forzinity (Current Submission)
Dose and Frequency:	40 mg (0.5 mL) once daily	• Patients weighing at least 30 kg: o 40 mg (0.5 mL) once daily (b) (4) • Patients with severe renal impairment (GFR less than 30 mL/min): o 20 mg (0.25 mL) once daily

Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Forzinity. We identified six names not previously analyzed. These names are included in Table 3 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 3 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 3. 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%	6
Low similarity name pair: combined match percentage score ≤54%	0

2.2.7 SAFETY ANALYSIS OF NAMES IDENTIFIED

Our analysis of the six names contained in Table 3 determined none of the names will pose a risk for confusion with Forzinity as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On September 9, 2025, DMEPA 2 communicated our determination to the Division of Cardiology and Nephrology (DCN).

3 CONCLUSION

The proposed proprietary name, Forzinity, is conditionally acceptable.

3.1 COMMENTS TO STEALTH BIOTHERAPEUTICS INC.

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

If any of the proposed product characteristics as stated in your submission, received on August 15, 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 4. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.[i]

Table 4. 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.

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

Table 4. 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 5-7) 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 5).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in

the confusion of drug names[j]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.

- Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 6).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 7) 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. Additionally, when applicable, at the same time DMEPA requests concurrence/non-

[j] 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

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 5. 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?		

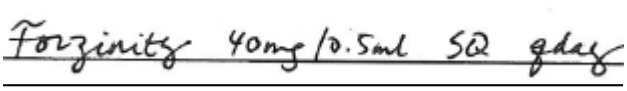
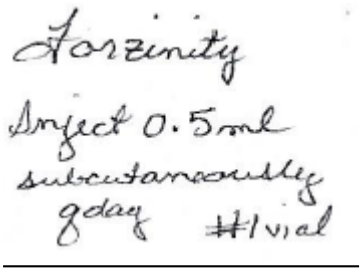
<table>
<tr><th colspan="3">Table 6: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to 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</td></tr>
<tr><td>Step 2</td><td colspan="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.</td></tr>
<tr><td></td><td>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</td><td>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?</td></tr>
</table>

Table 6: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	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 7. 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. Forzinity Study (Conducted on 8/22/2025)

Handwritten Medication Order Prescription	Verbal Prescription
Inpatient:  	Forzinity Inject 0.5 milliliters subcutaneously qday Dispense 1 vial
Outpatient:  	
Computerized Prescription Order Entry (CPOE) Study Sample (displayed as sans-serif, 12-point, bold font)	
Forzinity	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Forzinity People Received Study: 161 People Responded: 70					
Total	16	20	12	22	70
INTERPRETATION	INPATIENT WRITTEN	OUTPATIENT WRITTEN	VERBAL	CPOE	TOTAL
FLORZINITY	0	1	0	0	1
FORZENITI	0	0	1	0	1
FORZENITY	0	0	5	0	5
FORZINITG	1	0	0	0	1
FORZINITI	0	0	1	0	1
FORZINITY	11	13	5	22	51
FORZINITZ	3	0	0	0	3
LORZINITY	0	4	0	0	4
OFORZINITY	0	1	0	0	1
TORZINITY	1	1	0	0	2

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

No.	Proposed name: Forzinity Pronunciation: for zin' i tee Established name: elamipretide Dosage form: Injection Strength(s): 280 mg/3.5 mL (80 mg/mL) Dosage: Patients weighing at least 30 kg: 40 mg (0.5 mL) subcutaneously once daily; (b) (4) Patients with severe renal impairment (GFR less than 30 mL/min): 20 mg (0.25 mL) subcutaneously 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.	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: Forzinity Pronunciation: for zin' i tee Established name: elamipretide Dosage form: Injection Strength(s): 280 mg/3.5 mL (80 mg/mL) Dosage: Patients weighing at least 30 kg: 40 mg (0.5 mL) subcutaneously once daily; (b) (4) Patients with severe renal impairment (GFR less than 30 mL/min): 20 mg (0.25 mL) subcutaneously 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.	(b) (4) ***	56	(b) (4)

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.	Florfeniject	55	Veterinary product.

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

No.	Name	POCA Score (%)
1.	Palsonify***	60
2.	(b) (4) ***	60
3.	Comirnaty 2024-2025	58
4.	Ceritant	55

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

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/s/

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09/09/2025 07:46:38 AM

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PROPRIETARY NAME REVIEW

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

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

Date of This Review:	April 24, 2024
Application Type and Number:	NDA 215244
Product Name, Dosage Form, and Strength:	Forzinity (elamipretide) injection, 280 mg/3.5 mL (80 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Stealth BioTherapeutics Inc. (Stealth)
PNR ID #:	2024-1044725597
DMEPA 2 Safety Evaluator:	Sue Black, PharmD
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature & Labeling:	Hina Mehta, PharmD

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Stealth previously submitted the proposed proprietary name, Forzinity under IND 123553 on May 17, 2018 for elamipretide for the treatment of primary mitochondrial myopathy (PMM). On August 30, 2018, we found the name, Forzinity conditionally acceptable under IND 123553. [a]

On April 1, 2019, Stealth submitted the name, Forzinity, under IND 137429 for elamipretide for the treatment of Barth syndrome. On August 26, 2019, we found the name, Forzinity conditionally acceptable under IND 137429.[b]

Thus, Stealth submitted the proposed proprietary name, Forzinity, for review on January 29, 2024 under NDA 215244 for elamipretide for the treatment of Barth syndrome.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 29, 2024[c], and the prescribing information received on January 29, 2024[d].

Table 1. Relevant Product Information for Forzinity	
Intended pronunciation:	for zin' i tee
Active ingredient:	elamipretide
Indication:	Treatment of patients with Barth syndrome
Dosage Form:	injection
Strength:	280 mg/3.5 mL (80 mg/mL)
Route of administration:	subcutaneous
Usual dosage and frequency:	40 mg (or 0.5 mL) subcutaneous once daily

[a] Rider, B. Proprietary Name Review for Forzinity (IND 123553). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 AUG 30. PNR ID No. 2018-23121747.

[b] Little, C. Proprietary Name Review for Forzinity (IND 137429). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 AUG 26. PNR ID No. 2019-30479991.

[c] Proprietary Name Request (NDA 215244 and Forzinity). Needham (MA): Stealth BioTherapeutics Inc.; 2024 JAN 29. Available from: \\CDSESUB1\EVSPROD\nda215244\0008\m1\us\proprietary-name-request.pdf.

[d] Proposed prescribing information for Forzinity. Needham (MA): Stealth BioTherapeutics Inc.; 2024 JAN 29. Available from: \\CDSESUB1\EVSPROD\nda215244\0008\m1\us\draft-labeling-text-clean.pdf.

Table 1. Relevant Product Information for Forzinity	
How Supplied:	FORZINITY is supplied in single-patient-use [redacted] vials. The solution is a sterile, clear, colorless to yellow aqueous solution and contains preservative. • NDC 72507-800-04: 280 mg/3.5 mL (80 mg/mL) vial in packages of 4 vials.
Storage:	Store FORZINITY at 2°C to 8°C (36°F to 46°F). Do not freeze. Following the first dose, the [redacted] can be stored either refrigerated 2°C to 8°C (36°F to 46°F) or at room temperature between [redacted]

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Forzinity would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Forzinity. The Division of Cardiology and Nephrology (DCN) did not comment on the findings of OPDP's assessment for Forzinity.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

The proposed proprietary name, Forzinity, contains the United States Adopted Name (USAN) stem 'fo(s)-' in the prefix position of the name. The USAN stem 'fo-' is used by the USAN Council to indicate phosphor-derivatives products[e]. Proprietary names should not incorporate USAN stems in the position that USAN designates for the stem.[f] The use of a USAN stem within proprietary names, even when used consistently with the USAN meaning, can result in multiple similar proprietary names and proprietary names that are similar to established names, thus increasing the chance of confusion among those drugs, which may compromise patient safety.

[e] USAN stem search conducted on February 29, 2024

[f] Guidance for Industry: Developing Proprietary Names for Human Prescription Drug Products. Guidance December 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/best-practices-developing-proprietary-names-human-prescription-drug-products-guidance-industry.

To reduce the potential for confusion, USAN stems should usually not be incorporated into proprietary names.

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

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Stealth did not provide a derivation or intended meaning for the proposed proprietary name, Forzinity, in their submission.

This proprietary name is comprised of a single word that contains the letter strings "-or-" and "-in-" in the middle of the name, which are the abbreviations for "operating room" and the route of administration "intranasal", respectively. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the abbreviations "-or-" and "-in-" in the middle of the name are unlikely to be separated from the surrounding letters in a manner that could lead to confusion. Thus, in this case, we do not object to the inclusion of the letter strings "-or-" and "-in-". Beyond this abbreviation, we note that Forzinity does not contain any additional components (i.e., a modifier, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

On February 28, 2024, the Division of Cardiology and Nephrology (DCN) did not forward any comments or concerns relating to Forzinity at the initial phase of the review.

2.2.4 FDA NAME SIMULATION STUDIES

Seventy-eight (n=78) practitioners participated in DMEPA's prescription studies for Forzinity. 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.

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

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

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[i] identified 97 names with a combined 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 also evaluated the previously identified names taking into account the changes in product characteristics (i.e., storage from "room temperature" to "2-8°C"). Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. Therefore, we identified 14 names not previously analyzed. These names are included in Table 1 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 lists the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	13
Low similarity name pair: combined match percentage score ≤54%	0

2.2.7 SAFETY ANALYSIS OF NAMES WITH POTENTIAL ORTHOGRAPHIC, SPELLING, AND PHONETIC SIMILARITIES

Our analysis of the 14 names contained in Table 2 determined none of the names will pose a risk for confusion with Forzinity as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On April 23, 2024, DMEPA 2 communicated our determination to the Division of Cardiology and Nephrology (DCN).

3 CONCLUSION

The proposed proprietary name, Forzinity, is conditionally acceptable.

If you have any questions or need clarifications, please contact Carol Corbie, OSE project manager, at (240) 402-1124.

[i] POCA search conducted on February 28, 2024 in version 5.5.

3.1 COMMENTS TO STEALTH BIOTHERAPEUTICS INC.

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

If any of the proposed product characteristics as stated in your submission, received on January 29, 2024, 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.[j]

*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.

[j] 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 (Table 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 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[k]. 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, 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-

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

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 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?		

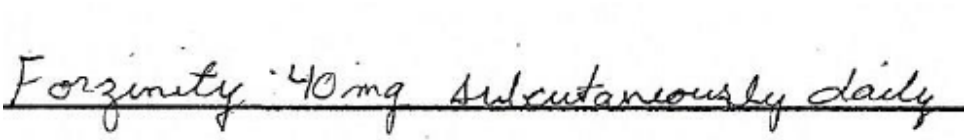
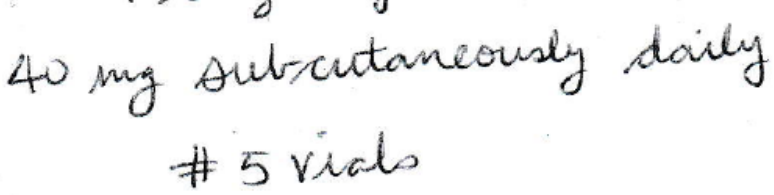
<table>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to 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</td></tr>
<tr><td>Step 2</td><td colspan="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.</td></tr>
<tr><td></td><td>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</td><td>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?</td></tr>
</table>

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	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?	

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. Forzinity Study (Conducted on 2/9/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Forzinity 40 mg subcutaneously daily Dispense 5 vials
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Forzinity	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Forzinity People Received Study: 165 People Responded: 78					
Total	18	22	15	23	78
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
FORZENATEE	0	0	1	0	1
FORZENATY	0	0	1	0	1
FORZENITY	0	0	3	0	3
FORZENITYE	0	0	1	0	1
FORZINITY	18	20	7	23	68
FORZURITY	0	1	0	0	1
FOZIRITY	0	1	0	0	1
VORZENATY	0	0	1	0	1
VORZINITI	0	0	1	0	1

APPEARS THIS WAY ON ORIGINAL

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

No.	Proposed name: Forzinity Established name: elamipretide Dosage form: injection Strength(s): 280 mg/3.5 mL (80 mg/mL) Usual dose: 40 mg (or 0.5 mL) subcutaneous 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) ***	78	Proposed proprietary name for IND (b) (4) found unacceptable, due to a conflict with a marketed product and another name under review, by DMEPA (OSE# (b) (4) dated (b) (4)). The name (b) (4) *** was submitted but withdrawn on (b) (4) (b) (4) On (b) (4) the name (b) (4) *** was submitted and is currently under review.

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

APPENDIX E. MODERATELY SIMILAR NAMES (e.g., combined POCA score is **≥55%** to **≤69%)** with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Forzinity Established name: elamipretide Dosage form: injection Strength(s): 280 mg/3.5 mL (80 mg/mL) Usual dose: 40 mg (or 0.5 mL) subcutaneous 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.	Definity Rt	59	Orthographically, the name pair begins with different letters (F vs. D) that when scripted look different. Additionally, Definity RT contains the letter 'f' in the third position which may be scripted with both an upstroke and downstroke, and if

No.	Proposed name: Forzinity Established name: elamipretide Dosage form: injection Strength(s): 280 mg/3.5 mL (80 mg/mL) Usual dose: 40 mg (or 0.5 mL) subcutaneous 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
			scripted in this fashion, would provide some orthographic differences. Forzinity contains the optional downstroke letter 'z' in the fourth position which can provide additional difference if scripted. In addition, Definity RT has a modifier 'RT' which provides additional differences between the name pair. Phonetically, the first syllables (for vs def) and the beginning of the second syllables (zin' vs in) provide differences. In addition, Definity RT has two extra syllables for the modifier 'RT'. Although Forzinity and Definity RT are single strength products [280 mg/3.5 mL (80 mg/mL) vs 2 mL)] where the strength may be omitted on an order and share the same dosage form (injection), the name pair differs in route of administration (subcutaneous vs intravenous) and frequency (daily vs one time). In addition, Definity RT is a ultrasound contrast agent used in echocardiograms which is administered by healthcare providers in specific settings. When all the aforementioned mitigations are considered in totality, the risk of name confusion between the name pair is minimized.
2.	Fedratinib	56	This name pair has sufficient orthographic and phonetic differences.
3.	Velsipity	56	This name pair has sufficient orthographic and phonetic differences.

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

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

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4) ***	61	Proposed proprietary name withdrawn by the Applicant (b) (4). The entire application (b) (4) was withdrawn by the Applicant on (b) (4).
2.	(b) (4) ***	58	Proposed proprietary name for IND 113764 found to be unacceptable by DMEPA due to misbranding concerns (OSE# (b) (4)). Subsequently, NDA 214520 was approved under the proprietary name Defencath.
3.	(b) (4) ***	56	Proposed proprietary name for IND (b) (4) and IND (b) (4) found unacceptable, due to conflict with a marketed product, by DMEPA (OSE# (b) (4) and (b) (4)). Subsequently, the proposed proprietary name (b) (4) *** was found conditionally acceptable for IND (b) (4) and IND (b) (4).
4.	(b) (4) ***	56	Proposed proprietary name for IND (b) (4) found unacceptable, due to a conflict with a marketed product, by DMEPA (OSE# (b) (4)). 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[I].

No.	Name	POCA Score (%)
1.	Comirnaty	58
2.	Comirnaty 2023-2024	58
3.	(b) (4) ***	56
4.	(b) (4) ***	55
5.	(b) (4) **	55
6.	(b) (4) ***	55

[I] 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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