

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

219876Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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:	July 1, 2025
Application Type and Number:	NDA 219876
Product Name, Dosage Form, and Strength:	Modeyso (dordaviprone) Capsules, 125 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Chimerix Inc. (Chimerix)
PNR ID #:	2025-1044726508
DMEPA 2 Safety Evaluator:	Janine Stewart, PharmD
DMEPA 2 Team Leader:	Tingting Gao, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Modeyso, which was found unacceptable under IND 136090 and NDA 219876 on February 21, 2025.^a The proposed proprietary name, Modeyso, was found to be vulnerable to medication errors due to confusion with another product, (b) (4) ***, under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Modeyso, was dependent upon which underlying application was approved first.

We note that the goal date for NDA 219876 is August 18, 2025, whereas the underlying application for (b) (4) *** remains in IND status. Therefore, if the proposed proprietary name, Modeyso, is granted approval under NDA 219876 on or before August 18, 2025, this application approval will precede approval of the application with the conflicting proposed name, (b) (4) ***.

Thus, Chimerix resubmitted the proposed proprietary name, Modeyso, for review on June 3, 2025 under NDA 219876.^b

2 DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Modeyso, DMEPA 2 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 proposed proprietary name. Additionally, DMEPA 2 searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The June 10, 2025 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Finally, DMEPA 2 evaluated the status of the underlying application of the conflicting name, (b) (4) ***, and determined that if NDA 219876 for Modeyso is approved on or before August 18, 2025, this application approval will precede approval of the application with the conflicting proposed name, (b) (4) ***, given the underlying application for (b) (4) *** remains in IND status.

Based upon our safety assessment of the proposed proprietary name, Modeyso, the application goal date for NDA 219876, and the status of the underlying application for (b) (4) ***, we find Modeyso conditionally acceptable.

^a Stewart, J. Proprietary Name Review for Modeyso (IND 136090 and NDA 219876). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2025 FEB 21. PNR ID No. IND 136090 and NDA 219876.

^b Request for Proprietary Name Review for Modeyso (NDA 219876). Durham (NC): Chimerix Inc.; 2025 JUN 03. Available from: <\\CDSESUB1\EVSPROD\nda219876\0033\m1\us\118-proprietary-names\request-for-proprietary-name-review-modeyso.pdf>.

2.2 COMMUNICATION OF DMEPA'S DETERMINATION

On July 1, 2025, DMEPA 2 communicated our determination to the Division of Oncology 2 (DO2).

3 CONCLUSION

We conclude that the proposed proprietary name, Modeyso, is conditionally acceptable.

3.1 COMMENTS TO CHIMERIX INC.

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

If any of the proposed product characteristics as stated in your submission, received on June 3, 2025, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

If your application receives a complete response, please submit a new request for review of your proposed proprietary name when you respond to the application deficiencies.

4 REFERENCE

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>.

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/

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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)

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Date of This Review:	February 21, 2025
Application Type and Number:	IND 136090 and NDA 219876
Product Name, Dosage Form, and Strength:	Modeyso (dordaviprone) Capsule, 125 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Chimerix Inc. (Chimerix)
PNR ID #:	2024-1044725969 and 2024-1044726173
DMEPA 2 Safety Evaluator:	Janine Stewart, PharmD
DMEPA 2 Team Leader:	Tingting Gao, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

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1 INTRODUCTION

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

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on September 3, 2024^b (IND 136090), December 18, 2024^c (NDA 219876) and the prescribing information received on December 18, 2024.^d

Table 1. Relevant Product Information for Modeyso	
Intended pronunciation:	moe-DAY-so
Active ingredient:	dordaviprone
Indication:	(b) (4)
Dosage Form:	Capsule
Strength:	125 mg
Route of administration:	Oral

^a Request for Proprietary Name Review for Modeyso (NDA 219876). (b) (4) 2024 Dec 18. Available from: <\\CDSESUB1\EVSPROD\nda219876\0001\m1\us\118-proprietary-names\request-for-proprietary-name-review-modeyso-dordaviprone.pdf>.

^b Request for Proprietary Name Review for Modeyso (IND 136090). Durham (NC): Chimerix Inc.; 2024 Sep 03. Available from: <\\CDSESUB1\EVSPROD\ind136090\0197\m1\us\118-proprietary-names\request-for-proprietary-name-review-modeyso.pdf>

^c Request for Proprietary Name Review for Modeyso (NDA 219876). Durham (NC): Chimerix, Inc.; 2024 Dec 18. Available from: <\\CDSESUB1\EVSPROD\nda219876\0001\m1\us\118-proprietary-names\request-for-proprietary-name-review-modeyso-dordaviprone.pdf>.

^d Proposed prescribing information for Modeyso. Durham (NC): Chimerix Inc.; 2024 Dec 18. Available from: <\\CDSESUB1\EVSPROD\nda219876\0001\m1\us\114-labeling\draft\labeling\spl\draft-uspi.docx>.

Table 1. Relevant Product Information for Modeyso	
Dose and frequency:	(b) (4)
How Supplied:	Supplied as 10-count bottles
Storage:	Store at 15°C to 25°C (59°F to 77°F); excursions permitted from 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Modeyso 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 Modeyso. The Division of Oncology 2 (DO2) did not comment on the findings of OPDP's assessment for Modeyso.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

There is no USAN stem present in the proposed proprietary name.^e

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Chimerix did not provide a derivation or intended meaning for the proposed proprietary name, Modeyso, in their submission. This proprietary name is comprised of a single word that contains the letter string “-od-” which is the medical abbreviation for “right eye”. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the

^e USAN stem search conducted on February 17, 2025.

location of the abbreviation “od” in the middle of the proposed proprietary name, Modeyso, make it unlikely for the letter string “od” to be separated from the surrounding letters in a manner that could lead to confusion. Thus, we do not object to the inclusion of the “od” letter string in this case.

Beyond these noted abbreviation, we note that Modeyso does not contain any additional components of the name (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

The Division of Oncology 2 (DO2) did not forward any comments or concerns relating to Modeyso at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

One hundred-one practitioners participated in DMEPA’s prescription simulation studies for Modeyso. 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^f identified 71 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides the number of names retrieved from our POCA search and (b) (4) external study. 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 $\geq 70\%$	2
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	67
Low similarity name pair: combined match percentage score $\leq 54\%$	3

^f POCA search conducted on January 24, 2025, in version 5.9.

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

We determined 71 of the 72 names will not pose a risk for confusion with Modeyso as described in Appendices C through H. However, the proposed proprietary name could be confused with (b) (4) ***. The rationale for the risk of confusion is described below.

Modeyso vs. (b) (4) ***

The proposed proprietary name, Modeyso, may be confused with another pending proposed proprietary name that is also under review, (b) (4) *** (b) (4)

(b) (4)

(b) (4)

We acknowledge that our conclusion differs from that of the (b) (4) external name study submitted in support of the proposed proprietary name. However, the pending proprietary name is also under review and thus was not identified by the (b) (4) external name study. Therefore, based on the totality of the information above, we find the proposed proprietary name, Modeyso, vulnerable to medication errors due to name confusion with (b) (4) ***.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On February 21, 2025, DMEPA 2 communicated our determination to the Division of Oncology 2 (DO2).

3 CONCLUSION

The proposed proprietary name, Modeyso, is not acceptable from a safety perspective. The proposed proprietary name, Modeyso, is vulnerable to name confusion with (b) (4) ***. Therefore, the decision to deny the proposed proprietary name will be communicated to Chimerix via letter (See Section 3.1).

3.1 COMMENTS TO CHIMERIX INC.

We have completed our review of the proposed proprietary name, Modeyso, and have concluded that this name is unacceptable for the following reasons:

The proposed proprietary name, Modeyso, could result in medication errors due to confusion with another product that is also under review. Therefore, the ultimate acceptability of your proposed proprietary name, Modeyso, is dependent upon which underlying application is approved first. If another product is approved prior to your product, with a name that would be confused with your proposed name Modeyso, you will be requested to submit another name.

We acknowledge that our conclusion differs from that of the (b) (4) external name study submitted in support of the proposed proprietary name. However, the pending proprietary name is also under review and thus was not identified by the (b) (4) external name study.

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.^k

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.

^k 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 $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 54\%$.

Using the criteria outlined in the check list (Tables 4-6) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category that cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 4).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
 - o 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 names¹. 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.

- o 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 are often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 5).
 - Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.
- c. FDA Prescription Simulation Studies: DMEPA also conducts prescription simulation studies using FDA health care professionals.

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.
- d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) for their comments or concerns with the proposed proprietary name and ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-

¹ 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 4. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is $\geq$ 70%).			
Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

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

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

	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?	
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Table 6. Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

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

APPENDIX B. PRESCRIPTION SIMULATION SAMPLES AND RESULTS

Figure 1. Modeyso Study (Conducted on 1/24/2025)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order: <i>Modeyso 625 mg PO once weekly</i> Outpatient Prescription: Patient _____ Date _____ Address _____ R <i>Modeyso</i> <i>Take 5 capsules po</i> <i>once weekly</i> <i>#20</i> Refill(s): _____ Dr. _____ DEA No. _____ Address _____ Telephone _____	Modeyso Take 5 capsules by mouth once weekly. Dispense 20
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Modeyso	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Modeyso					
People Received Study: 167					
People Responded: 101					
Total	26	27	20	28	101
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
MODAFO	0	0	1	0	1
MODASO	0	0	2	0	2
MODAYSO	0	0	6	0	6
MODESO	0	0	8	0	8
MODESSO	0	0	1	0	1
MODEYSO	25	25	1	28	79
MODEYSO 50	0	1	0	0	1
MODEYZO	1	0	0	0	1
MODEZO	0	0	1	0	1
MODYSO	0	1	0	0	1

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is $\geq 70\%$)

No.	Proposed name: Modeyso Pronunciation: moe-DAY-so Established name: dordaviprone Dosage form: Capsule Strength(s): 125 mg Dosage: 625 mg (five 125 mg capsules) once weekly.	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.	Modeyso	100	This name is the subject of this review.

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

No.	Name	POCA Score (%)
1.	(b) (4) ***	69
2.	Modicon	65
3.	Modicon 21	65
4.	Modicon 28	65
5.	Mannose	62
6.	Metasol	62
7.	Symdeko	60
8.	Medefoam 2	60
9.	Moderiba	60
10.	Mononessa	60
11.	Maltose	59
12.	Medi-Lyte	58
13.	Mitosol	58
14.	Mobisyl	58
15.	Mezofy***	56
16.	Voydeya	56

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

No.	Proposed name: Modeyso Pronunciation: moe-DAY-so Established name: dordaviprone Dosage form: Capsule Strength(s): 125 mg Dosage: 625 mg (five 125 mg capsules) once weekly.	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.	Amondys 45	66	This name pair has sufficient orthographic and phonetic differences.
2.	Modane	66	This name pair has sufficient orthographic and phonetic differences.
3.	Mydayis	63	This name pair has sufficient orthographic and phonetic differences.
4.	Modane Soft	62	This name pair has sufficient orthographic and phonetic differences.
5.	(b) (4) ***	60	This name pair has sufficient orthographic and phonetic differences.
6.	Mytesi	58	This name pair has sufficient orthographic and phonetic differences.
7.	Odefsey	56	This name pair has sufficient orthographic and phonetic differences.
8.	Dodex	56	This name pair has sufficient orthographic and phonetic differences.
9.	Meditest	55	This name pair has sufficient orthographic and phonetic differences.

APPENDIX F: LOW SIMILARITY NAMES (e.g., combined POCA score is $\leq 54\%$)

No.	Name	POCA Score (%)
1.	Soy-Dome	52
2.	Megace	54
3.	Modafinil	48

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.	Domoso	66	Veterinary Product.
2.	(b) (4) ***	64	Proposed proprietary name (b) (4) *** under IND 131008 found unacceptable by DMEPA on October 15, 2018 (OSE# 2018-22457747). NDA 212516 approved under the proprietary name Drizalma Sprinkle.
3.	Modulis	64	Veterinary Product.
4.	Moditen	63	International product marketed in Italy, Venezuela, Hungary, Russia, and Ukraine and formerly marketed in Ireland, Czech Republic, the Netherlands, and France.
5.	Modisal La	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Modisal (without the LA modifier) is an international product marketed in the UK and formerly marketed in Switzerland.
6.	Moduret	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	Codelsol	61	International product formerly marketed in Turkey.
8.	Codelson	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
9.	Medrysone	60	Brand discontinued with no generic equivalents available. NDA 106624 withdrawn FR effective 01/25/2008.
10.	(b) (4) ***	60	Proposed proprietary name for NDA 215429 found unacceptable by DMEPA due to conflict with a marketed product (OSE # 2021-1044724162 dated November 30, 2021). NDA 215429 was approved under the established name venlafaxine.

No.	Name	POCA Score (%)	Failure preventions
11.	Moderil	60	Brand discontinued with no generic equivalents available. NDA 010686 withdrawn FR effective 06/18/2009.
12.	My-O-Den	59	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
13.	Med-I-San	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
14.	Mogadon	58	International product marketed in many countries.
15.	Molasses	58	Product is not a drug. A viscous substance resulting from refining sugarcane or sugar beets into sugar. Primarily used to sweeten and flavor foods.
16.	(b) (4) ***	58	(b) (4)
17.	Modrasone	57	International product marketed in the United Kingdom and formerly marketed in Ireland.
18.	(b) (4) ***	57	Proposed proprietary name for ANDA 209323 withdrawn by the Applicant. ANDA 209323 is approved without a proprietary name. Subsequently, Applicant submitted a new proposed proprietary name, (b) (4) ***, under ANDA 209323 (b) (4) which was unacceptable due to a conflict with a marketed product, by DMEPA (OSE# (b) (4) (b) (4)). Additionally, the Applicant withdrew ANDA 209323 (b) (4).
19.	Emodepside	56	Veterinary Product.
20.	(b) (4) ***	56	Proposed proprietary name for ANDA 206201 found unacceptable by DMEPA (OSE# 2016-10345672-1 dated 04/17/2017). Subsequently, ANDA 206201 was withdrawn by the Applicant on 03/02/2020.
21.	Metosyn	56	International product marketed in Denmark, Norway, and the United Kingdom and formerly marketed in Singapore and Ireland.
22.	Mydex	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
23.	Mydocs	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
24.	Movodyl	55	Veterinary product.

APPENDIX H. Names not likely to be confused due to absence of attributes that are known to cause name confusion^m.

No.	Name	POCA Score (%)
1.	(b) (4) ***	64
2.	(b) (4) ***	62
3.	Verdeso	62
4.	(b) (4) ***	60
5.	Omontys	58
6.	(b) (4) ***	58
7.	Duodote	57
8.	(b) (4) ***	56
9.	Dygase	56
10.	Eumovate	56
11.	Nystose	56
12.	(b) (4) ***	56
13.	Nordette	55
14.	Nordette 28	55
15.	Nordette-21	55
16.	Nordette-28	55
17.	(b) (4) ***	55
18.	Vabysmo	55

^m 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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