

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

211723Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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

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

Date of This Review:	January 17, 2020
Application Type and Number:	NDA 211723
Product Name and Strength:	Tazverik (Tazemetostat) Tablets, 200 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Epizyme Inc. (Epizyme)
Panorama #:	2019-31950129-1
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, FISMP, BCPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Tazverik, based on the additional dose reduction information submitted in the proposed Prescribing Information (PI) for NDA 211723. Our previous proprietary name review^a evaluated the recommended dose of (b) (4) (800 mg) twice daily. The proposed PI received on January 13, 2020 contains the following additional dose reduction information in a tabular format:

Table #. Recommended Dose Reductions of TAZVERIK for Adverse Reactions

Dose Reduction	Dosage
First	600 mg orally twice daily
Second	400 mg orally twice daily*

*Permanently discontinue TAZVERIK in patients who are unable to tolerate 400 mg orally twice daily.

Table #. Recommended Dose Reductions of TAZVERIK for Moderate CYP3A Inhibitor

Current Dosage	Adjusted Dosage
800 mg orally twice daily	400 mg orally twice daily
600 mg orally twice daily	400 mg for first dose and 200 mg for second dose
400 mg orally twice daily	200 mg orally twice daily

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previously identified names taking into account the additional dose reduction information. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Tazverik.

Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The January 17, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Tazverik.

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Tazverik, is acceptable.

If you have any questions or need clarifications, please contact Latonia Ford, OSE Project Manager, at 301-796-4901.

^a Straka, M. Proprietary Name Review for Tazverik (IND 124608 and NDA 211723). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Aug 9. Panorama No.: 2019-29387701 and 2019-31950129.

4 REFERENCE

- 1. USAN Stems** (<https://www.ama-assn.org/about/united-states-adopted-names-approved-stems>)

USAN Stems List contains all the recognized USAN 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/

CHI-MING TU
01/17/2020 11:56:21 AM

PROPRIETARY NAME REVIEW

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

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Date of This Review:	August 9, 2019
Application Type and Number:	IND 124608 and NDA 211723
Product Name and Strength:	Tazverik (tazemetostat) Tablets, 200 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Epizyme Inc. (Epizyme)
Panorama #:	2019-29387701 and 2019-31950129
DMEPA Safety Evaluator:	Maximilian Straka, PharmD, FISMP
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, FISMP, BCPS

Contents

1	INTRODUCTION.....	1
1.1	Product Information.....	1
2	RESULTS.....	1
2.1	Misbranding Assessment.....	1
2.2	Safety Assessment.....	1
3	CONCLUSION.....	3
3.1	Comments to Epizyme Inc.....	3
	REFERENCES.....	4
	APPENDICES.....	5

1 INTRODUCTION

This review evaluates the proposed proprietary name, Tazverik, 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. Epizyme submitted an external name study, conducted by [REDACTED] (b) (4) for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on February 15, 2019 under IND 124608, and on May 23, 2019 under NDA 211723.

- Intended Pronunciation: taz ver' ik
- Active Ingredient: tazemetostat
- Indication of Use: Indicated for the treatment of adult patients with metastatic or locally advanced epithelioid sarcoma (ES) who are not eligible for curative surgery.
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 200 mg
- Dose and Frequency: [REDACTED] (b) (4) (800 mg), orally twice daily. [REDACTED] (b) (4)
[REDACTED]
- How Supplied: 240 tablets in 215 mL HDPE bottle with 2 g of desiccant, [REDACTED] (b) (4)
[REDACTED] cap.
- Storage: [REDACTED] (b) (4)
[REDACTED]

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Tazverik would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Oncology Products 2 (DOP2) concurred with the findings of OPDP's assessment for Tazverik.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Epizyme indicated in their submission that the proposed proprietary name, Tazverik, is a combination of the word tazemetostat which is the established name “tazemetostat” and the word maverick referring to “an original, an innovator”. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, June 6, 2019 e-mail, the Division of Oncology Products 2 (DOP2) did not forward any comments or concerns relating to Tazverik at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-nine (89) practitioners participated in DMEPA’s prescription studies for Tazverik. 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 verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search^b identified 70 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 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	68
Low similarity name pair: combined match percentage score $\leq 54\%$	23

^a USAN stem search conducted on June 5, 2019.

^b POCA search conducted on June 5, 2019 in version 4.3.

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

Our analysis of the 92 names contained in Table 1 determined none of the names will pose a risk for confusion with Tazverik as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Oncology Products 2 (DOP2) via e-mail on August 1, 2019. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Oncology Products 2 (DOP2) on August 6, 2019, they stated no additional concerns with the proposed proprietary name, Tazverik.

3 CONCLUSION

The proposed proprietary name, Tazverik, is acceptable.

If you have any questions or need clarifications, please contact Latonia Ford, OSE project manager, at 301-796-4901.

3.1 COMMENTS TO EPIZYME INC.

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

If any of the proposed product characteristics as stated in your submission, received on February 15, 2019 under IND 124608 and on May 23, 2019 under NDA 211723, are altered prior to approval of the marketing application, the name must be resubmitted for review.

REFERENCES

1. *USAN Stems* (<https://www.ama-assn.org/about/united-states-adopted-names-approved-stems>)

USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm

(<http://www.nlm.nih.gov/research/umls/rxnorm/overview.html>).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. **Preliminary Assessment:** We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. ^c

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

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

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

- b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:
- Highly similar pair: combined match percentage score $\geq 70\%$.
 - 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 (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
 - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names^d. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
 - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign

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

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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

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

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

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

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

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

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

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.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
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 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

Step 1	<p>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.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>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.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none">• 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	<p>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.</p>

	<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • 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 <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted? 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • 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?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Tazverik Study (Conducted on March 1, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
<p>Medication Order:</p> <p><u>Tazverik</u> (b) (4)</p>	<p>Tazverik (b) (4) by (b) (4) mouth (b) (4)</p>
<p>Outpatient Prescription:</p> <p>Tazverik (b) (4) by mouth (b) (4)</p>	<p>(b) (4)</p> <p>Dispense # 240</p>

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Tazverik

As of Date 6/18/2019

299 People Received Study
89 People Responded

Study Name: Tazverik

	Total	23	46	20	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL	
AZVERIK	1	0	0	1	
TASVAIRIK	0	1	0	1	
TASVARIC	0	1	0	1	
TASVARIX	0	1	0	1	
TASVERIC	0	7	0	7	
TASVERICK	0	1	0	1	
TASVERIK	0	1	0	1	
TASVERINK	0	1	0	1	
TAVERIK	0	0	1	1	
TAXVERIK	0	0	1	1	
TAZDERIC	0	1	0	1	
TAZERIC	0	1	0	1	
TAZFERIK	0	0	1	1	
TAZVARIC	0	4	0	4	
TAZVARICK	0	1	0	1	
TAZVARIQ	0	2	0	2	
TAZVERAC	0	1	0	1	
TAZVEREK	0	1	0	1	
TAZVERIC	0	8	0	8	
TAZVERICK	1	2	0	3	
TAZVERIK	21	9	16	46	
TAZVERIQ	0	1	0	1	
TAZVERRIC	0	1	0	1	
TAZVYRIC	0	1	0	1	
TOCZVERIK	0	0	1	1	

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

No.	Proposed name: Tazverik Established name: tazemetostat Dosage form: Tablets Strength(s): 200 mg Usual Dose: _____ ^{(b) (4)} (800 mg) by mouth _____ ^{(b) (4)}	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.	Tazverik***	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 (%)
2.	Antivert	58
3.	Balversa	56
4.	Namzaric	64
5.	Perseris	57
6.	Tazorac	66
7.	Teldrin	55
8.	Trazimera	61
9.	Triferic	63
10.	Trivaris	62
11.	Zegerid	56
12.	_____ ^{(b) (4)} ***	60

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: Tazverik Established name: tazemetostat Dosage form: Tablets Strength(s): 200 mg Usual Dose: _____ ^{(b) (4)} (800 mg) by mouth _____ ^{(b) (4)}	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
13.	Alavert	56	This name pair has sufficient orthographic and phonetic differences.
14.	Altavera	58	This name pair has sufficient orthographic and phonetic differences.
15.	Corvert	58	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Tazverik Established name: tazemetostat Dosage form: Tablets Strength(s): 200 mg Usual Dose: (b) (4) (800 mg) by mouth (b) (4)	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
16.	Doxteric	56	This name pair has sufficient orthographic and phonetic differences.
17.	Kao-Paverin	56	This name pair has sufficient orthographic and phonetic differences.
18.	Medivert	57	This name pair has sufficient orthographic and phonetic differences.
19.	Rabavert	58	This name pair has sufficient orthographic and phonetic differences.
20.	Silvera	56	This name pair has sufficient orthographic and phonetic differences.
21.	Somavert	58	This name pair has sufficient orthographic and phonetic differences.
22.	Tazicef	57	This name pair has sufficient orthographic and phonetic differences.
23.	Tecentriq	55	This name pair has sufficient orthographic and phonetic differences.
24.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.
25.	Testro Aq	55	This name pair has sufficient orthographic and phonetic differences.
26.	Tetravisc	57	This name pair has sufficient orthographic and phonetic differences.
27.	Tranzarel	56	This name pair has sufficient orthographic and phonetic differences.
28.	Trizivir	60	This name pair has sufficient orthographic and phonetic differences.
29.	Tuxarin	56	This name pair has sufficient orthographic and phonetic differences.
30.	Wal-vert	55	This name pair has sufficient orthographic and phonetic differences.
31.	Zerit	56	This name pair has sufficient orthographic and phonetic differences.
32.	Zerviate	60	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 (%)
33.	Advate	51
34.	Arzerra	54
35.	Avastin	37
36.	Azilect	48
37.	Darzalex	52
38.	Ethaquin	30
39.	Ethatab	28
40.	Ethaverine	54
41.	Ethavex-100	45
42.	Etravirine	52
43.	Isovex	33
44.	Katerzia***	54
45.	Kineret	54
46.	Mavik	49
47.	Optimark	50
48.	Stivarga	51
49.	Taltz	38
50.	Tarceva	52
51.	Terazosin	51
52.	Trandate	52
53.	Tysabri	50
54.	Varizig	50
55.	Zinc	24

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
56.	Alverine	56	Name identified in RxNorm. Unable to find product characteristics in commonly used databases.
57.	Drotaverin	58	Name identified in RxNorm. Unable to find product characteristics in commonly used databases.
58.	Ketanserin	56	Name identified in RxNorm. Unable to find product characteristics in commonly used databases.
59.	Tandearil	56	Brand discontinued with no generic equivalents available. NDA 012542 withdrawn FR effective 5/29/02.

No.	Name	POCA Score (%)	Failure preventions
60.	Tanderil	62	Name identified in RxNorm. Unable to find product characteristics in commonly used databases.
61.	Targiniq	55	Brand discontinued with no generic equivalents available. NDA 205777 withdrawn FR effective 11/28/2018.
62.	Tartrate	56	Product is not a drug. It is a salt or ester of the organic compound tartaric acid.
63.	(b) (4)***	56	Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA (OSE# 2019-28512596 dated 3/14/2019). IND (b) (4) is active and no new names have been submitted.
64.	Tavegil	56	International product marketed in multiple foreign countries.
65.	Terak	56	Name identified in RxNorm. Unable to find product characteristics in commonly used databases.
66.	Terra-Vet	56	Veterinary product
67.	(b) (4)***	57	Proposed proprietary name for IND 76809 found unacceptable by DMEPA (OSE# 2017-14444502 dated 10/6/2017). Subsequently, this IND was submitted under NDA 212839 and the proposed proprietary name Xcopri was found acceptable by DMEPA (OSE# 2018-27558023 dated 2/5/19). NDA 212839 was approved under the proprietary name Xcopri.
68.	(b) (4)***	55	Proposed proprietary name for IND 120040 found unacceptable by DMEPA (OSE# 2016-8229634 dated 11/15/2016). Subsequently, this IND was submitted under NDA 209776 and the proposed proprietary name Vabomere was found acceptable by DMEPA (OSE# 2017-14212506 dated 6/12/2017). NDA 209776 was approved under the proprietary name Vabomere.

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

No.	Name	POCA Score (%)
69.	Adcetris	56
70.	(b) (4)***	58
71.	(b) (4)***	56
72.	Cervarix	60
73.	Citravet	58
74.	Daktarin	57
75.	Darvocet	55
76.	Dixarit	58
77.	(b) (4)***	60
78.	Kava Root	58
79.	Kevzara	60
80.	(b) (4)***	60
81.	Mavyret	56
82.	Nazarin	56
83.	Paregoric	55
84.	(b) (4)***	57
85.	Sansert	56
86.	Servira	58
87.	Stavzor	58
88.	Vaseretic	56
89.	Vaseretic 10-25	56
90.	Vaseretic 5-12.5	56
91.	Zentrip	55
92.	Zovirax	55

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

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