CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

213072Orig1s000

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:	December 3, 2020
Application Type and Number:	NDA 213072
Product Name and Strength:	Roszet (rosuvastatin and ezetimibe) tablets, 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg, 40 mg/10 mg.
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Althera Life Sciences LLC (Althera)
Panorama #:	2020-43161348
DMEPA Safety Evaluator:	Sarah K. Vee, PharmD
DMEPA Team Leader:	Idalia E. Rychlik, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Roszet, which was found conditionally acceptable under NDA 213072 on November 1, 2019 and December 20, 2019.[a,b] The application received a complete response on May 26, 2020. Thus, Althera submitted the name, Roszet, under NDA 213072 for review on September 23, 2020. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Roszet would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) concurred with the findings of OPDP's assessment for Roszet.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we 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. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The November 23, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Roszet.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) via e-mail on December 2, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) on December 3, 2020, they stated no additional concerns with the proposed proprietary name, Roszet.

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, Roszet, is acceptable.

---

[a] Fanari M. Proprietary Name Review for Roszet (NDA 213072). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 NOV 01. Panorama No.: 2019-33814753.

[b] Fanari M. Proprietary Name Review for Roszet (NDA 213072). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 DEC 20. Panorama No.: 2019-33814753-1.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

3.1 COMMENTS TO ALTHERA LIFE SCIENCES LLC

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

If any of the proposed product characteristics as stated in your submission, received on September 23, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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/

SARAH K VEE
12/03/2020 12:53:57 PM

IDALIA E RYCHLIK
12/03/2020 01:50:01 PM

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:	December 20, 2019
Application Type and Number:	NDA 213072
Product Name and Strength:	Roszet (rosuvastatin and ezetimibe) tablet, 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg, and 40 mg/10 mg
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Althera
Panorama #:	2019-33814753-1
DMEPA Safety Evaluator:	Melina Fanari, R.Ph.
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA

Reference ID: 4368982

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Roszet, which was found conditionally acceptable under NDA 213072 on November 1, 2019.[a] We internally initiated this review to capture additional names not previously identified in our previous review. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

2.1.1 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[b] identified 79 names with the combined score of ≥55% or 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 note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 14 names not previously analyzed. These names are included in Table 1 below.

2.1.2 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 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 1. 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%	14
Low similarity name pair: combined match percentage score ≤54%	0

[a] Fanari, M. Proprietary Name Review for Roszet (NDA 213072). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Nov 1. Panorama No.: 2019-33814753.

[b] POCA search conducted on December 4, 2019 in version 4.3.

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

Our analysis of the 14 names contained in Table 1 determined none of the names will pose a risk for confusion with Roszet as described in Appendices C through H.

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, Roszet, is acceptable.

4 REFERENCE

1. *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.

APPENDICES

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)-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.	Reme-T	56
2.	Restall	55

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:** Roszet **Established name:** rosuvastatin and ezetimibe **Dosage form:** tablet **Strength(s):** 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg, and 40 mg/10 mg **Usual Dose:** 5 mg/10 mg to 40 mg/10 mg 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**
3.	Rosula	55	Orthographically, the names have a different shape in the suffix due to the placement of upstoke letter 'l' in Rosula (5th position) vs the upstroke and crossstroke letter 't' (6th position) in Roszet. Phonetically, Roszet has 2 syllables vs 3 syllables in Rosula. In addition, the syllales in the end of the name pair sound different ('szet vs 'sula'). The following differences in product characteristics may also help to mitigate the risk of errors:

No.	**Proposed name:** Roszet **Established name:** rosuvastatin and ezetimibe **Dosage form:** tablet **Strength(s):** 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg, and 40 mg/10 mg **Usual Dose:** 5 mg/10 mg to 40 mg/10 mg 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**
			Rosula is a topical sulfacetamide sodium/sulfur product available in multiple formulations/strengths (pads 10/5% or soap 10/4.5%). A prescription order will require a specific formulation which will help mitigate the risk of wrong drug errors.

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
4.	Rock Sauce	56	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
5.	Rennet	55	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
6.	Orasep	58
7.	Pro1tek	57

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

No.	Name	POCA Score (%)
8.	Isocet	56
9.	Propacet	56
10.	Propacet 100	56
11.	Propacet 100	56
12.	Losec	55
13.	Pre Sed	55
14.	(b) (4) ***	55

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/

MELINA N FANARI
12/20/2019 09:45:53 AM

SEVAN H KOLEJIAN
12/20/2019 10:12:38 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)

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

Date of This Review:	November 1, 2019
Application Type and Number:	NDA 213072
Product Name and Strength:	Roszet (rosuvastatin and ezetimibe) tablet, 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg, and 40 mg/10 mg
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Althera
Panorama #:	2019-33814753
Melina Fanari, R.Ph.	Melina Fanari, R.Ph.
Sevan Kolejian, PharmD, MBA	Sevan Kolejian, PharmD, MBA

Contents

1 INTRODUCTION 1
1.1 Regulatory History 1
1.2 Product Information 1
2 RESULTS 1
2.1 Misbranding Assessment 1
2.2 Safety Assessment 2
3 CONCLUSION 5
3.1 Comments to the Applicant/Sponsor 5
4 REFERENCES 7
APPENDICES 8

1 INTRODUCTION

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

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on August 14, 2019.

- Intended Pronunciation:
- Active Ingredient: rosuvastatin and ezetimibe
- Indication of Use:

  Adjunct to diet to:

  - reduce (b) (4) LDL-C, (b) (4) in patients with primary ((b) (4) non-familial) hyperlipidemia (b) (4).

  - reduce (b) (4) LDL-C in patients with homozygous familial hypercholesterolemia (HoFH), as an adjunct to other (b) (4) lowering treatments
- Route of Administration: oral
- Dosage Form: tablet
- Strength: 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg, and 40 mg/10 mg
- Dose and Frequency: Take one tablet once daily
- How Supplied: Bottles of 30 (b) (4)
- Storage: Store at controlled room temperature, 20-25ºC (68-77ºF) [see USP Controlled Room Temperature]. Protect from moisture.
- Reference Listed Drug/Reference Product: Crestor (N21366) & Zetia (N21445)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Roszet would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and

Reference ID: 4568955

the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP's assessment for Roszet.

2.2 SAFETY ASSESSMENT

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

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

Althera indicated in their submission that the proposed proprietary name, Roszet, is a combination of two active ingredients rosuvastatin and ezetimibe. This proprietary name is comprised of two words 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, September 5, 2019 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) did not forward any comments or concerns relating to Roszet at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-one practitioners participated in DMEPA's prescription studies for Roszet. 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 64 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

[a] USAN stem search conducted on August 20, 2019.

[b] POCA search conducted on August 20, 2019 in version 4.3.

Reference ID: 4768753

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 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 1. 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%	62
Low similarity name pair: combined match percentage score ≤54%	2

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

Our analysis of the 64 names contained in Table 1 determined none of the names will pose a risk for confusion with Roszet 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 Metabolism and Endocrinology Products (DMEP) via e-mail on October 31, 2019. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Metabolism and Endocrinology Products (DMEP) on November 1, 2019, they stated no additional concerns with the proposed proprietary name, Roszet.

3 CONCLUSION

The proposed proprietary name, Roszet, is acceptable.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

3.1 COMMENTS TO ALTHERA

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

If any of the proposed product characteristics as stated in your submission, received on August 14, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

Reference ID: 4768953

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

Reference ID: 4368953

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.

Reference ID: 4768753

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

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

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

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

Reference ID: 4368953

- Low similarity: combined match percentage score ≤54%.

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

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

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

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

Reference ID: 4368955

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.

Reference ID: 4768953

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

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

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

Reference ID: 4768753

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

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

Reference ID: 4768953

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

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

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

Reference ID: 4768953

Appendix B: **Prescription Simulation Samples and Results**

Figure 1. Roszet Study (Conducted on August 23, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Roszet 20mg/ (b) (4) po once daily	Roszet 10 mg/10 mg 1 tablet po QD #30
Outpatient Prescription: Address _____ ℞ Roszet 10 mg/10mg 1 tablet by mouth once daily #30 MEDWATCH 1-800-FDA-1088 Refill(s): _____ Dr. OSE	

FDA Prescription Simulation Responses (Aggregate Report)

216 People Received Study
81 People Responded

Study Name: Roszet

Total	20	39	22	81
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
ROCETTE	0	1	0	1
ROSETE	0	1	0	1
ROSS ZET	0	1	0	1
ROSSET	0	2	0	2

Reference ID: 4768955

ROSSETT	0	2	0	2
ROSSETTE	0	1	0	1
ROSSVET	0	1	0	1
ROSSZET	0	2	0	2
ROSSZETTE	0	1	0	1
ROSZET	19	9	21	49
ROS-ZET	0	1	0	1
ROSZET 10MG/10MG	0	1	0	1
ROSZETTE	0	4	0	4
ROSZIT	0	1	0	1
ROSZT	1	0	0	1
ROTHCET	0	1	0	1
ROTHZET	0	4	0	4
ROXICET	0	1	0	1
ROZET	0	1	0	1
ROZET (b) (4)	0	0	1	1
ROZETT	0	1	0	1
ROZETTE	0	2	0	2
ROZZETTE	0	1	0	1

Reference ID: 4768955

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)-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.	Lerosett	66
2.	Retet	63
3.	Rosadan	62
4.	Robitet	61
5.	Robitet 500	61
6.	Retisert	60
7.	Riomet	60
8.	Rotateq	60
9.	Rozerem	60
10.	Respa-1st	59
11.	Res-Q-Dent	59
12.	Restone	59
13.	Estrostep 21	58
14.	Rosaderm	56
15.	Ruconest	56

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:** Roszet **Established name:** rosuvastatin and ezetimibe **Dosage form:** tablet **Strength(s):** 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg, and 40 mg/10 mg **Usual Dose:** 5 mg/10 mg to 40 mg/10 mg 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**
16.	Rozex Deactivated according to RedBook however generics available.	68	Orthographically, the upstoke letter 't' in Roszet provides some orthographic differences. Phonetically, the second syllables of this name pair sound different (zex vs zet). The following differences in product characteristics may also help to mitigate the risk of errors:

Reference ID: 4768753

No.	**Proposed name:** Roszet **Established name:** rosuvastatin and ezetimibe **Dosage form:** tablet **Strength(s):** 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg, and 40 mg/10 mg **Usual Dose:** 5 mg/10 mg to 40 mg/10 mg 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**
			• Strength/Dose: Rozex (Metronidazole)is available in a 0.75 % topical gel or cream vs. Roszet is available in strengths of 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg, and 40 mg/10 mg. A strength must be included on a prescription for Roszet, and there is no overlap in strength. • Dosage Form/Route of Administration: Rozex is available as a cream or gel to be applied topically vs. Roszet is an oral tablet. The prescription order for Rozex will need to specify the dosage form. Therefore, due to the above-mentioned factors we find this name pair acceptable.
17.	Rosac (sulfacetamide and sulfur) Deactivated according to RedBook however generics available.	64	The upstoke letter ‘t’ in Roszet provides some orthographic differences. Phonetically, the second syllables of this name pair sound different (sac vs zet). The following differences in product characteristics may also help to mitigate the risk of errors: • Strength/Dose: Rosac is available in various concentrations depending on the formulation (9%/4%, 10%/2% and 10%/5%) vs. Roszet is available in strengths of 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg, and 40 mg/10 mg. A strength must be included on a

Reference ID: 4768953

No.	**Proposed name:** Roszet **Established name:** rosuvastatin and ezetimibe **Dosage form:** tablet **Strength(s):** 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg, and 40 mg/10 mg **Usual Dose:** 5 mg/10 mg to 40 mg/10 mg 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**
			prescription for Roszet, and there is no overlap in strength. • Dosage Form/Route of Administration: Rosac is available in various formulations (wash, cleanser, cream and cleansing pads) to be applied topically vs. Roszet is an oral tablet. A prescription/order for Rosac would need to specify which formulation to dispense and there is no overlap in dosage form with Roszet. Therefore, due to the above-mentioned factors we find this name pair acceptable.
18.	Sotret	66	This name pair has sufficient orthographic and phonetic differences.
19.	Roxicet	62	This name pair has sufficient orthographic and phonetic differences.
20.	Roxicet 5/500	62	This name pair has sufficient orthographic and phonetic differences.
21.	Remsed	58	This name pair has sufficient orthographic and phonetic differences.
22.	Leustat	56	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
23.	Ortho-Est	52(O71)
24.	Uroeze	49(71)

Reference ID: 4768953

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
25.	Rosin	64	Product is not a drug. It is a powder available for bulk compounding or in dentifrice product. Also contained in the veterinary product Keratex KHP.
26.	Rotersept	62	International product formally marketed in Belgium, Ireland, UK and Germany.
27.	Rohist	62	International product formally marketed in South Africa.
28.	Rondec	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
29.	(b) (4) ***	60	(b) (4)
30.	Atrosept	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
31.	Ro-A-Vit	58	International product formally marketed in the UK.
32.	Creosote	56	Product is not a drug. It is a by product that comes from burning wood and is typically used as a preservative or antiseptic.
33.	Rondec-Tr	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
34.	Rusyde	55	International product marketed in the UK.
35.	Rau-Sed	55	Brand discontinued and with no generic equivalents available. NDA 9357 withdrawn FR effective 03/20/2000.

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 (%)
36.	Orostat	68
37.	Procet	68
38.	Prostep	68
39.	Prosed	64

[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

Reference ID: 4368753

No.	Name	POCA Score (%)
40.	Prostap 3	64
41.	Ergostat	62
42.	Propet	62
43.	Urolet	62
44.	Lorcet	60
45.	Orastat	60
46.	Pretz-D	60
47.	Sorbet	60
48.	Triostat	60
49.	Pro-Fast	59
50.	Grastek	58
51.	Threostat	58
52.	Trest	58
53.	Prosed Ds	57
54.	Tootsweet	57
55.	Crest	56
56.	Fosveset	56
57.	Kbrovet	56
58.	Progest	56
59.	Pro-Vent	56
60.	Serostim	56
61.	Seroxat	56
62.	Uristat	56
63.	Zortress	56
64.	Freeze It	55

Reference ID: 4768753

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/

MELINA N FANARI
11/01/2019 01:14:31 PM

SEVAN H KOLEJIAN
11/01/2019 01:36:18 PM