CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208647Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	September 13, 2018
Application Type and Number:	NDA 208647
Product Name and Strength:	Ezallor (rosuvastatin) oral capsules, 5 mg, 10 mg, 20 mg, and 40 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sun Pharma Global FZE
Panorama #:	2018-24212361
DMEPA Safety Evaluator:	Stephanie DeGraw, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Ezallor, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Ezallor*** on October 5, 2015. We found the name, Ezallor*** to be acceptable under NDA 208647 on December 21, 2015[a]. However, the application received a complete response on June 22, 2016. Therefore, the Applicant resubmitted the name, Ezallor, for review on June 18, 2018 as part of the resubmission under NDA 208647.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on June 18, 2018.

- Intended Pronunciation: Ez-Aah-Lor
- Active Ingredient: Rosuvastatin
- Indication of Use: 1. Treatment of adult patients with hypertriglyceridemia.
  2. Treatment of adult patients with primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia).
  3. Treatment of adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C, total-C, and ApoB
- Route of Administration: Oral
- Dosage Form: Capsule
- Strength: 5 mg, 10 mg, 20 mg, 40 mg
- Dose and Frequency: 5 mg to 40 mg once daily
- How Supplied: 30-count and 90-count child-resistant bottles
  30-count (3x10) unit-dose blister packs
- Storage: Controlled room temperature
- Reference Listed Drug/Reference Product: CRESTOR (rosuvastatin calcium) Tablets NDA 021366

[a] Rahimi, L. Proprietary Name Review for Ezallor*** (NDA 208647). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 DEC 21. Panorama No. 2015-1649968.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Ezallor has a name derivation of "easy to administrate Rosuvastatin." 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, July 27, 2018 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

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

However, in the voice study, one participant interpreted the proposed name as "Exelor" which is a close variation to currently marketed product Exelon. We note that there are phonetic differences between this name pair. The first syllables "Ez" vs. "Ex", second syllables "ah" vs. "e", and third syllables "llor" vs. "lon" sound different when spoken. FDA's phonetic and orthographic computer analysis (POCA) calculates a low phonetic score (45) for this name pair. Additionally, this name pair is further differentiated by strength (1.5 mg, 3 mg, 4.5 mg, and 6 mg vs. 5 mg, 10 mg, 20 mg, and 40 mg). Based on the phonetic differences and the difference in strengths we find that this name pair has minimal potential of confusion.

Appendix B contains the results from the verbal and written prescription studies.

[b] USAN stem search conducted on July 2, 2018.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 118 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥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 31 names not previously analyzed. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 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. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	23
Low similarity name pair: combined match percentage score ≤54%	7

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

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

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Metabolism and Endocrinology Products (DMEP) via e-mail on September 11, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DMEP on September 13,2018, they stated no additional concerns with the proposed proprietary name, Ezallor.

[c] POCA search conducted on July 3, 2018 in version 4.2.

3 CONCLUSION

The proposed proprietary name is acceptable.

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

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed characteristics as stated in your submission, received on June 18, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

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

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

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

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

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

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

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[e]. 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

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

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 staff also conducts a prescription simulation studies using FDA health care professionals.

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

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

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

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

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

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

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

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

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

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

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be

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

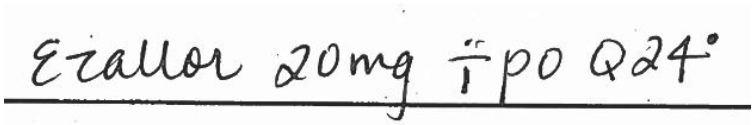
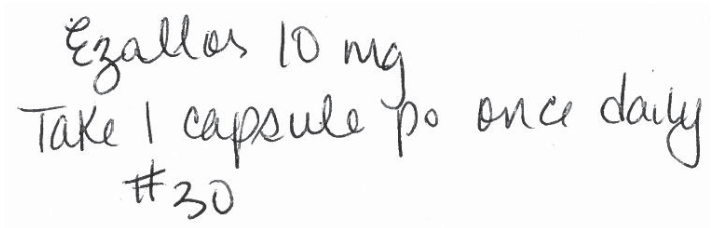
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Ezallor Study (Conducted on August 3, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

304 People Received Study
82 People Responded

Study Name: Ezallor

Total	22	21	18	21
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ESALORE	0	1	0	1
EXALLOR	1	0	0	1
EXELOR	0	1	0	1
EZALLAS	1	0	0	1
EZALLOR	14	0	21	56
EZALLOS	6	0	0	6
EZALOR	0	12	0	12
EZALORE	0	1	0	1
EZELOR	0	2	0	2
EZOLOR	0	1	0	1

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

No.	Proposed name: Ezallor Established name: rosuvastatin Dosage form: capsule Strength(s): 5 mg, 10 mg, 20 mg, 40 mg Usual Dose: 5mg to 40 mg once daily	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	Zerlor	75	Ezallor contains an additional upstroke, letter -l-, in its suffix which provides some orthographic differences from Zerlor. Further, Ezallor is three syllables whereas Zerlor is two syllables. Additionally, Zerlor and generic formulations of Zerlor may no longer be available for purchase from manufacturers or wholesalers. In addition to the above differences, the following differences in product characteristics may also help to mitigate the risk of errors: • Strength: Zerlor is available in one dosage strength combination (712.8 mg/60 mg/32 mg) which differs from the dosage strengths of Ezallor (5 mg, 10 mg, 20 mg, 40 mg); therefore, there is no overlap in strength. Additionally, a strength would not need to be specified on an order for Zerlor whereas it would be required for Ezallor. • Frequency: Zerlor is administered multiple times per day as needed whereas Ezallor is administered once daily; therefore, there is no overlap in frequency of administration. Therefore, in this scenario, due to the above-mentioned factors and the phonetic and orthographic differences, we find this name pair acceptable

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 (%)
2.	Zelboraf	58
3.	Benz-All	56
4.	Kolorz	56
5.	Rea Lo 39	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: Ezallor Established name: rosuvastatin Dosage form: capsule Strength(s): 5 mg, 10 mg, 20 mg, 40 mg Usual Dose: 5mg to 40 mg once daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
6.	Vazalore***	69	This name pair has sufficient orthographic and phonetic differences. The following differences in product characteristics may also help to mitigate the risk of errors: • Dosage strength: Vazalore is available in one dosage strength (325 mg) whereas Ezallor will have multiple dosage strengths (5 mg, 10 mg, 20 mg, and 40 mg); therefore, there is no overlap in dosage strength. Additionally, a strength must be specified for Ezallor, but may not be specified for Vazalore*** which further mitigates the risk of error. • Frequency: Vazalore is administered every 4 or 6 hours whereas Ezallor will be administered once daily; therefore, there is no overlap in frequency of administration. Therefore, in this scenario, due to the above-mentioned factors and the phonetic and orthographic differences, we find this name pair acceptable.
7.	Duzallo	63	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Ezallor Established name: rosuvastatin Dosage form: capsule Strength(s): 5 mg, 10 mg, 20 mg, 40 mg Usual Dose: 5mg to 40 mg once daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
8.	Edluar	63	This name pair has sufficient orthographic and phonetic differences.
9.	Rea-Lo	56	This name pair has sufficient orthographic and phonetic differences. The difference in route of administration may also help to mitigate the risk of errors: • Rea-Lo is administered topically whereas Ezallor will be administered orally; therefore, there is no overlap in route of administration. Therefore, in this scenario, due to the above-mentioned factors and the phonetic and orthographic differences, we find this name pair acceptable.
10.	Esmolol	55	This name pair has sufficient orthographic and phonetic differences. The difference in route of administration may also help to mitigate the risk of errors: • Esmolol is administered as an intravenous injection or infusion whereas Ezallor will be administered orally; therefore, there is no overlap in route of administration. Therefore, in this scenario, due to the above-mentioned factors and the phonetic and orthographic differences, we find this name pair acceptable.

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

No.	Name	POCA Score (%)
11.	Allersol	54
12.	Corzall	52
13.	Otezla (b) (4)***	52
14.	Zaleplon	52
15.	Aller-Flo	50
16.	Loraz	49
17.	Re All 12	46

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
18.	(b) (4)	58	The proposed proprietary name (b) (4) was found unacceptable on February 25, 2015 and no new names have been submitted.
19.	Aloral	57	Formally marketed proprietary name for allopurinol in the UK.
20.	(b) (4)	55	The proposed proprietary name (b) (4) for NDA (b) (4) was withdrawn by the sponsor on December 19, 2017. Application was approved under proprietary name Lumify on December 22, 2017.
21.	Elyzol	56	Proprietary name for metronidazole products marketed in Mexico, Italy, and the UK.

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

No.	Name	POCA Score (%)
22.	Kelnor 1/50***	59
23.	Relera	58
24.	Avelox	56
25.	Clolar	56
26.	Reluri	56
27.	Terazol 3	56
28.	Terazol 7	56
29.	Zazole	56
30.	(b) (4)	55
31.	Xeloda	55

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

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/s/

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09/13/2018

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:	December 21, 2015
Application Type and Number:	NDA 208647
Product Name and Strength:	Ezallor (rosuvastatin) oral capsules, 5 mg, 10 mg, 20 mg, 40 mg
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sun Pharma Global FZE
Panorama #:	2015-1649968
DMEPA Primary Reviewer:	Leeza Rahimi, Pharm.D.
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1 INTRODUCTION

This review evaluates the proposed proprietary name, Ezallor, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name

1.1 PRODUCT INFORMATION

The following product information is provided in the October 5, 2015 proprietary name submission.

- Intended Pronunciation: Ez-Aah-Lor
- Active Ingredient: Rosuvastatin
- Indication of Use: 1.Treatment of adult patients with hypertriglyceridemia

  2. Treatment of patients with primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia) 3. Treatment of patients with homozygous
- familial hypercholesterolemia (HoFH) to reduce LDL-C, total-C, and ApoB
- Route of Administration: Oral
- Dosage Form: Oral Capsules
- Strength: 5 mg, 10 mg, 20 mg, 40 mg
- Dose and Frequency: Administered as a single dose at any time of day, with or without food. Once daily with the dose range of 5 mg to 40 mg; usual starting dose :10 mg to 20 mg
- How Supplied: All strengths supplied in:

  Bottles of 30's with Child Resistant Closure

  Bottles of 90's with Child Resistant Closure

  Unit-dose blister pack of 30 (3 × 10) capsules
- Storage: Store at 20º to 25ºC (68º to 77ºF); excursions permitted between 15° and 30°C (59° and 86°F)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Metabolic and Endocrinology Products (DMEP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[1].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Ezallor has a name derivation of easy to administrate Rosuvastatin . The finding was communicated with OPDP via email and their response on December 7, 2015 confirmed that they have no concern. 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 FDA Name Simulation Studies

Sixty-four practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, October 27, 2015 e-mail, the Division of Metabolic and Endocrinology Products (DMEP) forwarded a comment relating to the proposed proprietary name at the initial phase of the review.

The statement was forwarded to DMEPA: "*Makes me think of easy swallow – which I guess is what they are going for. Also kinda close to ezetimibe which is also a lipid lowering drug - trade name Zetia.*"

DMEPA did not find the name Zetia or Ezetimibe to be a concern due to very low Phonetic and Orthographic Computer Analysis (POCA) combined scores of 20% and 22% (see Appendices A for explanation of how DMEPA conducts Name Risk Assessment and Appendix F for POCA score listing for those named). Additionally, the Applicant's name derivation indicated that Ezallor refers to easy administration, which OPDP did not identify as misbranding.

[1]USAN stem search conducted on October 10, 2015.

Phonetic and Orthographic Computer Analysis (POCA) Search Results
Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	3
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	143
Low similarity name pair: combined match percentage score ≤49%	2

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

Our analysis of the 148 names contained in Table 1 determined 148 names will not pose a risk for confusion as described in Appendices C through H.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of (DMEP) via e-mail on December 14, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DMEP on December 14, 2015, they stated no additional concerns with the proposed proprietary name, Ezallor.

3 CONCLUSIONS

The proposed proprietary name 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 THE APPLICANT

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

If any of the proposed product characteristics as stated in your October 5, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

[2] POCA search conducted on November 7, 2015.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

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. [3]

[3] 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 medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
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 50% 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 ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

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 with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it 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, etc.) may be limited when the strength or dose overlaps. We review such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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

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

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

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

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

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

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

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥50% to ≤69%).

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

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

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA 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. Ezallor Study (Conducted on November 16, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Ezallor 10mg Give one capsule daily	Ezallor 10 mg Take one capsule po daily #30
Outpatient Prescription: Ezallor 10mg Take one cap p o daily #30	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

242 People Received Study
64 People Responded

Study Name: Ezallor

Total	23	20	21	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ENGALLOR	1	0	0	1
ENZALLAR	4	0	0	4
ENZALLOR	4	0	0	4
ESALOR	0	1	0	1
ESALORE	0	1	0	1
ESILOR	0	1	0	1
ESILUR	0	1	0	1
ESOLOR	0	3	0	3
ESOLORE	0	1	0	1
ESOLUR	0	1	0	1
ESOLURE	0	1	0	1
EVERLOARD	0	1	0	1
EXALLOR	0	0	1	1
EYALLOR	2	0	0	2
EZALLAR	1	0	0	1
EZALLOR	10	0	20	30
EZALOR	0	2	0	2
EZALURE	0	1	0	1
EZELOR	0	1	0	1
EZLOW	0	1	0	1
EZOLLER	1	0	0	1
EZOLOR	0	3	0	3
EZSALOR	0	1	0	1

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

No.	**Proposed name: Ezallor** **Established name: Rosuvastatin** **Dosage form: Oral Capsule** **Strength(s): 5 mg, 10 mg, 20 mg, 40 mg** **Usual Dose: 10 mg-20 mg**	**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.	EZALLOR	100	Subject of the study
2.	REVALOR	75	Revalor is an animal drug implant, and it is only dispensed in veterinarian pharmacies. The two products have very different settings of use The prefixes of the name pair have sufficient orthographic differences. The first and second syllables of the name pair sound different
3.	ANOLOR	70	The prefixes and infixes of the name pair have sufficient orthographic differences. The first and second syllables of the name pair sound different.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	(b) (4)	54
2.	EPIKLOR	62
3.	EUDAL SR	62
4.	QDALL AR	62
5.	ISOCLOR	60
6.	PANLOR	60
7.	DILOR-G	59
8.	EVALOSE	58
9.	NODOLOR	58
10.	ALDOCLOR	57
11.	ALDOCLOR-150	57
12.	ALDOCLOR-250	57
13.	DYMELOR	57
14.	AK-CHLOR	56
15.	CALDOLOR	56
16.	DURAFLOR	56
17.	EPIFLUR	56
18.	VALCHLOR	56
19.	RESFLOR	55
20.	ALLERDUR	54
21.	ALORA	54
22.	E-400 CLEAR	54
23.	ENSTILAR	54
24.	SUCLOR	54
25.	(b) (4)	54
26.	ADDERALL 10	52
27.	ADDERALL 12.5	52
28.	ADDERALL 15	52

No.	Name	POCA Score (%)
29.	ADDERALL 20	52
30.	ADDERALL 30	52
31.	ADDERALL 5	52
32.	ADDERALL 7.5	52
33.	ALLER-CHLOR	52
34.	ELLURA	52
35.	EXALL	52
36.	INDICLOR	52
37.	PEDIACHLOR	52
38.	RANICLOR	52
39.	RETADOLOR	52
40.	EVOREL 100	51
41.	EVOREL 25	51
42.	EVOREL 50	51
43.	EVOREL 75	51
44.	LEVALL G	51
45.	ALL CLEAR	50
46.	CEFACLOR ER	50
47.	DALLERGY	50
48.	EXELON	50
49.	EYE-LERT	50
50.	LEVALL-12	50
51.	PSEUCLOR	50
52.	IBULAR	63 (Pho 73)
53.	ZERLOR	66 (Pho 73)

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name: Ezallor** **Established name: Rosuvastatin** **Dosage form: Oral Capsule** **Strength(s): 5 mg, 10 mg, 20 mg, 40 mg** **Usual Dose: 10 mg-20 mg**	**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.	DILOR	68	The prefixes and infixes of this name pair have sufficient orthographic differences The first syllables of this name pair sound different, and Ezallor *** contains an extra syllable
2.	DILOR-400	68	The prefixes and infixes of this name pair have sufficient orthographic differences. The dash in Dilor-400 helps distinguish it from Ezallor*** The first and second syllables of the name pair have sufficient phonetic differences
3.	PAMELOR	58	The prefixes and infixes of the name pair have sufficient orthographic differences The first and second syllables of the name pair sound different
4.	(b) (4)	53	The infixes and suffixes of the name pair have sufficient orthographic differences The second and third syllables of the name pair sound different
5.	(b) (4)	52	The infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different
6.	ADDERALL	52	The prefixes, infixes, and suffixes of the name pair have sufficient orthographic differences The first, second, and third syllables of the name pair sound different

No.	Proposed name: Ezallor Established name: Rosuvastatin Dosage form: Oral Capsule Strength(s): 5 mg, 10 mg, 20 mg, 40 mg Usual Dose: 10 mg-20 mg	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
7.	EDARBYCLOR	52	The infixes of the name pair have sufficient orthographic differences The second syllables of the name pair sound different. In addition Edarbyclor has an extra syllable
8.	EFFEXOR	51	The infixes of the name pair have sufficient orthographic differences The first and second syllables of the name pair sound different
9.	ENDOLOR	68	The prefixes and infixes of the name pair have sufficient orthographic differences. The second syllables of the name pair have sound different. In addition, Endolor is a deactivated name, but generic is still available
10.	CECLOR	64	The prefixes and infixes of the name pair have sufficient orthographic differences The first syllables of the name pair sound different, and Ezallor*** has an extra syllable
11.	CEFACLOR	64	The prefixes and infixes of the name pair have sufficient orthographic differences The first and second syllables of the name pair sound different

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤49%)

No.	Name	POCA Score (%)
1.	ZETIA	20
2.	EZETIMIBE	22

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.	ALOR	63	Discontinued product due to safety concerns
2.	ALTAFLOR	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
3.	EYEFLUR	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
4.	EZOL	54	Drug withdrawn from the market for safety concerns
5.	REGRELOR	54	Drug not found, chemical compound (not a drug)
6.	(b) (4)	51	(b) (4)
7.	LEVALLORPHAN	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
8.	TALL OIL	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
9.	NUFLOR	53	Veterinarian drug
10.	E-PILO-1	50	Not available in U.S. International Product
11.	E-PILO-2	50	Not available in U.S. International Product
12.	E-PILO-4	50	Not available in U.S. International Product

No.	Name	POCA Score (%)	Failure preventions
13.	E-PILO-6	50	Not available in U.S. International Product

Appendix H: Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
1.	ABLAVAR	51
2.	ACLARO	50
3.	ACULAR	60
4.	ACYLOVIR	55
5.	ADALAT AR	54
6.	AK-FLUOR	51
7.	AK-FLUOR 10%	51
8.	AK-FLUOR 25%	51
9.	ALASURE	54
10.	ALEVE ER	52
11.	AMELIOR	58
12.	ANABAR	50
13.	AQUAFLUR	50
14.	AVACLYR	62
15.	AZOLID	52
16.	AZOR	56
17.	BASAGLAR	51
18.	BAZA CLEAR	52
19.	BELLAMOR	54
20.	CURALER	52
21.	DELCORT	52
22.	DERMAZOR	50
23.	DIALAR	63
24.	DILACOR	54
25.	DOLMAR	54
26.	FAZACLO	50
27.	GALFER	55
28.	HYZAAR	50

No.	Name	POCA Score (%)
29.	IMVIVOR	50
30.	INDOLAR	56
31.	ISTALOL	54
32.	IZBAR	50
33.	KELNOR	55
34.	KETALAR	62
35.	LIVALO	51
36.	LOZI-FLUR	50
37.	MAZANOR	55
38.	MEVACOR	58
39.	OBIZUR	50
40.	ORALAIR 100	54
41.	ORALAIR 300	54
42.	OXTELLAR	52
43.	RELADOR	54
44.	REMULAR	52
45.	SULAR	54
46.	SULFUR	50
47.	SYNALAR	54
48.	SYNALAR 1:10	54
49.	SYNALAR 1:4	54
50.	TESSALON	52
51.	VALOID	50
52.	VALSTAR	51
53.	VANCOR	50
54.	VASCOR	54
55.	VELPHORO	50
56.	VETALAR	62
57.	VRAYLAR	52
58.	XALKORI	60

No.	Name	POCA Score (%)
59.	XOLAIR	58
60.	ZACLIR	68
61.	ZADITOR	50
62.	ZELAPAR	52
63.	ZELNORM	55
64.	ZEMPLAR	50
65.	ZOCOR	50
66.	ZYFLO CR	52

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/s/

LEEZA RAHIMI
12/21/2015

YELENA L MASLOV
12/22/2015