

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

209529Orig1s000

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:	February 21, 2020
Application Type and Number:	NDA 209529
Product Name and Strength:	Vesicare LS (solifenacin succinate) oral suspension 1 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Astellas Pharma US, Inc. (Astellas)
Panorama #:	2019-36429190
DMEPA Safety Evaluator:	Denise V. Baugh, PharmD, BCPS
DMEPA Team Leader:	Briana Rider, PharmD, CPPS

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Vesicare LS, 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. Astellas submitted an external name study, conducted by [REDACTED]^{(b) (4)} for this proposed proprietary name which was previously reviewed by DMEPA^a.

1.1 REGULATORY HISTORY

Astellas is proposing the proprietary name Vesicare LS for NDA 209529 for solifenacin succinate 1 mg/mL oral suspension. Vesicare was approved on November 19, 2004 and is currently marketed as 5 mg and 10 mg oral tablets under NDA 021518.

Astellas previously submitted the proposed proprietary name, Vesicare LS on January 27, 2017 and February 28, 2017 under IND 58135 and NDA 209529, respectively and the name was found to be conditionally acceptable^a. However, NDA 209529 received a Complete Response (CR) action August 28, 2017 and the Applicant was instructed to re-submit the proprietary name for our re-review with their response to the CR.

Thus, Astellas re-submitted the name, Vesicare LS, for review on November 27, 2019 upon their Class 2 resubmission of NDA 209529.

^a Rider, B. Proprietary Name Review for Vesicare LS (IND 58135, NDA 209529). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 May 22. Panorama No. 2017-12846543; 2017-13569661.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 27, 2019 and December 12, 2019.

Table 1. Relevant Product Information for Vesicare LS and Vesicare																				
Product Name	Vesicare LS	Vesicare ^b																		
Intended Pronunciation	Ves-ih-care el es	Ves-ih-care																		
Application #	NDA 209529	NDA 021518																		
Initial Approval Date	N/A	November 19, 2004																		
Active Ingredient	Solifenacin succinate	Solifenacin succinate																		
Indication	Treatment of neurogenic detrusor overactivity in patients aged 2 years to less than 18 years of age	Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency.																		
Route of Administration	oral	oral																		
Dosage Form	suspension	tablets																		
Strength	1 mg/mL	5 mg 10 mg																		
Dose and Frequency	Dose is weight-based (see table below) and is given once daily <table border="1"> <thead> <tr> <th>Weight range (kg)</th> <th>Starting dose (mL)¹</th> <th>Maximum dose (mL)¹</th> </tr> </thead> <tbody> <tr> <td>9 to 15</td> <td>2</td> <td>4</td> </tr> <tr> <td>> 15 to 30</td> <td>3</td> <td>5</td> </tr> <tr> <td>> 30 to 45</td> <td>3</td> <td>6</td> </tr> <tr> <td>> 45 to 60</td> <td>4</td> <td>8</td> </tr> <tr> <td>> 60</td> <td>5</td> <td>10</td> </tr> </tbody> </table>	Weight range (kg)	Starting dose (mL) ¹	Maximum dose (mL) ¹	9 to 15	2	4	> 15 to 30	3	5	> 30 to 45	3	6	> 45 to 60	4	8	> 60	5	10	5 mg once daily; if tolerated, may increase to 10 mg once daily
Weight range (kg)	Starting dose (mL) ¹	Maximum dose (mL) ¹																		
9 to 15	2	4																		
> 15 to 30	3	5																		
> 30 to 45	3	6																		
> 45 to 60	4	8																		
> 60	5	10																		
How Supplied	150 mL bottle with child resistant cap	Available in bottles of 30 count and 90 count; available in unit dose blister packs of 100																		
Storage	25° C (77° F) with excursions permitted from 15° C to 30° C (59° F to 86° F) [see USP Controlled Room Temperature];	25° C (77° F) with excursions permitted from 15° C to 30° C (59° F																		

^b Vesicare [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. 2020 JAN 30. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021518s0181bl.pdf

	Store in original bottle. Discard any unusual product 28 days after opening the bottle.	to 86° F) [see USP Controlled Room Temperature];
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2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Vesicare LS would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Bone, Reproductive and Urologic Products (DBRUP) concurred with the findings of OPDP's assessment for Vesicare LS.

2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) Search*

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

2.2.2 *Components of the Proposed Proprietary Name*

The proposed proprietary name, Vesicare LS, is comprised of two words, the root name 'Vesicare' and the modifier 'LS'. The product with the root name Vesicare (NDA 021518) was approved on November 19, 2004 and is currently marketed as 5 mg and 10 mg tablets. We assess the root name, Vesicare, in Section 2.2.5 below. We assessed the modifier 'LS' in Section 2.2.6 below.

2.2.3 *Comments from Other Review Disciplines at Initial Review*

In response to the OSE, December 30, 2019 e-mail, the Division of Bone, Reproductive and Urologic Products (DBRUP) did not forward any comments or concerns relating to Vesicare LS at the initial phase of the review.

2.2.4 *FDA Name Simulation Studies*

Eighty-two practitioners participated in DMEPA's prescription studies for Vesicare LS. Five study participants [outpatient study (n = 1), inpatient study (n = 1), CPOE study (n = 3)] omitted the proposed modifier 'LS'. We discuss the risk associated with omission of the modifier in Section 2.2.6 below.

The responses did not overlap with any other currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline.

^c USAN stem search conducted on December 16, 2019.

Appendix B contains the results from the prescription simulation studies.

2.2.5 Medication Error Data Selection of Cases

On February 1, 2017, we searched the FDA Adverse Event Reporting System (FAERS) database for name confusion errors involving Vesicare. The results of our search are documented in our previous review of the proposed proprietary name, Vesicare LS.^d

On December 19, 2019, we conducted a gap search of the FAERS database using the strategy listed in Table 2 (see Appendix A1 for a description of FAERS database) for name confusion errors involving the name, ‘Vesicare’ reported since the date of our last search that would be relevant for this review.

Table 2. FAERS Search Strategy	
FAERS Field	Search Terms
Initial FDA Receive Dates	02/01/2017 (date of previous review) to 12/19/2019
Product Name	Vesicare
Verbatim Name(s)	----
Product Active Ingredient	----
Drug Role	Primary Suspect
Event	DMEPA Official PNR Name Confusion Search Terms
Country (derived)	USA

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

Our review of the 36 cases submitted to FAERS since the previous search, found one case that referred to name confusion, which is further evaluated below.

Vesicare vs Vessel Care (n = 1)

One isolated case, reported in April 2017, describes name confusion involving the names Vesicare and Vessel Care. Vessel Care (methyl care) is a multi-ingredient^e dietary supplement intended to support ‘healthy methylation and homocysteine metabolism’. The dose is 2 capsules orally once daily or as directed by a healthcare provider and is available in 120 count bottles. In the case, the reporter states that the drug name ‘Vessel Care’ was misinterpreted as ‘Vesicare’ in

^d Rider, B. Proprietary Name Review for Vesicare LS (IND 58135, NDA 209529). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 May 22. Panorama No. 2017-12846543; 2017-13569661.

^e Two capsules contain riboflavin 1.6 mg, pyridoxine 25 mg, folate 800 mcg, methylcobalamin 1 mg, zinc 1.5 mg, manganese citrate 0.4 mg, molybdenum glycinate 15 mcg, N-AcetylL-Cysteine 600 mg, and Betaine HC 500 mg.

the patient's Home Medication List and a therapeutic substitution was made. As a result, the patient received a 'few' doses of oxybutynin 5 mg and the patient experienced urinary retention which required a foley catheter. However, physicians thought that the urinary retention could also have been caused by anesthesia. This error was assessed in OSE RCM # 2017-1092 and it was determined that no regulatory action was indicated at the time.

We reviewed the name pair, Vesicare LS and Vessel Care, for potential risk of confusion. We note that this name pair shares the same route of administration (oral), dose (2 [mL] vs 2 [capsules]), and frequency of administration (daily). However, we did not identify a liquid formulation of Vessel Care nor did we find instructions for compounding a liquid preparation using the product. Therefore, the differences in dosage form (oral suspension versus capsules) may help differentiate the two products, if included on a prescription. Additionally, we anticipate that the presence of the modifier 'LS' may help to mitigate the potential for wrong drug errors given that, if included, the proposed modifier will provide additional differentiation.

Upon further investigation of the marketed name, Vessel Care, it appears that the product has undergone a name change and is now marketed as 'Methyl Care'. As such, the first 4 letters of this name pair ('Vesi' vs. 'Meth') are sufficiently different orthographically and phonetically, which may help mitigate the risk of name confusion. When all of the aforementioned mitigations are considered in totality, we find the risk of name confusion between Vesicare LS and Vessel Care is mitigated to an acceptable level.

Thus, we find the use of the root name, Vesicare, acceptable for the proposed product.

2.2.6 Safety Assessment of the Modifier, LS

In our previous review^f of the proposed proprietary name, Vesicare LS, we evaluated:

- Sponsor submitted data in support of the modifier 'LS';
- the proposed modifier for risk of confusion;
- whether the modifier helps to distinguish the proposed Vesicare LS product from the currently marketed product;
- the risk of medication errors involving dispensing of the wrong dosage form and the risk for adverse clinical consequences; and
- the appropriateness of the modifier 'LS'.

We agree with the findings from our previous evaluation of the proposed modifier, LS.

As described in Section 2.2.4, the modifier, LS, was omitted in the December 13, 2019 FDA Prescription Simulation Study. We note, omission and oversight of modifiers is cited in literature as a common cause of medication errors.^g We discussed the risk of wrong dosage form medication errors with the review team and, at this time, there are no clinical concerns if 5 mg or 10 mg oral tablets were dispensed and administered instead of the intended 5 mg or 10 mg oral suspension, or vice versa. In the event that Vesicare tablets are dispensed and the oral solution is prescribed, or vice versa, the patient may experience a delay in therapy until they are able to

^f Rider, B. Proprietary Name Review for Vesicare LS (IND 58135, NDA 209529). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 May 22. Panorama No. 2017-12846543; 2017-13569661.

^g Lesar TS. Prescribing Errors Involving Medication Dosage Forms. J Gen Intern Med. 2002; 17(8): 579-587.

obtain the intended dosage form; we find this risk acceptable. Although we acknowledge modifiers may be omitted or overlooked, when used, they can assist in differentiating products and may help to prevent potential product selection errors. The proposed modifier, LS, may serve as a signal to health care practitioners that this product differs from the marketed oral tablet formulation of solifenacin, which is marketed under the root name, Vesicare. Therefore, we find the proposed modifier, LS, is acceptable for use in this situation.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Bone, Reproductive and Urologic Products (DBRUP) via e-mail on February 12, 2020. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Bone, Reproductive and Urologic Products (DBRUP) on February 20, 2020, they stated no additional concerns with the proposed proprietary name, Vesicare.

3 CONCLUSION

The proposed proprietary name, Vesicare LS, is acceptable.

If you have any questions or need clarifications, please contact Oyinlola Fashina, OSE Project Manager, at 301-796-4446.

3.1 COMMENTS TO ASTELLAS

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

If any of the proposed product characteristics as stated in your submission, received on November 27, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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.

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.^h

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

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

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

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

- Highly similar pair: combined match percentage score $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.

- Low similarity: combined match percentage score $\leq 54\%$.

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

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

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

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

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

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

- d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) 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.

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

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

Step 1	<p>Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none">• Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa.• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.• Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	<p>Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses.</p>

	<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted? 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

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

Appendix A1: Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm>.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Vesicare LS Study (Conducted on December 13, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
<p>Medication Order:</p> <hr/> <p>Vesicare LS 5mg po once daily</p> <hr/>	<p>“Vesicare LS Take 4 ml by mouth daily. Dispense 150 mL”</p>
<p>Outpatient Prescription:</p> <p>Vesicare LS</p> <p>4ml po once daily</p> <p>#150ml</p>	
<p>CPOE Study Sample (Font: sans-serif, 12 point, bold)</p>	
<p>Vesicare LS</p>	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Vesicare LS

As of Date 1/28/2020

210 People Received Study
82 People Responded

Study Name: Vesicare LS

INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
	17	32	14	19	
Total					
VESICAORE LS	1	0	0	0	1
VESICARE	1	3	0	1	5
VESICARE LS	13	29	12	18	72
VESICORE LS	2	0	0	0	2
VEZICARE LS	0	0	1	0	1
ZEZICARE LS	0	0	1	0	1

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/

DENISE V BAUGH
02/21/2020 07:04:49 AM

BRIANA B RIDER
02/21/2020 01:41:59 PM

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:	May 22, 2017
Application Type and Number:	IND 58135; NDA 209529
Product Name and Strength:	Vesicare LS (solifenacin succinate) oral suspension 1 mg/mL
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Astellas Pharma Global Development
Panorama #:	2017-12846543; 2017-13569661
DMEPA Primary Reviewer:	Briana Rider, PharmD
DMEPA Team Leader:	Lolita White, PharmD
DMEPA Deputy Director (Acting):	Danielle Harris, PharmD, BCPS

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Astellas Pharma Global Development is proposing the proprietary name Vesicare LS, under NDA 209529 for their solifenacin succinate 1 mg/mL oral suspension. Vesicare 5 mg and 10 mg oral tablets were approved under NDA 021518 on November 19, 2004 and are currently marketed.

On January 27, 2017 and February 28, 2017 the Sponsor submitted the proposed proprietary name Vesicare LS for Agency review for their oral suspension product line extension under IND 58135 and NDA 209529, respectively. On March 24, 2017 we submitted an information request (IR) requesting that Astellas Pharma Global Development provide a justification for the use of the modifier “LS” as part of their proposed proprietary name, Vesicare LS. The Sponsor provided responses to the IR on March 30, 2017 (See Section 2.2.3).

1.2 PRODUCT INFORMATION

The following product information is provided in the January 27, 2017 and February 28, 2017 proprietary name submissions.

Table 1. Relevant Product Information for Vesicare LS and the Vesicare		
Product Name	Vesicare LS	Vesicare
Intended Pronunciation	VES-ih-care el es	VES-ih-care
Application #	IND 58135; NDA 209529	NDA 021518
Initial Approval Date	N/A	November 19, 2004
Active Ingredient	solifenacin succinate	solifenacin succinate
Indication	Treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged 2 years and older.	Treatment of overactive bladder (OAB) with symptoms of urinary incontinence, urgency, and urinary frequency.
Route of Administration	Oral	Oral
Dosage Form	Oral Suspension	Tablet
Strength	1 mg/mL	5 mg, 10 mg
Dose and Frequency	Recommended dose is determined based on patient weight and is dosed once daily.	Recommended dose is 5 mg once daily. If the 5 mg dose is well tolerated, the dose may

	<table border="1"> <caption>Table 1 Dose According to Patient Body Weight</caption> <thead> <tr> <th>Weight range (kg)</th> <th>Starting dose (mL)§¹</th> <th>Maximum dose (mL)§²</th> </tr> </thead> <tbody> <tr> <td>9 to 15</td> <td>2</td> <td>4</td> </tr> <tr> <td>> 15 to 30</td> <td>3</td> <td>5</td> </tr> <tr> <td>> 30 to 45</td> <td>3</td> <td>6</td> </tr> <tr> <td>> 45</td> <td>4</td> <td>8</td> </tr> </tbody> </table>	Weight range (kg)	Starting dose (mL)§ ¹	Maximum dose (mL)§ ²	9 to 15	2	4	> 15 to 30	3	5	> 30 to 45	3	6	> 45	4	8	be increased to 10 mg once daily.
Weight range (kg)	Starting dose (mL)§ ¹	Maximum dose (mL)§ ²															
9 to 15	2	4															
> 15 to 30	3	5															
> 30 to 45	3	6															
> 45	4	8															
How Supplied	150 mL bottles	5 mg, 10 mg <ul style="list-style-type: none"> • Bottle of 30 • Bottle of 90 • Unit Dose Pack of 100 															
Storage	Store at 25°C (77°F) with excursions permitted from 15°C to 30°C (59°F - 86°F).	Store at 25°C (77°F) with excursions permitted from 15°C to 30°C (59°F - 86°F).															
Container Closure	150 mL amber polyethylene terephthalate (PET) bottles capped with child-resistant high-density polyethylene-polypropylene caps with a pulp and vinylseal liner.	High-density polyethylene (HDPE) bottles and blister packages.															

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 Bone, Reproductive, and Urologic Products (DBRUP) 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^a.

2.2.2 Components of the Proposed Proprietary Name

The proposed proprietary name, Vesicare LS, is comprised of two words, the root name “Vesicare” and the modifier “LS.” The product with the root name Vesicare was approved on November 19, 2004 and is currently marketed as 5 mg and 10 mg tablets. We assess the use of the root name, Vesicare, in Section 2.2.5 below. We assess the proposed modifier ‘LS’ in Section 2.2.6 below.

^a USAN stem search conducted on February 27, 2017.

2.2.3 FDA Name Simulation Studies

Eighty-one practitioners participated in DMEPA’s prescription studies. One participant in the FDA Prescription Simulation Studies misinterpreted the modifier “LS” as being “LF”. We considered the risk of medication error should one confuse Vesicare LS with Vesicare LF. Vesicare LF does not overlap with any marketed products nor does it sound or look similar to any currently marketed products or any products in the pipeline. Furthermore, the modifier “LF” does not have an established meaning, is not a medical abbreviation commonly used for prescription communication, is not on ISMP’s List of Error-Prone Abbreviations, Symbols, and Dose Designations^b, and is not a USAN Stem. 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, February 22, 2017 e-mail, the Division of Bone, Reproductive, and Urologic Products (DBRUP) forwarded the following comments and concerns relating to the proposed proprietary name at the initial phase of the review:

- The prescription will be written as Vesicare LS 1 mg/mL, which on its face looks confusing, and could be even worse written by hand. For example, is the drug name Vesicare LS1?
- Also, what does LS mean? Is it an acronym for something? Or, is it just a meaningless suffix?
- What if the prescriber leaves off the suffix “LS”? A child could wind up receiving a big dose of solifenacin via tablet.
- “VESIcare LS” could be written incorrectly as “VESIcare SL”, which could lead to attempted sublingual administration of the suspension.

We address these concerns in section 2.2.6 Safety assessment of the modifier ‘LS’.

2.2.5 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A1 for a description of FAERS database) for name confusion errors involving Vesicare that would be relevant for this review.

Table 2. FAERS Search Strategy	
Search Date	February 1, 2017
Drug Name	Vesicare
Event (MedDRA Terms)	DMEPA Official PNR Name Confusion Search Terms Event List: Preferred Terms:

^b ISMP’s List of Error-Prone Abbreviations, Symbols, and Dose Designations [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2015 [cited 2017 MAY 16]. Available from: <http://www.ismp.org/tools/errorproneabbreviations.pdf>.

	<p>CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR DRUG ADMINISTRATION ERROR) DRUG DISPENSING ERROR DRUG PRESCRIBING ERROR INTERCEPTED DRUG DISPENSING ERROR INTERCEPTED DRUG PRESCRIBING ERROR INTERCEPTED MEDICATION ERROR MEDICATION ERROR PRODUCT NAME CONFUSION TRANSCRIPTION MEDICATION ERROR</p> <p>Lower Level Terms: INTERCEPTED PRODUCT SELECTION ERROR INTERCEPTED WRONG DRUG PRODUCT SELECTED INTERCEPTED WRONG DRUG SELECTED PRODUCT SELECTION ERROR WRONG DEVICE DISPENSED WRONG DRUG ADMINISTERED WRONG DRUG DISPENSED WRONG DRUG PRESCRIBED WRONG DRUG PRODUCT SELECTED WRONG DRUG SELECTED WRONG PRODUCT SELECTED</p>
Date Limits	To: 02/01/2017

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

After individual review, 72 reports were not included in the final analysis for the following reasons: 6 cases were duplicates and 66 cases were unrelated to name confusion.

Following exclusions, the search yielded 8 relevant cases.

Of the eight cases, five cases (n = 5) describe name confusion involving Vesicare and Visicol (sodium phosphate monobasic monohydrate, USP and sodium phosphate dibasic anhydrous, USP), two cases (n = 2) describe name confusion involving Vesicare and Vasotec (enalapril maleate), and one case (n = 1) describes name confusion involving Vesicare 10 mg and Xarelto (rivaroxaban) 10 mg.

Vesicare vs Visicol (n=5)

The name pair Vesicare and Visicol was previously reviewed for risk of confusion and found to pose risk of error.^c Approved on September 21, 2000 under NDA 21097, Visicol (sodium

^c Pincock, L. Postmarketing Safety Review of Vesicare tablets NDA 021518 and Visicol tablets NDA 021097, Silver Spring (MD): FDA, CDER, OSE, DMETS (US); 2006 APR 18. RCM No.: 06-0161.

phosphate monobasic monohydrate, USP and sodium phosphate dibasic anhydrous, USP) is indicated for cleansing of the bowel as a preparation for colonoscopy, in adults 18 years of age and older and is available in a single strength (1.102 g sodium phosphate monobasic monohydrate, USP and 0.398 g sodium phosphate dibasic anhydrous, USP) for a total of 1.5 g of sodium phosphate. However, on February 13, 2013 Salix Pharmaceuticals, Inc. requested to withdrawal Visicol NDA 021097 not for reasons of safety or efficacy.

We considered whether risk of name confusion exists for Vesicare and the discontinued product Visicol. We note the last manufactured lot of Visicol expired in February 2012 and the application is pending Federal Register Notice of Withdrawal publication. Although we know that prescribers utilize proprietary names for discontinued brand drug products with existing generic equivalents^d, no new cases of drug name confusion involving Vesicare and Visicol have been reported to FAERS since 2007.

Vesicare vs Vasotec (n=2)

Two cases describe name confusion involving Vesicare and Vasotec. Vasotec (enalapril maleate) is an oral tablet indicated for the treatment of hypertension, heart failure, and asymptomatic left ventricular dysfunction in adults as well as pediatric hypertension. In one case the patient received Vesicare 5 mg tablets instead of Vasotec 10 mg tablets as prescribed. The other case describes a near miss where Vesicare 10 mg one daily was misinterpreted as Vasotec 10 mg one daily. Neither of the two cases reported the outcome as serious. Although Vasotec is available as 2.5 mg, 5 mg, 10 mg, and 20 mg tablets, the reported mix-ups have only involved the strengths which overlap between Vesicare and Vasotec (i.e., 5 mg and 10 mg).

We reviewed the name pair Vesicare LS and Vasotec for potential risk of confusion. We note that the Vasotec Prescribing Information (PI) contains instructions for the preparation of a suspension. We also note that the Vasotec suspension and proposed Vesicare LS product share overlapping product characteristics. Vesicare LS and the Vasotec suspension share a common route of administration (oral), patient population (pediatric), dosage form (suspension), frequency of administration (daily), strength (1 mg/mL), and the potential for overlapping doses (2 mg, 3 mg, 4 mg, 5 mg). We are concerned that name confusion involving Vesicare and Vasotec may be compounded by the introduction of an oral suspension formulation of Vesicare due to overlapping product characteristics. We searched the (b) (4) database to determine if there were occurrences of Vasotec for the suspension formulation. However, our search did not yield any results. We also note that Epaned, a commercially available enalapril maleate oral solution, was approved in 2016 which may decrease the need to compound a suspension out of Vasotec tablets. Furthermore, we anticipate that the presence of the modifier “LS” may help to mitigate the potential for wrong drug errors given that, if included, the proposed modifier will provide additional differentiation.

Vesicare vs Xarelto (n = 1)

^d Tu, CM, Taylor, K, and Chai, G. Use of Proprietary Names by Prescribers for Discontinued Brand Drug Products With Existing Generic Equivalents. Drug Information Journal, published online August 21, 2012, available at http://dij.sagepub.com/content/early/2012/08/21/0092861512456282_full.pdf+html

One case (n = 1) describes a drug dispensing error in which Xarelto (rivaroxaban) 10 mg was dispensed instead of Vesicare 10 mg. The report does not include contributing factors. However, Vesicare and Xarelto may be located next to one another in the pharmacy if stored alphabetically by brand name.

We considered confusion with the name pair Vesicare and Xarelto. We find that the two products have sufficient orthographic and phonetic differences and do not pose risk of error of confusion. We anticipate that the presence of the modifier “LS” may help to mitigate the potential for wrong drug errors given that, if included, the proposed modifier will provide further differentiation.

Thus, we find the use of the root name Vesicare, acceptable for the proposed product.

2.2.6 Safety Assessment of the Modifier, LS

We evaluated the proposed modifier ‘LS’ for risk of confusion and to determine if the modifier helps to distinguish the proposed Vesicare LS product from the currently marketed Vesicare product.

Vesicare LS is the second product proposed by the Applicant for the currently marketed Vesicare product line. Because Vesicare and Vesicare LS will co-exist in the market place once approved, we evaluated the risk of confusion between these two products.

The root name Vesicare is currently approved as 5 mg and 10 mg oral tablets for the treatment of overactive bladder (OAB) in adults with symptoms of urinary incontinence, urgency, and urinary frequency and has been marketed since 2004. The proposed product represents a new dosage form (oral suspension vs. tablet) for use in a new indication (neurogenic detrusor overactivity (NDO) vs OAB)) in a new population (pediatric vs. adults). Since product line extensions involving an oral liquid dosage form do not typically require the use of a modifier, we sent an information request (IR), dated March 24, 2017, requesting the sponsor provide their rationale for proposing a modifier. In the Sponsor’s response, dated 03/30/2017, the Sponsor provided the following rationale for use of the modifier “LS” as part of the proposed proprietary name, Vesicare LS. The Sponsor states:

- The proposed modifier “LS” is intended to mean “Liquid Suspension”
- The current (oral tablet) and proposed (oral suspension) dosage forms are intended for treatment of different indications (OAB versus NDO) and in different patient populations (adults versus pediatric)
- Unique populations of healthcare providers typically diagnose and treat overactive bladder in adults as compared to NDO in pediatric patients.

The sponsor asserts that in order to emphasize the important differences between the products, a modifier is proposed to support differentiation during commercial use, to facilitate selection of the appropriate dosage form by a healthcare provider, and to minimize the potential for errors.

We agree with the Sponsor that the addition of a modifier ‘LS’ provides differentiation from the currently marketed product, Vesicare. The modifier may signal to healthcare practitioners that this product differs from the currently marketed Vesicare tablets, which may reduce the potential for wrong dosage form medication errors. We recognize there are limitations to this approach since the omission or oversight of modifiers in prescribing, dispensing, and administration has

been cited as a source of error, particularly for those drugs that use modifiers to distinguish between members of the same product line.^e

We considered the risk of medication errors involving the dispensing of the wrong dosage form and the risk for adverse clinical outcomes. Per the Agency Clinical Pharmacology reviewer, the results of the submitted bioequivalence study (905-CL-080) suggest that the suspension formulation (1 mg/mL *10 mL) is bioequivalent to the tablet at an equivalent dose (i.e., 10 mg). While only the 10 mg dose was studied in bioequivalence study 905-CL-080, it may be concluded that other doses are also bioequivalent once dosage form proportionality and similar dissolution are confirmed. Therefore, the two products would be considered clinically substitutable at the 10 mg dose. However, we acknowledge in the event that Vesicare tablets are dispensed and the oral solution is prescribed, or vice versa, the patient may experience a delay in therapy until they are able to obtain the intended dosage form. We find this risk acceptable.

We evaluated the appropriateness of the modifier ‘LS’. The Applicant proposed the use of a modifier, “LS” to differentiate the newly proposed dosage form (oral suspension) from the original dosage form (tablet). The Applicant indicates that the modifier “LS” is intended to mean “Liquid Suspension.” We found that the proposed modifier, LS, is not a medical abbreviation commonly used for prescription communication^f, is not a USAN Stem^g, is not on ISMP’s List of Error-Prone Abbreviations, Symbols, and Dose Designations^h, and does not appear to present any overt safety concerns from a look-alike or sound-alike perspective.

As part of our evaluation of the appropriateness of the modifier ‘LS’, we reviewed other products which use ‘LS’ as part of their proprietary name. The Orange Book currently lists two products with the modifier “LS”, Acular LS and Micro-K LS.

Acular LS is ketorolac tromethamine ophthalmic solution 0.4% and was approved in 2003 for the reduction of ocular pain and ocular symptoms of foreign body sensation, burning/stinging, tearing and photophobia following refractory surgery. According to the March 21, 2003 Clinical Pharmacology/Biopharmaceutics Review of NDA 021528,ⁱ the Acular LS formulation represents a 20% reduction in concentration of the active ingredient, ketorolac tromethamine, compared to the 0.5% preserved formulation (Acular) and 0.5% non-preserved formulation (Acular PF), which have been marketed since 1992 for the treatment of ocular itching due to allergic conjunctivitis. Based on the decreased concentration of Acular LS versus Acular and Acular PF, the modifier LS in this product appears to indicate “low strength”.

^e Lesar TS. Prescribing Errors Involving Medication Dosage Forms. *J Gen Intern Med.* 2002; 17(8): 579-587.

^f Davis, N. Medical Abbreviations 30,000 Conveniences at the Expense of Communication and Safety. 14th ed. Warminster, PA; 2009.

^g USAN stem search conducted on February 27, 2017.

^h ISMP’s List of Error-Prone Abbreviations, Symbols, and Dose Designations [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2015 [cited 2017 MAY 16]. Available from: <http://www.ismp.org/tools/errorproneabbreviations.pdf>.

ⁱ Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/21528_Acular.cfm

Micro-K LS is a discontinued brand of potassium chloride extended-release formulation for liquid suspension. The product was indicated for 1) the treatment of patients with hypokalemia, with or without metabolic alkalosis; in digitalis intoxication; and in patients with hypokalemia lamial periodic paralysis, and 2) the prevention of hypokalemia in patients who would be at particular risk if hyperkalemia were to develop. The product was withdrawn FR effective June 8, 2011. There are no generics available. While it is unclear what the Sponsor’s intended meaning of the modifier LS is for this product, the dosage form was a liquid so it is feasible that the LS indicated liquid suspension.

We considered these precedent uses and apparent meanings of LS, and determined there is no clearly defined meaning for the modifier, LS. We find that the Sponsor’s proposed meaning, Liquid Suspension, is consistent with the apparent meaning of the modifier as used in the Micro-K LS product. We also note that the proposed oral suspension will be available in a 1 mg/mL strength, which is a lower strength than the currently available tablet formulation strengths, 5 mg and 10 mg, and thus, is consistent with the apparent meaning of the modifier as used in the Acular LS product. Furthermore, based on our postmarketing surveillance activities, we are not aware of any medication error concerns stemming from the use of the modifier LS. Therefore, we determined that the precedent uses and apparent meanings of LS for Acular LS and Micro-K LS do not pose safety concerns precluding the use of LS for the proposed product.

To support the use of the “LS” modifier in the proposed proprietary name Vesicare LS, the Applicant submitted an external name study, conducted by (b) (4). The 2016 (b) (4) assessment of the proposed LS modifier included one hundred fifty (150) (b) (4) study participants who were asked to:

- Identify the meaning conveyed by the modifier alone, without the presence of the base brand and unaided (without exposure to the product profile) (**Table 2**);
- Review the base brand and modifier combination unaided (without exposure to the product profile) and explain what the modifier tells them about the product (**Table 3**);
- Review the product profile (aided) and provide any meaning(s) conveyed by the modifier (**Table 4**).

If the respondents found that the modifier did not convey any particular meaning, they could select “no meaning.” The results are shown in the following tables:

Table 2: (b) (4) Study Results for Meaning Conveyed by Modifier LS Alone (unaided)

Meaning	U.S. Overall (n=150)	
	#	%
NO MEANING	51	34%
PEDIATRICS	50	33.3%
CHILDREN	31	20.7%
PEDIATRIC DOSE	6	4.0%
PEDIATRIC MEDICATION	4	2.7%
PEDIATRIC USE	4	2.7%
CHILDRENS STRENGTH	1	0.7%
OBVIOUS	1	0.7%
ORAL SUSPENSION	1	0.7%
Total	150	100%

Table 3: (b) (4) Study Results for Meaning Conveyed by Root Name Plus Modifier (Vesicare LS) (unaided)

Meaning	U.S. Overall n = 150	
	#	%
NO MEANING	143	95.3%
INCONTINENCE/BLADDER CONTROL	3	2%
ORAL SUSPENSION	2	1.3%
CHILDREN	1	0.7%
LIQUID FORMULATION	1	0.7%
Total	150	100%

Table 4: (b) (4) Study Results for Meaning Conveyed by Root Name Plus Modifier (Vesicare LS) (aided)

Meaning	U.S. Overall n = 150	
	#	%
NO MEANING	141	94%
ORAL SUSPENSION	2	1.3%
ORTHOPEDIC	2	1.3%
DISTINCTIVE	1	0.7%
FLEXIBLE	1	0.7%
FLEXIBLE DOSING	1	0.7%
LIQUID FORMULATION	1	0.7%
PEDIATRIC DOSE	1	0.7%
Total	150	100%

We reviewed the Sponsor submitted data in support of the modifier ‘LS’. We find that while none of the 150 (b) (4) study participants interpreted the modifier “LS” as meaning “Liquid Suspension” a small percentage of participants interpreted the modifier as meaning “oral suspension” or “liquid formulation.” The majority of participants indicated that the modifier “LS” did not convey any particular meaning when provided with the root name Vesicare plus the modifier (Table 3 and Table 4). Without the presence of the base brand Vesicare and without exposure to the product profile, the majority of participants (64%, n = 96 of 150) indicated that the modifier conveys pediatric/children’s (Table 2). Although this is not the intended meaning of the modifier as proposed by the Sponsor, the interpretation is consistent with the proposed patient population (treatment of NDO in pediatric patients aged 2 years and older). None of the study participants interpreted the modifier “LS” as meaning “low strength” or an analogous term.

Based upon feedback from the Division of Neurology Products (DNP), we considered the risk of the modifier ‘LS’ being misinterpreted as the common term for sublingual ‘SL’ and the data show no evidence of risk for wrong route of administration error. Because misspelling of the modifier “LS” as “SL” results in the medical abbreviation for sublingual and is commonly used for prescription communication, we confirmed that the modifier “LS” was not misinterpreted as “SL” in either the external study (conducted by (b) (4)) or the FDA name simulation study (see Appendix B). Based on our own data and the data from the (b) (4) study, there are no results to support this error may occur.

We acknowledge that name simulation studies include a small numbers of participants and are not sufficiently powered to rule out negative findings. Therefore, we considered the likelihood of a wrong route of administration error (sublingual versus oral) reaching the patient and causing harm. We determined that since the product is intended to be swallowed, the risk of accidental SL administration causing harm is low.

We evaluated concerns that a prescription for Vesicare LS 1 mg/mL may be misinterpreted as Vesicare LS1 and lead to medication error. While we are aware of medication errors that have occurred due to a lower case “L” at the end of a proprietary name being misread as the numerical “1” (e.g., Tegretol300 mg misinterpreted as 1300 mg ^j), we are not aware of medication errors resulting from part of the product concentration being misinterpreted as part of a modifier. For example, several oral liquids (suspension, solution) exist with a modifier preceding the concentration (e.g., Cheratussin AC 10 mg – 100 mg / 5 mL, Tirosint-Sol 13 mcg/mL, Children’s Elixsure IB 100 mg/5 mL). We also confirmed that the modifier was not misinterpreted as LS1 in the FDA name simulation study or the external study. Furthermore, because Vesicare LS will be available in a single strength (i.e., 1 mg/mL) the strength may be omitted on a prescription altogether.^k We also anticipate that a dose or volume would be included on a prescription for Vesicare LS in accordance with the recommended dosing table provided in the proposed prescribing information. Therefore, we find this risk of the modifier LS being misinterpreted as a strength to be low.

Based on the totality of information considered above, we find the use of the proposed modifier, “LS”, acceptable for this product.

2.2.7 Communication of DMEPA’s Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Bone, Reproductive, and Urologic Products (DBRUP) via e-mail on May 16, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DBRUP on May 22, 2017, they stated no additional concerns with the proposed proprietary name, Vesicare LS.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Mammah Borbor, OSE project manager, at 301-796-7731.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your January 27, 2017 and February 28, 2017 proprietary name submissions are altered prior to approval of the marketing application, the name must be resubmitted for review.

^j Institute for Safe Medication Practices. Safety briefs: Beware of drug names that end in the letter “L.” ISMP Med Saf Alert Community/Ambulatory Care. 2016; 15(12): 3.

^k Institute for Safe Medication Practices. Safety briefs: Ranexa and Prenexa too similar. ISMP Med Saf Alert Community/Ambulatory Care. 2012; 11(3): 1-4.

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 support 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.¹

¹ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

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

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

- b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:
- Highly similar pair: combined match percentage score $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 54\%$.

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

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

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

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 a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.
- c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

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

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

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

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

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

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

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

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

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of	Y/N	Do the syllables have different phonologic processes, such vowel reduction, assimilation,

	upstroke/downstroke letters present in the names?		or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

Step 1	<p>Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice
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	<p>versa.</p> <ul style="list-style-type: none"> • 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 		
<p>Step 2</p>	<p>Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses.</p>		
	<table border="1"> <tr> <td data-bbox="285 722 818 1873"> <p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> • Are the lengths of the names dissimilar* when scripted? <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> • Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when </td> <td data-bbox="818 722 1351 1873"> <p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently? </td> </tr> </table>	<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> • Are the lengths of the names dissimilar* when scripted? <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> • Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?
<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> • Are the lengths of the names dissimilar* when scripted? <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> • Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently? 		

	scripted?	
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

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

Appendix A1: Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the

Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm>.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Vesicare LS Study (Conducted on February 13, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Vesicare LS 5mg po once daily</i></p>	<p>“Vesicare LS –take 4 mL by mouth once daily. Dispense 150 mL”</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Vesicare LS 4mL po once daily #150 mL</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Vesicare LS					299 People Received Study 81 People Responded
Total	28	19	34		
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL	
VERICARE LS	7	0	0	7	
VESCIARE LS	0	0	1	1	
VESICAR LS	0	2	0	2	
VESICARE LS	21	13	33	67	
VEVICARE LS	0	1	0	1	
VISICARE LS	0	1	0	1	
ZESICARE LS	0	1	0	1	
ZEZACARE LF	0	1	0	1	

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/s/

BRIANA B RIDER
05/22/2017

LOLITA G WHITE
05/23/2017

LOLITA G WHITE on behalf of DANIELLE M HARRIS
05/23/2017