CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208251Orig1s000

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)

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Date of This Review:	March 31, 2016
Application Type and Number:	NDA 208251
Product Name and Strength:	Otovel (ciprofloxacin and fluocinolone acetonide) Otic Solution
Total Product Strength:	0.3% / 0.025%
Product Type:	Multi ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Premier Research (U.S. Agent for SALVAT)
Panorama #:	2016-2707184
DMEPA Primary Reviewer:	Sevan Kolejian, Pharm. D.
DMEPA Team Leader:	Vicky Borders-Hemphill, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Otovel, 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

(b)(4)

Thus, the Applicant submitted the proposed proprietary name, Otovel, for review on January 29, 2016.

1.2 PRODUCT INFORMATION

The following product information is provided in the January 29, 2016 proprietary name submission.

- Intended Pronunciation: OH-toe-vel
- Active Ingredient: ciprofloxacin 0.3% and fluocinolone acetonide 0.025%
- Indication of Use: Ciprofloxacin 0.3% plus fluocinolone acetonide 0.025% otic solution is indicated for acute otitis media in pediatric patients (aged 6 months and older) with tympanostomy tubes (AOMT).
- Route of Administration: Otic use
- Dosage Form: otic single use (b) (4)
- Strength: ciprofloxacin 0.3% and fluocinolone acetonide 0.025%

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[1] Kapoor, Rachna, Proprietary Name Review for (b)(4) *** (IND 107809). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2013 DEC 27. OSE RCM No.: 2012-1779.

[2] Kolejian, Sevan, Proprietary Name Review for (b)(4) *** (NDA 208251). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 DEC 28. OSE RCM No.: 2015-1763566.

- Dose and Frequency: contents of one single use (b) (4) should be instilled into the affected ear twice daily for 7 days.
- How Supplied: The drug product will be supplied in single use (b) (4) vials containing 0.25 mL of ciprofloxacin 0.3% plus fluocinolone acetonide 0.025% otic solution.
- Storage: store at room temperature at 15ºC to 25ºC (59°F to 77°F)
- Container and Closure Systems: supplied in blue translucent single-use 0.25 mL vials. Fourteen single-use vials are packaged in a protective foil pouch contained in a carton.

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 Anti- Infective Products (DAIP) did not provide any comments. DMEPA 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[3].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Otovel in their submission. 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

Seventy practitioners participated in DMEPA's prescription studies. The responses do 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. One participant commented that the proposed name reminds them of the proprietary name Actonel. We evaluated the proprietary name Actonel in Appendix D.

[3]USAN stem search conducted on February 10, 2016.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, February 26, 2016 e-mail, the Division of Anti- Infective Products (DAIP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 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[4] organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified in the external study conducted by (b)(4).

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	None
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	194
Low similarity name pair: combined match percentage score ≤49%	4

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

Our analysis of the 198 names contained in Table 1 will not pose a risk for confusion as described in Appendices C through H.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Anti- Infective Products (DAIP) via e-mail on March 23, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Anti- Infective Products (DAIP) on March 26, 2016 they stated no additional concerns with the proposed proprietary name, Otovel.

3 CONCLUSIONS

The proposed proprietary name is acceptable.
If you have further questions or need clarifications, please contact Karen Townsend, OSE project manager, at 301-796-5413.

3.1 COMMENTS TO THE APPLICANT

[4] POCA search conducted on February 10, 2016.

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

If any of the proposed product characteristics as stated in your January 29, 2016 submission 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.

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. [5]

[5] 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. Otovel Study (Conducted on February 19, 2016)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Otovel Twice daily to right ear Outpatient Prescription: Otovel UAD twice daily for 7days #1	Otovel Use as directed twice daily for 7 days Dispense #1

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Otovel
251 People Received study
70 People Responded

Total	**23**	**22**	**25**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ALTOVEL	1	0	0	1
AUTOVEL	0	1	0	1
OTAVEL	0	4	0	4
OTAVELL	0	1	0	1
OTAVELLE	0	2	0	2
OTAVIL	0	2	0	2
OTEVEL	0	3	0	3
OTEVILLE	0	1	0	1
OTIVEL	0	2	0	2
OTIVELL	0	1	0	1
OTIVELLE	0	1	0	1
OTONEL	2	0	0	2
OTOVEB	0	0	2	2
OTOVEL	18	1	16	35
OTOVELL	0	1	0	1
OTOVELLE	0	1	0	1
OTOVET	0	0	3	3
OTOVIL	0	0	2	2
OTOVOL	0	0	1	1
OTSVEL	0	0	1	1
OTUVAIL	0	1	0	1
QTOVEL	2	0	0	2

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

No.	**Proposed name: Otovel** **Established name:** (ciprofloxacin and fluocinolone acetonide) **Dosage form:** Otic Solution **Strength(s):** 0.3% and 0.025% **Usual Dose:** instilled 0.25 ml (one vial) into the affected ear canal twice daily for 7 days.	**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.	Otovel		*Subject of this review.*

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.	Actonel	64
2.	Akovaz*** (Phonetic score is 70)	51
3.	(b) (4)***	50
4.	(b) (4)***	50
5.	Aurovela***	50
6.	Eutonyl (Phenotic score is 77)	65
7.	Oestrogel	51
8.	Onmel	62
9.	Onxol	56
10.	Opticyl	58
11.	Optivar	52
12.	Orajel	55
13.	Oreticyl 50	52
14.	Provil (phenotic score is 71)	64
15.	Oruvail	56
16.	Otezla	60
17.	Cerovel	57
18.	Ovral	56
19.	Ovral-28	56
20.	Orgafol	50
21.	Savella	53
22.	Sumavel	54
23.	Toviaz	54

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: Otovel** **Established name:** (ciprofloxacin and fluocinolone acetonide) **Dosage form:** Otic Solution **Strength(s):** 0.3% and 0.025% **Usual Dose:** instilled 0.25 ml (one vial) into the affected ear canal twice daily for 7 days.	**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.	Motofen	52	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences The first and third syllables of this name pair sound different.
2.	Ocu-Sul	62	The prefixes of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different.
3.	Ocu-Sul 10	62	The prefixes of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different.

No.	**Proposed name: Otovel** **Established name:** (ciprofloxacin and fluocinolone acetonide) **Dosage form:** Otic Solution **Strength(s):** 0.3% and 0.025% **Usual Dose:** instilled 0.25 ml (one vial) into the affected ear canal twice daily for 7 days.	**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**
4.	Ocu-Sul 15	62	The prefixes of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different.
5.	Ocu-Sul 30	62	The prefixes of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different.
6.	Ocu-Trol	52	The prefixes and infixes of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different.
7.	Oreticyl	52	The prefixes, infixes and suffixes of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different. Oreticyl has an extra syllable.

No.	**Proposed name: Otovel** **Established name:** (ciprofloxacin and fluocinolone acetonide) **Dosage form:** Otic Solution **Strength(s):** 0.3% and 0.025% **Usual Dose:** instilled 0.25 ml (one vial) into the affected ear canal twice daily for 7 days.	**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.	Oreticyl 25	52	The prefixes, infixes and suffixes of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different. Oreticyl has an extra syllable.
9.	Oscal 500	52	The prefixes and infixes of this name pair have sufficient orthographic differences The second syllables of this name pair sound different. Otovel name contains an extra syllable.
10.	Otic Care	50	The infixes and suffixes of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different.
11.	Otimar	54	The suffixes of this name pair have sufficient orthographic differences The third syllables of this name pair sound different.

No.	**Proposed name: Otovel** **Established name:** (ciprofloxacin and fluocinolone acetonide) **Dosage form:** Otic Solution **Strength(s):** 0.3% and 0.025% **Usual Dose:** instilled 0.25 ml (one vial) into the affected ear canal twice daily for 7 days.	**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**
12.	Oti-Sone	52	The suffixes of this name pair have sufficient orthographic differences The third syllables of this name pair sound different.
13.	Otobione	51	The suffixes of this name pair have sufficient orthographic differences The third syllables of this name pair sound different. Otobione name contains an extra syllable.
14.	Oto-End	50	The suffixes of this name pair have sufficient orthographic differences The third syllables of this name pair sound different.
15.	Otosol Hc	58	The suffixes of this name pair have sufficient orthographic differences The third syllables of this name pair sound different. Otosol Hc name contains a modifier which may provide orthographic and phonetic difference if included.

No.	**Proposed name: Otovel** **Established name:** (ciprofloxacin and fluocinolone acetonide) **Dosage form:** Otic Solution **Strength(s):** 0.3% and 0.025% **Usual Dose:** instilled 0.25 ml (one vial) into the affected ear canal twice daily for 7 days.	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
16.	Ovidrel	57	The prefixes and infixes of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different.

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

No.	Name	POCA Score (%)
1.	Ativan	46
2.	Ocella	46
3.	Ofloxacin	23
4.	Ovastat	31

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.	Croton Oil	50	Product is not a drug. It is oil used in chemical peels.
2.	Epodyl (Phonetic score is 75)	57	International product marketed in UK, Netherland, Austria.
3.	(b)(4) ***(Phonetic score is 77)	62	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
4.	(b)(4) ***	54	Proposed proprietary name found unacceptable by DMEPA (OSE# (b) (4)). IND (b) (4) is withdrawn as of 9/8/2011.
5.	Hypnovel	54	International product marketed in France, Autralia, Ireland, New Zealand and UK.
6.	Ketovail	60	International product marketed in UK.
7.	Level	54	International product marketed in Brazil.
8.	Nuvel	61	Product is not a drug. It is name of a company that makes skin care products.
9.	Omni Gel	50	Product is not a drug. It is brand name for company that makes several products.
10.	Optil	62	International product marketed in the United Kingdom.
11.	Oti-Med	57	Product withdrawn from the market due to safety concerns.
12.	Oto Care	58	Product withdrawn from the market due to safety concerns.
13.	Oto-End	50	Product withdrawn from the market due to safety concerns.
14.	(b)(4) ***	55	Proposed proprietary name withdrawn by the Applicant. Product approved under new proprietary name, Vogelxo.
15.	Otozin	62	Product withdrawn from the market due to safety concerns.

No.	Name	POCA Score (%)	Failure preventions
16.	Otozone	60	Product withdrawn from the market due to safety concerns.
17.	Oxy Oral	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
18.	(b)(4)***	66	Proposed proprietary name found unacceptable by DMEPA (OSE# (b) (4) and request for proprietary name withdrawn.
19.	(b)(4)***	66	Proposed proprietary name found unacceptable by DMEPA (OSE# (b) (4)) and request for proprietary name withdrawn.
20.	(b)(4)***	66	Proposed proprietary name found unacceptable by DMEPA (OSE# (b) (4) and request for proprietary name withdrawn.
21.	(b)(4)***	66	Proposed proprietary name found unacceptable by DMEPA (OSE# (b) (4)) and request for proprietary name withdrawn.
22.	Photocil	66	Name identified in POCA in RxNorm. Unable to find product characteristics in internal databases and commonly used drug databases.
23.	Osthol	50	Product is not a drug. It is a coumarin compound isolated from Cnidium monnieri, Angelica pubescens, and A. archangelica.

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

No.	Name	POCA Score (%)
1.	Lotrel	64
2.	Beta-Val	63
3.	Proval #3	63
4.	Cytomel	62
5.	Dioval 40	62
6.	Duo-Vil	62
7.	Motazol	60
8.	Zidoval	60
9.	Butibel	59
10.	Catosal	58
11.	Docusil	58
12.	Evorel 100	58
13.	Evorel 25	58
14.	Evorel 50	58
15.	Evorel 75	58
16.	Isosol	58
17.	Mitosol	58
18.	Norval	58
19.	T/Gel	58
20.	Tisseel	58
21.	(b)(4)***	58
22.	Torisel	58
23.	Totarol	58
24.	Tri-Zel	58
25.	Advil	57
26.	Imotil	57
27.	Monojel	57
28.	Ketonal	56
29.	(b)(4)***	56

No.	Name	POCA Score (%)
30.	Mucosil-10	56
31.	Mucosil-20	56
32.	(b)(4)***	56
33.	Sosol	56
34.	Steviol	56
35.	Terrell	56
36.	Trosyl	56
37.	Tusal	56
38.	(b)(4)***	55
39.	Dovaril	55
40.	(b)(4) **	55
41.	Mozobil	55
42.	Tavegil	55
43.	Triavil	55
44.	Triavil 2-10	55
45.	Triavil 2-25	55
46.	Triavil 4-10	55
47.	Triavil 4-25	55
48.	Triavil 4-50	55
49.	1-Octanol	54
50.	2-Octanol	54
51.	Aogel	54
52.	Axotal	54
53.	(b)(4)***	54
54.	Cobal	54
55.	Cobal-1000	54
56.	D-Val	54
57.	Entrocel	54
58.	Epitol	54
59.	Glo-Sel	54

No.	Name	POCA Score (%)
60.	Lo-Trol	54
61.	Novarel	54
62.	Propel	54
63.	(b)(4) **	54
64.	Sotalol	54
65.	Tachosil	54
66.	Toprol	54
67.	Totamol	54
68.	Vetoryl	54
69.	Xodol	54
70.	Acnomel	53
71.	Acuvail	53
72.	Doral	53
73.	Gormel	53
74.	Gormel 10	53
75.	(b)(4) **	53
76.	Pseudoval	53
77.	Tolazil	53
78.	Apoquel	52
79.	Cologel	52
80.	Corzall	52
81.	Doxal	52
82.	Doxil	52
83.	Edetol	52
84.	Elavil	52
85.	Excel	52
86.	Lomotil	52
87.	Micotil	52
88.	Novasal	52
89.	Phenobel	52

No.	Name	POCA Score (%)
90.	Projel-20	52
91.	Prosol	52
92.	Rauval	52
93.	Stoxil	52
94.	Teril	52
95.	Testopel	52
96.	Urodol	52
97.	Ustell	52
98.	Vi-Twel	52
99.	Agoral	51
100.	Atopalm	51
101.	Docusol	51
102.	Lo/Ovral	51
103.	Lo/Ovral-28	51
104.	Nortrel	51
105.	Nortrel 0.5/35-21	51
106.	Nortrel 0.5/35-28	51
107.	Nortrel 1/35-21	51
108.	Nortrel 1/35-28	51
109.	Nortrel 7/7/7	51
110.	Vitazol	51
111.	Antizol	50
112.	Bactocill	50
113.	Citrucel	50
114.	Dicel	50
115.	Docal	50
116.	(b)(4) **	50
117.	(b)(4) **	50
118.	Exsel	50
119.	Isollyl	50

No.	Name	POCA Score (%)
120.	Ketozole	50
121.	Mio-Rel	50
122.	Monocal	50
123.	Murocel	50
124.	Norzol	50
125.	Propofol	50
126.	Purell	50
127.	Soprodal	50
128.	Tall Oil	50
129.	Taxol	50
130.	Toradol	50
131.	Vosol	50
132.	(b)(4)***	50

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/s/

SEVAN H KOLEJIAN
03/31/2016

BRENDA V BORDERS-HEMPHILL
03/31/2016

PROPRIETARY NAME REVIEW

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

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Date of This Review:	December 28, 2015
Application Type and Number:	NDA 208251
Product Name and Strength:	(b)(4) (ciprofloxacin and fluocinolone acetonide) Otic Solution
Total Product Strength:	0.3% / 0.025%
Product Type:	Multi ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Premier Research (U.S. Agent for SALVAT)
Panorama #:	2015- 1763566
DMEPA Primary Reviewer:	Sevan Kolejian, Pharm. D.
DMEPA Team Leader:	Vicky Borders-Hemphill, PharmD
DMEPA Associate Director:	Irene Z. Chan, PharmD, BCPS
DMEPA Director:	Todd Bridges, RPh.

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/s/

SEVAN H KOLEJIAN
12/28/2015

BRENDA V BORDERS-HEMPHILL
12/28/2015

IRENE Z CHAN
12/28/2015

IRENE Z CHAN on behalf of TODD D BRIDGES
12/28/2015