

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205474Orig1s000

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:	November 12, 2014
Application Type and Number:	NDA 205474
Product Name and Strength:	Obredon (Hydrocodone Bitartrate and Guaifenesin) Oral Solution, 2.5 mg/200 mg per 5 mL
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sovereign Pharmaceuticals, LLC
Submission Date:	October 1, 2014 and October 24, 2014
Panorama #:	2014-40703
DMEPA Primary Reviewer:	Lissa C. Owens, PharmD
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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The Sponsor previously submitted the proposed name, (b) (4) on January 14, 2014. The name was found unacceptable by DMEPA (OSE RCM 2014-16812 dated April 6, 2014) due to potential confusion between other (b) (4) products containing different active ingredients and due to the misleading modifier. At that time we informed the Sponsor that their potential secondary name ((b) (4)) would most likely be found unacceptable for the aforementioned safety reasons.

On, July 18, 2014 the Sponsor submitted the proposed name, (b) (4). This name was found unacceptable by Office of Promotional Drug Products (OPDP) in OSE RCM 2014-25902 dated August 28, 2014.

On October 1, 2014 the Sponsor submitted the proposed name (b) (4). This name was found unacceptable due to the presence of a United States Adopted Names (USAN) stem (b) (4). The alternate name, (b) (4) also was unacceptable due to orthographic similarity to the marketed product, (b) (4). This information was relayed to the Sponsor via teleconference on October 24, 2014. The Applicant subsequently submitted the name Obredon replacing (b) (4) to address the USAN stem concern.

1.2 PRODUCT INFORMATION

The following product information is provided in the October 24, 2014 proprietary name submission.

- Intended Pronunciation: ɔ̄'-br[oe]-don
- Active Ingredient: Hydrocodone Bitartrate and Guaifenesin
- Indication of Use: Symptomatic relief of cough and to loosen mucus associated with the common cold
- Route of Administration: Oral
- Dosage Form: Oral Solution
- Strength: 2.5 mg/200 mg per 5 mL
- Dose and Frequency: 10 mL every 4 to 6 hours
- How Supplied: White HDPE bottles of 16 fl. oz. and 4 fl. oz.
- Storage: 20° to 25°C (68° to 77°F)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name does not misbrand the proposed product. DMEPA and the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) 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 name¹.

2.2.2 *Components of the Proposed Proprietary Name*

The Applicant did not provide a derivation or intended meaning for the proposed name, Obredon 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*

The FDA simulation study was conducted using the proposed name, (b)(4). Although the applicant changed (b)(4) to Obredon) in the name, the study was not repeated as we did not anticipate any new findings/outcome of the study with the (b)(4) name. 86 practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Fifty-two participants (Inpatient: n=28 Outpatient: n=24) interpreted the name as (b)(4). Six participants (Voice: n=6) interpreted the name as (b)(4), Four participants (Voice: n=5) as (b)(4). Appendix B contains the results from the verbal and written prescription studies.

2.2.4 *Comments from Other Review Disciplines at Initial Review*

In response to the OSE, October 10, 2014 e-mail, the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

¹USAN stem search conducted on November 3, 2014.

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 $\geq 50\%$ retrieved from our POCA search² organized as highly similar, moderately similar or low similarity for further evaluation. Although the applicant changed (b) (4) to Obredon) in the name, the POCA search was not repeated as we did not anticipate any new findings/outcome of the search (b) (4) in the name.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	3
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	299
Low similarity name pair: combined match percentage score $\leq 49\%$	0

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

Our analysis of the 302 names contained in Table 1 determined that none of the names will 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 Pulmonary, Allergy, and Rheumatology Products (DPAAP) via e-mail on November 5, 2014. At that time we also requested additional information or concerns that could inform our review. DPAAP did not respond with additional concerns with the proposed proprietary name, Obredon.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Nichelle Rashid, OSE project manager, at 301-796-3904.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your October 24, 2014 submission are altered, the name must be resubmitted for review.

² POCA search conducted on September 8, 2014.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present.

Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNCE. OPDP or DNCE 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 DNCE provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.³

³ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/about/MedErrors.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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 49\%$.

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 $\geq 70\%$).

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 50\%$ to $\leq 69\%$).

<p>Step 1</p>	<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
<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 <u>with</u> 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? <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 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 $\leq 49\%$).

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. (b) (4) **Study (Conducted on October 10, 2014)**

Handwritten Requisition Medication Order	Verbal Prescription
<u>Medication Order:</u> (b) (4)	(b) (4) 4 oz. 1 teaspoonful every 4 hours
<u>Outpatient Prescription:</u> (b) (4)	

259 People Received Study
86 People Responded

Study Name: (b) (4)

	Total	26	28	32	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL	
AUBREDIN	0	1	0	1	
OBEEDEN	0	1	0	1	
OBREADEN	0	2	0	2	
OBREDA	0	1	0	1	
(b) (4)	24	0	28	52	
(b) (4) 4OZ	1	0	0	1	
OBREDEN	0	6	0	6	
OBREDIEN	0	1	0	1	
OBREDIN	0	2	0	2	
OBREDION	0	1	0	1	
OBREDON	1	0	2	3	
OBREEDAN	0	1	0	1	
OBREEDEN	0	4	0	4	
OBREEDIN	0	2	0	2	

OBRENDAN	0	0	1	1
OBRIDEN	0	1	0	1
OBRIEDEN	0	4	0	4
OPRADERM?	0	1	0	1
OSREDAN	0	0	1	1

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

No.	Proposed name: Obredon Strength(s): 2.5 mg/200 mg per 5 mL Usual Dose: 10 mL every 4 to 6 hours	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion
1.	(b) (4)	94%	Previous name for this NDA that has been withdrawn, new proposed name is Obredon***
2.	(b) (4) ***	81%	Product denied due to USAN Stem. New name submitted is (b) (4) ***
3.	(b) (4) ***	71%	The first letter 'O' versus 'B' make the name pair appear differently when scripted. The first and second syllables sound different

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

No.	Proposed Name	POCA Score (%)
1.	Predone	64
2.	Ubretid	64
3.	Oradent	62
4.	Operidine	59
5.	Ocu-Pred-A	58
6.	Ovaban	58
7.	Orbenin	57
8.	Ocusan	54

9.	Oprisine	54
10.	Octreoscan	54
11.	Brethine	53
12.	Omnipen	53
13.	Omnipen-N	53
14.	Opustan	53
15.	Ovadine	53
16.	Oprelvekin	52
17.	Oxilan	52
18.	Orabid	52
19.	Oxilan-300	52
20.	Oxilan-350	52
21.	Oradexon	52
22.	Oxeladin	52
23.	Predef	52
24.	Predfoam	52
25.	Orazinc 220	51
26.	Orazinc 110	51
27.	Ornacyn	51
28.	Threda	51
29.	Orasone	50
30.	Tobramycin	50
31.	Pred-G	50
32.	Nobrium	50

33.	Pro red AC	50
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Appendix E: Moderately Similar Names (e.g., combined POCA score is $\geq 50\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Obredon Strength(s): 2.5 mg/200 mg per 5 mL Usual Dose: 10 mL every 4 to 6 hours	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.	Orfadin	62	The infix of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different
2.	Orgadin	62	The prefix and infix of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different
3.	Obestin-30	60	The infix and suffix of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
4.	Orbivan	60	The prefix and suffix of this name pair have sufficient orthographic differences The first and third syllables of this name pair sound different.
5.	Obephen	60	The infix of this name pair have sufficient orthographic differences The second syllables of this name pair sound different.
6.	Ibren	58	The prefix of this name pair has sufficient orthographic differences. The proposed name contains an extra syllable
7.	Abreva	58	The suffix of this name pair has sufficient orthographic differences. The first and third syllables of this name pair sound different.
8.	Tobralcon	56	The prefix and suffix of this name pair have sufficient orthographic differences The first and third syllables of this name pair sound

			different
9.	Obezine	56	The suffix of this name pair have sufficient orthographic differences The third syllables of this name pair sound different.
10.	Orvaten	56	The prefix and infix of this name pair has sufficient orthographic differences. The first and second syllables of this name pair sound different.
11.	Brevicon	56	The infix and suffix of this name pair has sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
12.	Orapred	54	The infix and suffix of this name pair has sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
13.	Tobrex	54	The prefix of this name pair has sufficient orthographic differences. The proposed name contains an extra syllable
14.	Tobradex	53	The prefix this name pair have sufficient orthographic differences The first and third syllables of this name pair sound different.
15.	Predair	53	The prefix of this name pair have sufficient orthographic differences The proposed name contains an extra syllable.
16.	Predalone 50	52	The infix and suffix of this name pair have sufficient orthographic differences The first, second, and third syllable of this name pair sound different
17.	Ocu-Pred	51	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
18.	Organ-1 NR	50	The infix and suffix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sound

			different.
19.	Breonesin	50	The infix and suffix of this name pair have sufficient orthographic differences Breonesin contains an extra syllable
20.	Predator	50	The infix and suffix of this name pair has sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.

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

No.	Name	POCA Score (%)
1.	n/a	

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
1.	Otrivine	67	Product discontinued. There are no generics available
2.	Otrivin	67	Product discontinued. There are no generics available
3.	Oreton	64	Product discontinued. There are no generics
4.	(b) (4)***	64	Name withdrawn and application received a CR
5.	Uridon	60	Product discontinued. There are no generics available
6.	Miradon	59	Product discontinued. There are no generics available

7.	Oat Bran	58	Product discontinued. There are no generics available
8.	Predate-50	56	Product discontinued. There are no generics available
9.	(b) (4) ***	56	Named denied and withdrawn.
10.	Pipobroman	55	Product discontinued. There are no generics available
11.	(b) (4) ***	54	Name withdrawn
12.	(b) (4) ***	54	Name denied. New name submitted however product received a CR
13.	Mooredec	54	Product discontinued. There are no generics available
14.	Orgaran	54	Product discontinued. There are no generics available
15.	Otocidin	54	Product discontinued. There are no generics available
16.	Tobrasone	54	Product discontinued. There are no generics available
17.	Ceradon	54	Product discontinued. There are no generics available
18.	(b) (4) ***	53	Name denied. New name has not been submitted
19.	Ovrette	52	Product discontinued. There are no generics available

			available
20.	D.C. red No. 36	52	Not a medicinal product
21.	D&C red No. 34	52	Not a medicinal product
22.	D.C. red No. 33	52	Not a medicinal product
23.	D&C red no. 30	52	Not a medicinal product
24.	D&C red NO. 28	52	Not a medicinal product
25.	D & C red No. 27	52	Not a medicinal product
26.	D&C red NO. 21	52	Not a medicinal product
27.	D&C red NO. 7	52	Not a medicinal product
28.	D&C red NO. 6	52	Not a medicinal product
29.	Orazinc	51	Product discontinued. There are no generics available
30.	Ordrine	51	Product discontinued. There are no generics available
31.	Mogadon	50	Product not available in the United States per F&C. No dosing information found

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

No.	Name	POCA
1.	B-12 Resin	67
2.	Doredin	66
3.	Mobidin	66
4.	Brom Tann	64
5.	Barogan	62

6.	Torecan	62
7.	Treagan	62
8.	Triban	62
9.	Tritan	62
10.	Prandin	61
11.	Brovana	60
12.	Buproban	60
13.	Dristan	60
14.	Duratan	60
15.	Iduridin	60
16.	Precian	60
17.	Pre-Pen	60
18.	Progan	60
19.	Re Tann	60
20.	Tridane	60
21.	Xuriden	60
22.	Bromatan	59
23.	Repan	59
24.	Zopressin	59
25.	Crotan	58
26.	Drolban	58
27.	Procan	58
28.	Prodrin	58

29.	Propan	58
30.	Tremin	58
31.	Tretten	58
32.	Trovan	58
33.	Bran	57
34.	Brufen	57
35.	Eprident	57
36.	Verelan	57
37.	Berman	56
38.	Biperiden	56
39.	Endodan	56
40.	Eraldin	56
41.	Froben	56
42.	Ibrin	56
43.	Iotrolan	56
44.	Jeridin	56
45.	Metrodin	56
46.	Mobilan	56
47.	Naprelan	56
48.	Neo-Fradin	56
49.	Percodan	56
50.	Perestan	56
51.	Preludan	56

52.	Puregon	56
53.	Reglan	56
54.	Rosadan	56
55.	Triotann	56
56.	Volraman	56
57.	Atopen	55
58.	Brofed	55
59.	Doxidan	55
60.	Lotrimin	55
61.	Refludan	55
62.	Aprodine	54
63.	Atridine	54
64.	Briellyn	54
65.	Clodan	54
66.	Cortan	54
67.	Diprivan	54
68.	Eperzan	54
69.	Garetain	54
70.	Hetrazan	54
71.	Io-Blend	54
72.	Kerydin	54
73.	Lodrane	54
74.	Lodrane 24	54

75.	Mirbetan	54
76.	Nitrotan	54
77.	Presgen	54
78.	Probalan	54
79.	Ridramin	54
80.	Triveen	54
81.	Uridine	54
82.	Anergan	53
83.	Anergan 50	53
84.	Bromfed	53
85.	Bromine	53
86.	Etrafon	53
87.	Etrafon 2-10	53
88.	Panretin	53
89.	Pregard	53
90.	Ukidan	53
91.	Veregen	53
92.	1,4-Sorbitan	52
93.	Abraxan	52
94.	Adrenalin	52
95.	Almodan	52
96.	Atrogen	52
97.	Balagan	52

98.	Banan	52
99.	Beldin	52
100.	Ben Tann	52
101.	Betagan	52
102.	Betatan	52
103.	Bosentan	52
104.	Bricanyl	52
105.	Bromanyl	52
106.	Bromaphen	52
107.	Bronitin	52
108.	Combigan	52
109.	Compreon	52
110.	Cordran	52
111.	Dermosedan	52
112.	Dormosedan	52
113.	Duradrin	52
114.	Eradacin	52
115.	Imbrilon	52
116.	Lidodan	52
117.	Losartan	52
118.	Metreton	52
119.	Moban	52
120.	Modrenal	52

121.	Prefrin	52
122.	Premarin	52
123.	Priften	52
124.	Proben-C	52
125.	Profen	52
126.	Robafen	52
127.	Sarenin	52
128.	Serutan	52
129.	Soprodal	52
130.	Sorbitan	52
131.	Tedrigen	52
132.	Trimand	52
133.	Uretron	52
134.	Uritin	52
135.	Virgan	52
136.	Zartan	52
137.	Arestin	51
138.	Avlotran	51
139.	Bepadin	51
140.	Brivudine	51
141.	Fibro-vein	51
142.	Hirudin	51
143.	Med-I-San	51

144.	My-O-Den	51
145.	Neugranin	51
146.	Pre Sed	51
147.	Procapan	51
148.	Ry-Tann	51
149.	Zofran	51
150.	Abatren	50
151.	Adagen	50
152.	Arranon	50
153.	Asbron	50
154.	Atralin	50
155.	Auralgan	50
156.	Bactroban	50
157.	Barophen	50
158.	Biogen	50
159.	Brolene	50
160.	Bromapp	50
161.	Bromday	50
162.	Bromdec	50
163.	Ceresin	50
164.	Cordran-N	50
165.	Daricon	50
166.	Ditropan	50

167.	Dromoran	50
168.	Freezone	50
169.	Hemoban	50
170.	Ibrance	50
171.	Ketodan	50
172.	Ladropen	50
173.	Lutrelin	50
174.	Brolene	50
175.	lypressin	50
176.	Moditen	50
177.	Motrin	50
178.	Motrin IB	50
179.	Myorisan	50
180.	Paroven	50
181.	Prenbritin	50
182.	Piriton	50
183.	Poly Tan	50
184.	Polytan	50
185.	Prehone	50
186.	Pridinol	50
187.	Pripsen	50
188.	Program	50
189.	Pro-Med	50

190.	Propane	50
191.	Prosed	50
192.	Pyril Tann-12	50
193.	Radent	50
194.	Rregroton	50
195.	Remedy 4-in-1	50
196.	Renamin	50
197.	Renamin 6.5	50
198.	Retaane	50
199.	Rifadin	50
200.	Roclatan	50
201.	Secretin	50
202.	Spritam	50
203.	Supprelin	50
204.	Tadenan	50
205.	Taractan	50
206.	Rifadin	50
207.	Travatan	50
208.	Triacin	50
209.	Tridione	50
210.	Tridrane	50
211.	Ureacin-10	50
212.	Ureacin-20	50

213.	Urimin	50
214.	Vazotan	50
215.	Zirgan	50

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/s/

LISSA C OWENS
11/12/2014

KENDRA C WORTHY
11/12/2014

LUBNA A MERCHANT
11/12/2014

PROPRIETARY NAME REVIEW

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

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Date of This Review:	August 28, 2014
Application Type and Number:	NDA 205 ^{(b) (4)}
Product Name and Strength:	^{(b) (4)} (guaifenesin and hydrocodone bitartate) Solution 200 mg/2.5 mg per 5 mL
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sovereign Pharmaceuticals, LLC
Submission Date:	July 18, 2014
Panorama #:	2014-205474
DMEPA Primary Reviewer:	Teresa McMillan, PharmD
DMEPA Associate Director:	Lubna Merchant, PharmD, MS

1 INTRODUCTION

This review evaluates the proposed proprietary name (b) (4) for NDA 205 (b) (4). The proposed proprietary name was submitted by Sovereign Pharmaceuticals, LLC for evaluation on July 18, 2014. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 PRODUCT INFORMATION

- Active Ingredients: guaifenesin and hydrocodone bitartate
- Indication of Use: (b) (4)
- Route of Administration: Oral
- Dosage Form: Solution
- Strength: 200 mg/2.5 mg per 5 mL
- Dose and Frequency:

Adult (b) (4)

- How Supplied: Clear raspberry flavored liquid available in white HDPE bottles of 16 fl oz (473 mL) and 4 fl oz (118 mL)
- Storage: Store at 20-25°C (68-77°F)

2 DISCUSSION

(b) (4)

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TERESA S MCMILLAN
08/28/2014

LUBNA A MERCHANT
08/28/2014

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review

Date: April 6, 2014

Reviewer: Lissa C. Owens, PharmD
Division of Medication Error Prevention and Analysis

Associate Director: Lubna Merchant, M.S., PharmD
Division of Medication Error Prevention and Analysis

Acting Division Director: Kellie Taylor, PharmD, MPH
Division of Medication Error Prevention and Analysis

Drug Name and Strength: (b) (4) (Guaifenesin and Hydrocodone Bitartrate)
Oral Solution, 2.5 mg/200 mg

Application Type/Number: NDA 205474

Applicant/Sponsor: Sovereign Pharmaceuticals, LLC

OSE RCM #: 2014-16812

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1 INTRODUCTION

This review evaluates the proposed proprietary name, [REDACTED] ^{(b) (4)}, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 PRODUCT INFORMATION

The following product information is provided in the January 14, 2014 proprietary name submission.

- Active Ingredient: Guaifenesin and Hydrocodone Bitartrate
- Indication of Use: [REDACTED] ^{(b) (4)}
- Route of Administration: Oral
- Dosage Form: Oral Solution
- Strength: 200 mg/2.5 mg
- Dose and Frequency: [REDACTED] ^{(b) (4)}
- How Supplied: Clear raspberry flavored liquid in white HDPE bottles of 16 ounces and 4 ounces
- Storage: 20°C to 25°C (68°F to 77°F)

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Pulmonary, Allergy, and Rheumatology Products concurred with the findings of OPDP's promotional 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*

The January 25, 2014 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

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