CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206756Orig1s000

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:	August 29, 2014
Application Type and Number:	NDA 206756
Product Name and Strength:	Stiolto Respimat (Tiotropium Bromide and Olodaterol) Inhalation Spray, 2.5 mcg/2.5 mcg per inhalation
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Boehringer Ingelheim Pharmaceuticals, Inc.
Submission Date:	June 13, 2014
Panorama #:	2014-25589
DMEPA Primary Reviewer:	Lissa C. Owens, PharmD
DMEPA Associate Director:	Lubna Merchant, M.S., PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Stiolto Respimat, 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. The Applicant did not submit an external name study, for this product.

1.1 REGULATORY HISTORY

The applicant previously submitted the proposed proprietary name, Stiolto Respimat on July 16, 2013 under the IND. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Stiolto Respimat, conditionally acceptable in OSE Review #2013-1684, dated December 9, 2013.

1.2 PRODUCT INFORMATION

The following product information is provided in the June 13, 2014 proprietary name submission.

- Intended Pronunciation: stē-ŌL-tō
- Active Ingredient: Tiotropium Bromide and Olodaterol
- Indication of Use: Maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema
- Route of Administration: Oral
- Dosage Form: Oral Inhalation
- Strength: 2.5 mcg/2.5 mcg
- Dose and Frequency: Two actuations once daily
- How Supplied: Labeled carton containing one Respimat cartridge and one Stiolto inhaler
- Storage: 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°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 (DPARP) 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

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Stiolto Respimat in their submission. The proprietary name is comprised of two words, the root name 'Stiolto' and the modifier 'Respimat'. The root name and the modifier do not contain any components (i.e., route of administration, numbers, etc.) that are misleading or can contribute to medication errors.

Our evaluation of the modifier is discussed in Section 2.2.8.

2.2.3 Medication Error Data Selection of Cases

Since the Respimat device is currently marketed (Combivent Respimat and Striverdi Respimat), we searched the FDA Adverse Event Reporting System (FAERS) database to identify medication errors involving 'Respimat' which would be relevant for this review. The August 19, 2014 search of the FDA Adverse Event Reporting System (FAERS) database used the following search terms: trade name: "Combivent Respimat" and "Striverdi Respimat", Medication Errors (HLGT), Product Packaging Issues (HLT), Product Label Issues (HLT), Product Quality Issues (NEC) (HLT).

There were no reports of name confusion retrieved from this search.

2.2.4 FDA Name Simulation Studies

100 practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. Forty-eight participants (outpatient: n= 29, voice: n=1, inpatient: n=18) interpreted the name correctly as 'Stiolto Respimat', seven participants (inpatient: n=7) interpreted the name as 'Stiolto Respemat', and four participants (voice: n=4) interpreted the name as 'Stialto Respimat'. Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines at Initial Review

In response to the OSE e –mail on June 26, 2014, 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.

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[1]USAN stem search conducted on August 11, 2014

2.2.6 *Phonetic and Orthographic Computer Analysis (POCA) Search Results*

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

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	82
Low similarity name pair: combined match percentage score ≤49%	0

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

Our analysis of the 83 names contained in Table 1 determined that none of the names will pose a risk for confusion as described in Appendices C through G.

2.2.8 *FMEA of Modifier Respimat*

The Applicant proposes to use the modifier 'Respimat' for this product. The proposed modifier refers to the device that is used with the medication. The Applicant did not provide data to support that the proposed modifier is understood by health care practitioners and patients; however, the naming convention of adding a modifier to represent a specific device has been used before.

The Respimat device used with this product is identical to the Respimat device used with the currently marketed products, Combivent Respimat and Striverdi Respimat. In our search of the FAERS database, we did not identify any cases of name confusion reported with the use of this modifier. Therefore, we believe the modifier Respimat is appropriate for this product as there is precedence for it in the marketplace. Additionally, we do not anticipate any confusion between Combivent Respimat, Striverdi Respimat, and Stiolto Respimat given the root names are different.

We note that modifiers may be omitted. If the modifier, Respimat, is omitted there is no other Stiolto product currently marketed and therefore there will be no product confusion at this time. Additionally, we did not identify any names that can be confused with 'Respimat' during our searches. Therefore, we do not find the modifier, Respimat, misleading or vulnerable to confusion and find it acceptable for this product.

[2] POCA search conducted on July 10, 2014.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) via e-mail on August 13, 2014. At that time we also requested additional information or concerns that could inform our review. DPARP did not forward any additional concerns with the proposed proprietary name, Stiolto Respimat.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

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, Stiolto Respimat, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your June 13, 2014 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.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name.

1. **Promotional Assessment**: For prescription drug products, the promotional review of the proposed name is conducted by OPDP. For over-the-counter (OTC) drug products, the promotional review of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. 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]

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

	Affirmative answers to these questions indicate a potential area of concern.
Y/N	Does the name have obvious Similarities in Spelling and Pronunciation to other Names?
Y/N	Are there Manufacturing Characteristics in the Proprietary Name?
Y/N	Are there Medical and/or Coined Abbreviations in the Proprietary Name?
Y/N	Are there Inert or Inactive Ingredients referenced in the Proprietary Name?
Y/N	Does the Proprietary Name include combinations of Active Ingredients
Y/N	Is there a United States Adopted Name (USAN) Stem in the Proprietary Name?
Y/N	Is this the same Proprietary Name for Products containing Different Active Ingredients?
Y/N	Is this a Proprietary Name of a discontinued product?

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

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. Based on our root cause analysis of post marketing experience errors, we find the expression of strength and dose, which is often located in close proximity to the drug name itself on prescriptions and medication orders, is an important factor in mitigating or potentiating confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion is limited (e.g., route, frequency, dosage form, etc.).

- For highly similar names, there is little that can mitigate a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are likely to be rejected by FDA. (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, 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 (e.g., route, frequency, dosage form, etc.) to mitigate confusion may be limited when the strength or dose overlaps. FDA will review these 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 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 (See Table 5).

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 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 do not share a common strength or dose (see Step 1 of the Moderately Similar Checklist).			
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 have a higher potential for confusion and should be evaluated further (see Step 2). For single strength products, also consider circumstances where the strength may not be expressed. For any combination drug products, 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: o 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. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion between 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 there are data that suggest a name with low similarity might be vulnerable to confusion with your proposed name (for example, misinterpretation of the proposed name as a marketed product 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. Stiolto Respimat Study (Conducted on June 26, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Stiolto Respimat 2 inhalations once daily	Stiolto Respimat #1 UAD
Outpatient Prescription: Stiolto Respimat UAD #1	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

265 People Received Study
100 People Responded

Study Name: Stiolto Respimat

Total	**38**	**28**	**34**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
? RESPIMAT	0	1	0	1
???? RESPIMAT	0	0	1	1
DIALTO RESPIMAT	0	1	0	1
DIULTO RESPIMAT	0	1	0	1
ITIOLTO RESPIMAT	0	0	2	2
ITIOLTOA RESPIMATE	0	0	1	1
NIOLTO RESPIMAT	0	1	0	1
SIALTO RESPIMAT	0	2	0	2
SIELTO RESPIMAT	0	1	0	1
STIALOT RESPIMAT	0	1	0	1
STIALTO RESCUEMAT	0	1	0	1
STIALTO RESP MED	0	1	0	1
STIALTO RESPIMAT	0	4	0	4
STIALTO RESPIMED	0	1	0	1
STIALTO RESPIMET	0	1	0	1
STIALTO RESPIRANT	1	0	0	1
STIOLOTO RESPIMAT	1	0	0	1
STIOLTC RESPIMAT	1	0	0	1
STIOLTE RESPIMAT	1	0	1	2
STIOLTO	2	0	0	2
STIOLTO RESPINAT	0	0	1	1
STIOLTO RESPEMAT	0	0	7	7
STIOLTO RESPIMAT	29	1	18	48
STIOLTO RESPINAT	1	0	0	1
STIOLTO RESPIRANT	0	0	1	1
STIOLTO RESPIRMAT	1	0	0	1
STIOLTO RESPIRNAT	0	0	1	1
STIOTO RESPIMAT	0	0	1	1
STIOTO VESTMAX	0	1	0	1
STOLTC RESPIMAT	1	0	0	1

STRIOLOTO RESTIMAT	0	1	0	1
STYALTO	0	2	0	2
STYALTO RESPIMAT	0	2	0	2
STYOLTO RESPIMAT	0	2	0	2
STYOLTO RESPUMAT	0	1	0	1
STYULTO RESPIMAD	0	1	0	1
VIOLTI	0	1	0	1

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

No.	Proposed name: Stiolto Respimat Strength(s): 2.5 mcg/2.5 mcg Usual Dose: 2 inhalations daily	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Or Failure prevention reasons
1.	Stiolto	100	Name is the subject of this review

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

No.	Name	POCA Score (%)
1.	Stalevo	66
2.	Stalevo 100	66
3.	Stalevo 125	66
4.	Stalevo 150	66
5.	Stalevo 200	66
6.	Stalevo 50	66
7.	Stalevo 75	66
8.	Saleto	60
9.	Saleto-200	60
10.	Saleto-400	60
11.	Saleto-600	60
12.	Saleto-800	60
13.	Stie-Cort	59
14.	Stadol	58
15.	Diocto	56
16.	Stilbetin	54
17.	Prialt	52

18.	Sarisol No. 1	52
19.	Sarisol No. 2	52
20.	Tycolet	52
21.	Cetacort	52
22.	Caltro	50
23.	Diulo	50
24.	Salitop	50
25.	Sotalol	50
26.	Stavzor	50

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

No.	**Proposed name: Stiolto Respimat** **Strength(s):2.5 mcg/2.5 mcg** **Usual Dose:2 inhalations once daily**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Stimate	58	When compared to the root name, the suffixes of this name pair have sufficient orthographic differences When compared to the root name, the proposed name contains an extra syllable
2.	Spacol T/S	58	When compared to the root name, the prefixes and suffixes of this name pair have sufficient orthographic differences Spacol T/S contains an extra syllable
3.	Statrol	54	When compared to the root name, the suffixes of this name pair have sufficient orthographic differences When compared to the root name, the proposed name contains an extra syllable
4.	Striant	54	When compared to the root name, the suffixes of this name pair have sufficient orthographic differences When compared to the root name, the proposed name contains an extra syllable
5.	Physiolite	53	When compared to the root name, the prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences Physiolite contains an extra syllable.
6.	Stribild	52	When compared to the root name, the infixes and suffixes of this name pair have sufficient orthographic differences When compared to the root name, the proposed name contains an extra syllable
7.	Sulten-10	52	When compared to the root name, the infixes and suffixes of this name pair have sufficient orthographic differences When compared to the root name, the first, second, and third syllables sound different.
8.	Xarelto	51	When compared to the root name, the prefixes of this name pair have sufficient orthographic differences When compared to the root name, the first and second syllables sound different

9.	Fiortal	50	When compared to the root name, the prefixes and suffixes of this name pair have sufficient orthographic differences When compared to the root name, the first, second, and third syllables sound different
10.	Istalol	50	When compared to the root name, the prefixes and suffixes of this name pair have sufficient orthographic differences When compared to the root name, the first, second, and third syllables sound different
11.	Strontium	50	When compared to the root name, the infixes and suffixes of this name pair have sufficient orthographic differences When compared to the root name, the first, second, and third syllables sound different
12.	Strontium-89	50	When compared to the root name, the infixes and suffixes of this name pair have sufficient orthographic differences Strontium -89 contains extra syllables
13.	Sulfo-Lo	50	When compared to the root name, the infixes and suffixes of this name pair have sufficient orthographic differences When compared to the root name, the first and second syllables sound different
14.	Tol-Tab	50	When compared to the root name, the prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences When compared to the root name, the proposed name contains an extra syllable

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.	(b) (4) ***	66	Secondary name. Product approved under primary name, 'Xgeva'
2.	(b) (4) ***	62	Name denied by DDMAC and approved as 'Belviq'
3.	S-T Forte	62	Product is discontinued with no generics available
4.	S-T Forte 2	62	Product is discontinued with no generics available

5.	(b) (4) ***	62	Name denied by DDMAC. The applicant then submitted (b) (4) *** which was denied by OPDP (b) (4) (7/29/14). A new name has not been submitted.
6.	Stilnoct	60	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
7.	(b) (4) ***	58	(b) (4) the product was approved under 'Folotyn' in the NDA phase.
8.	(b) (4) ***	58	Secondary name. Approved under the primary name, 'Cuvposa'
9.	Spirono	58	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
10.	(b) (4) ***	57	Name withdrawn by Applicant and approved under 'Stribild'
11.	(b) (4) ***	56	Name denied and approved under 'Bethkis'
12.	Stesolid	56	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
13.	Steviol	56	Product is a compounding powder not available separately. It is listed as 'Steviol Glycosides'
14.	Stimlor	56	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
15.	(b) (4) ***	54	Name withdrawn by Applicant. Currently being evaluated under the name 'Mitigare***'
16.	(b) (4) ***	54	Secondary name to (b) (4) *** which was denied.

			However (b) (4) *** has not been submitted to the Agency
17.	Estriol	54	Bulk Powder used for compounding. Not available separately.
18.	Skim milk	54	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
19.	Stahist	54	Product discontinued with no generics available
20.	Stannate	54	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
21.	Stool-Lax	54	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
22.	Osteolite	53	Product discontinued with no generics available
23.	(b) (4) ***	52	Name denied and approved as 'Marlissa'
24.	Citiolone	52	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
25.	D&C Violet No. 2	52	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
26.	(b) (4) ***	52	Name denied by OPDP and approved as 'Glydo'
27.	Saleto-D	52	Product discontinued with no generics available
28.	Stamoist	52	Product discontinued with no generics available
29.	Stamoist E	52	Product discontinued with no generics available
30.	Star-Otic	52	Product discontinued with no

			generics available
31.	Stilline	52	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
32.	(b) (4)	51	Name denied and approved as 'Binosto'
33.	82 Strontium	50	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
34.	85 Strontium	50	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
35.	Dialyte	50	Product discontinued with no generics available
36.	Pronto	50	Product discontinued with no generics available
37.	Salsalte	50	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
38.	Sea Salt	50	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
39.	Sil Tex	50	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases

40.	Sno Pilo	50	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
41.	Steiro Lotion	50	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
42.	Zimulti***	50	(b) (4) . No activity since 2007.

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/s/

LISSA C OWENS
08/29/2014

LUBNA A MERCHANT
08/29/2014