

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

207930Orig1s000

PROPRIETARY NAME REVIEW(S)

MEMORANDUM

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)

Date of This Memorandum: July 2, 2015
Application Type and Number: NDA 207930
Product Name and Strength: Utibron Neohaler (Indacaterol and Glycopyrrolate) Capsules for Inhalation, 27.5 mcg/15.6 mcg
Product Type: Multi-Ingredient Product
Rx or OTC: Rx
Applicant/Sponsor Name: Novartis Pharmaceuticals
Panorama #: 2015-81167
DMEPA Primary Reviewer: Lissa C. Owens, PharmD
DMEPA Associate Director: Lubna Merchant, PharmD, MS

1 PURPOSE OF MEMO

During clearance of this proprietary name review, it was noted that there was a discrepancy in the June 25, 2015 DMEPA review with the strength of the product. This addendum clarifies the correct strength of the product.

2 CONCLUSIONS

We note that in our original review we listed the strength of the product as 27.5 mcg/12.5 mcg which was the strength proposed under the IND. However, the NDA was submitted with the strength as 27.5 mcg/15.6 mcg. We have re-reviewed the names found in POCA and we maintain our original conclusion listed in the original review.

PROPRIETARY NAME REVIEW

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

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DMEPA Team Leader:	Kendra Worthy, PharmD
DMEPA Associate Director:	Lubna Merchant, PharmD, MS

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3 INTRODUCTION

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

3.1 REGULATORY HISTORY

The proposed proprietary name, (b) (4) was previously reviewed under IND 076377 and found unacceptable due to orthographic and phonetic similarity to the currently marketed product, (b) (4). The Applicant submitted a request for reconsideration of the proposed proprietary name, (b) (4) on December 31, 2014 in which we maintained our objection to the name (b) (4).

Thus, the Applicant submitted the name, Utibron Neohaler, for review on May 1, 2015.

3.2 PRODUCT INFORMATION

The following product information is provided in the May 1, 2015 proprietary name submission.

- Intended Pronunciation: oo-TEE-bron NEE-o-hail-er
- Active Ingredient: Indacaterol and Glycopyrrolate
- Indication of Use: Long-term twice daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema
- Route of Administration: Oral Inhalation
- Dosage Form: Inhalation powder hard capsules for pulmonary administration using a single-dose dry powder inhaler
- Strength: 27.5 mcg/12.5 mcg
- Dose and Frequency: One inhalation twice daily
- How supplied: 10 blister cards, each containing 6 capsules; Neohaler inhaler consists of a cap and a base.
- Storage: Should not be stored above 25°C. Should be stored in the original package to protect from moisture. Must be kept out of the reach and sight of children.

4 RESULTS

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

4.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) concurred with the findings of OPDP's assessment of the proposed name.

4.2 SAFETY ASSESSMENT

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

4.2.1 *United States Adopted Names (USAN) Search*

There is no USAN stem present in the proprietary name¹.

4.2.2 *Components of the Proposed Proprietary Name*

The Applicant indicated in their submission that the name Utibron was (b) (4)

The Applicant also indicated in their submission the proprietary name Neohaler has been assessed as acceptable for the inhaler in conjunction with Arcapta Neohaler (Indacaterol). The same device name has also been provisionally approved for Seebri Neohaler (glycopyrrolate), for which the NDA was also submitted in December 2014 (submitted under NDA 207923). The inhaler provided in the fixed-dose combination drug product Utibron Neohaler is identical to that used in both single-ingredient products Arcapta Neohaler and Seebri Neohaler, except for color and markings.

As stated, 'Neohaler' is used with the currently marketed product, Arcapta Neohaler (Indacaterol inhalation powder). However, we do not anticipate any confusion between Arcapta Neohaler and Utibron Neohaler given the root names are different. The applicant did not provide data to support that the proposed modifier is understood by health care practitioners and patients; however, the naming convention to use a modifier to represent a specific device has been used before (e.g Advair Diskus and Flovent Diskus). The Neohaler device is not available on its own and we do not anticipate that the modifier 'Neohaler' will be written on its own without the root name.

We note that modifiers may sometimes be omitted. If the modifier Neohaler is omitted, there is no other Utibron 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 'Neohaler' during our sound alike and look alike searches. Therefore, we do not find the modifier, Neohaler, misleading or vulnerable to confusion and find it acceptable for this product.

¹USAN stem search conducted on May 12, 2015.

4.2.4 *FDA Name Simulation Studies*

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

4.2.5 *Comments from Other Review Disciplines at Initial Review*

In response to the OSE, May 12, 2015 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.

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

Table 1 lists the number of names with the combined orthographic and phonetic score of $\geq 50\%$ retrieved from our POCA search² 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 $\geq 70\%$	5
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	241
Low similarity name pair: combined match percentage score $\leq 49\%$	0

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

Our analysis of the 246 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

4.2.8 *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 June 15, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DPARP on June 22, 2015, they stated no additional concerns with the proposed proprietary name, Utibron Neohaler.

5 CONCLUSIONS

The proposed proprietary name is acceptable.

² POCA search conducted on May 28, 2015.

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

5.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your May 1, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

6 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 $\geq 70\%$).

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 do not share a common strength or dose.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of 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>

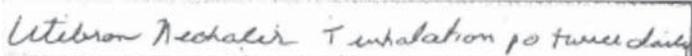
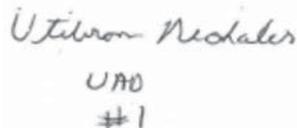
<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> • 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. Utibron Neohaler Study (Conducted on April 21, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
<p>Medication Order:</p>  <p><i>Utibron Neohaler 1 inhalation po twice daily</i></p>	<p>Utibron Neohaler</p> <p>UAD</p> <p>#1</p>
<p>Outpatient Prescription:</p>  <p><i>Utibron Neohaler</i> UAD #1</p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Utibron Neohaler

As of Date 6/3/2015

247 People Received Study
78 People Responded

Study Name: Utibron Neohaler

	Total	31	21	26	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL	
BUTOBAN INHALER	0	1	0	1	
DUDIBRON NEOHALER	0	1	0	1	
EUTABRAUN NEOHALER	0	1	0	1	
LITIBRAM NEOHALER	0	0	1	1	
LITIBRAN NEOHALER	0	0	1	1	
LITIBRON NEHALER	0	0	1	1	
LITIBRON NEOHALER	0	0	2	2	
LITIBRON NEOHALIR	0	0	1	1	
ODABRAN NEOHALOR	0	1	0	1	
OODABRON NEOHALER	0	1	0	1	
OODEBRON NEO-HALER	0	1	0	1	
OOTEBRAUN NEOHALER	0	1	0	1	
OUDOBRAUN INHALER	0	1	0	1	
OUDOBRON NEOHALER	0	1	0	1	
UDABRON NEOHALER	0	2	0	2	
UDEBRAND	0	1	0	1	
UDEBRON NEOHALER	0	2	0	2	
UDIBROM INHALER	0	1	0	1	
UDIBRON NEOHALER	0	1	0	1	
UDOBRON NEOHALER	0	1	0	1	
ULTIBRON NIOHALER	1	0	0	1	
UTABRON NEOHALER	0	1	0	1	
UTABRON NUHALER	0	1	0	1	
UTABROWN NEOHALER	0	1	0	1	
UTIBRAN NEOHALER	0	0	5	5	
UTIBROM NEOHALER	1	0	0	1	
UTIBRON	2	0	0	2	
UTIBRON (CAN'T READ SECOND WORD)	1	0	0	1	
UTIBRON INHALER	4	0	0	4	
UTIBRON NEDALER	1	0	0	1	
UTIBRON NEOHALER	15	1	14	30	
UTIBRON NEOHALIR	0	0	1	1	

UTIBRON NICHALER	1	0	0	1
UTIBRON NIOHALER	1	0	0	1
UTIBRUN NEOHALER	1	0	0	1
UTILRON NEOHALER	1	0	0	1
VTIBRON MEDHALER	1	0	0	1
VTIBRON NEOHALER	1	0	0	1

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

No.	Proposed name: Utibron Neohaler Established name: Indacaterol and Glycopyrrolate Dosage form: Capsules containing dry powder for oral inhalation Strength(s): 27.5 mcg/12.5 mcg Usual Dose: 1 capsule twice daily	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	Utibron***	100	Name is the subject of this review
2.	Quibron	76	Name discontinued under the ANDA. Actual name is Quibron-T and Quibron-T/SR. There is no overlap or numerical similarity in strength, dose and frequency.
3.	Timpron	72	Found in Rx Norm. No information found in common drug references
4.	(b) (4)	72	Name denied based on orthographic and phonetic similarity to (b) (4)
5.	Uni-Tren	72	Found in Rx Norm. No information found in common drug references

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.	Name	POCA Score (%)
1.	Uniferon	67
2.	Dibromm DM	66
3.	Ibren	64
4.	Ibrin	63
5.	Quibron-T	63

6.	Antiben	60
7.	Uni-pro	60
8.	Femiron	58
9.	Lupron	57
10.	Axiron	56
11.	Nitrong	56
12.	Tiopronin	56
13.	Ultraprin	56
14.	Unipen	56
15.	Utimox	56
16.	Utrona-C	56
17.	Zemuron	56
18.	Enduron	55
19.	Decadron	54
20.	(b) (4)	54
21.	Metastron	54
22.	Unipres	54
23.	Utira	54
24.	Vitron-C	54
25.	Didronel	53
26.	Intron A	53
27.	Nu-iron	53
28.	Nu-iron 150	53
29.	Betaseron	52

30.	Boron	52
31.	Ceron	52
32.	Etidronate	52
33.	Folvron	52
34.	Mivacron	52
35.	Phenetron	52
36.	Un-aspirin	52
37.	Encron	51
38.	Ibrance	51
39.	Betaprone	50
40.	Calphron	50
41.	Debrox	50
42.	Estrone	50
43.	Iron	50
44.	Iron 300	50
45.	Mol-iron	50
46.	Quibron T-SR	50
47.	Quibron-T/SR	50
48.	Sylatron	50
49.	Trex brom	50
50.	Unisom	50
51.	Unithroid	50

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.	<p>Proposed name: Utibron Neohaler</p> <p>Established name: Indacaterol and Glycopyrrolate</p> <p>Dosage form: Capsules containing dry powder for oral inhalation</p> <p>Strength(s): 27.5 mcg/12.5 mcg</p> <p>Usual Dose: 1 capsule twice daily</p>	POCA Score (%)	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
1.	Xibrom	64	<p>When compared to the root name, the prefix, infix, and suffix, of this name pair have sufficient orthographic differences.</p> <p>When compared to the modifier, the prefixes of this name pair have sufficient orthographic differences.</p> <p>When compared to the root name, the first and second syllables of this name pair sound different.</p> <p>When compared to the modifier, the first and second syllables of this name pair sound different.</p>
2.	Isochron	56	<p>When compared to the modifier, the infix and suffix of this name pair have sufficient orthographic differences.</p> <p>When compared to the modifier, Redihaler contains an extra syllable.</p>
3.	Mepron	56	<p>When compared to the modifier, the infix and suffix of this name pair have sufficient orthographic differences.</p> <p>When compared to the modifier, Ritalin-SR contains an extra syllable.</p>
4.	Pseubrom	56	<p>When compared to the root name, the prefix, infix, and suffix, of this name pair have sufficient orthographic differences.</p> <p>When compared to the root name, the first and second syllables of this name pair sound different.</p> <p>When compared to the modifier, Redihaler contains an extra</p>

			syllable.
5.	Librium	54	When compared to the root name, the prefix, infix, and suffix have sufficient orthographic differences. When compared to the root name, Carvedilol has extra syllables
6.	Saluron	51	When compared to the root name, the prefix, infix, and suffix, of this name pair have sufficient orthographic differences. When compared to the modifier, the prefixes of this name pair have sufficient orthographic differences. When compared to the root name, Utibron contains an extra syllable. When compared to the modifier, the first and second syllables of this name pair sound different.
7.	Alosetron	50	When compared to the modifier, the infix and suffix of this name pair have sufficient orthographic differences. When compared to the modifier, the second, third, and fourth 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	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.	Simron	68	Product discontinued with no generics available
2.	Dibrom	68	Product discontinued with no generics available

3.	Asbron	67	Product discontinued with no generics available
4.	Accurbron	64	Product discontinued with no generics available
5.	Eutron	64	Product discontinued with no generics available
6.	Uniparin	64	No information found in common drug references
7.	Uretron	64	Product discontinued with no generics available
8.	Butibufen	61	No information found in common drug references
9.	Asbron G	60	Product discontinued with no generics available
10.	ED bron G	60	No information found in common drug references
11.	Equibron G	60	Product discontinued with no generics available
12.	EQUI-bron G	60	No information found in common drug references
13.	Fepron	60	No information found in common drug references
14.	Ukidan	60	No information found in common drug references
15.	Ultrabrom	60	Product discontinued with no generics available
16.	Uniprim	60	Product is only available as a powder for horses.
17.	Actron	59	Product discontinued with no generics available
18.	(b) (4)	59	Name withdrawn by Applicant. Approved under 'Xtandi'
19.	Pacitron	58	No information found in common drug references
20.	Uridon	58	Product discontinued with no generics available

21.	Uticort	58	Product discontinued with no generics available
22.	Danthron	56	Product discontinued with no generics available
23.	Imferon	56	No information found in common drug references
24.	Securon	55	Product discontinued with no generics available
25.	Tibolone	55	No information found in common drug references
26.	Unburn	55	No information found in common drug references
27.	Chibroxin	54	Product discontinued with no generics available
28.	Dibrom SR	54	No information found in common drug references
29.	Disobrom	54	Product discontinued with no generics available
30.	Pancron	54	No information found in common drug references
31.	DURA ron	53	No information found in common drug references
32.	Lentaron	53	No information found in common drug references
33.	Timpron 250 EC	53	No information found in common drug references
34.	Timpron 500 EC	53	No information found in common drug references
35.	Trilitron	53	Product discontinued with no generics available
36.	Actibine	52	Product discontinued with no generics available
37.	Anhydron	52	Product discontinued with no generics available
38.	Betaferon	52	No information found in common drug references
39.	Biostron	52	No information found in

			common drug references
40.	Lufenuron	52	Product is a veterinary powder
41.	UNI bronchial	52	No information found in common drug references
42.	Uni-lan	52	Product discontinued with no generics available
43.	Uni-tann	52	Product discontinued with no generics available
44.	Fipronil	51	No information found in common drug references
45.	Dipyron	50	Product discontinued with no generics available
46.	Genetron 12	50	No information found in common drug references
47.	U-tri-lone	50	No information found in common drug references

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

No.	Name	POCA Score (%)
1.	Abatren	55
2.	Acticon	52
3.	Acuprin 81	60
4.	Addaprin	53
5.	Aleudrin	52
6.	Alidrin	58
7.	Altafrin	54
8.	Amidrine	51
9.	Ampitrin	54
10.	Anefrin	50
11.	Antagon	50
12.	A-phedrin	54

13.	Aspirin	50
14.	Ativan	54
15.	Betadren	58
16.	Bindren	57
17.	Bran	52
18.	Bridion	50
19.	Budeprion	54
20.	Bufferin	51
21.	Butabarb	51
22.	Butamben	56
23.	Butrans	52
24.	Calabren	50
25.	Caprin	52
26.	Citroma	52
27.	Cuprofen	51
28.	Cyrcin	50
29.	Cytadren	58
30.	Differin	52
31.	Diprivan	50
32.	Ditropan	52
33.	Dutoprol	50
34.	Ecotrin	56
35.	Ecpirin	50
36.	Edecrin	52
37.	Emblon	50
38.	Entaprin	58
39.	Epidrin	65
40.	Epifrin	60
41.	Epipram	52
42.	Estybon	57
43.	Eumydrin	60

44.	Fetrin	54
45.	Fibercon	56
46.	Fostimon	52
47.	Fucidin	51
48.	Ibifon 600	58
49.	Ibuprin	62
50.	Ibuprofen	52
51.	Ibuprohm	50
52.	Ic-green	55
53.	Imbrilon	52
54.	Imigran	58
55.	Imuran	50
56.	Innopran	56
57.	Isibloom	55
58.	Isovorin	52
59.	Iver-on	58
60.	Kutapressin	50
61.	Leukeran	52
62.	Lipidro	50
63.	Liquiprin	50
64.	Medipren	54
65.	Mestinon	50
66.	Metandren	50
67.	Midrin	58
68.	Miniprin	52
69.	Minirin	50
70.	Minitran	52
71.	Mitaban	52
72.	Mitran	56
73.	Nuprin	56
74.	Nutropin	50

75.	Oat bran	65
76.	Obredon	54
77.	Octodrine	50
78.	Ocu-phrin	58
79.	Ocu-pred	50
80.	Ocu-trol	50
81.	Opilon	53
82.	Opticrom	58
83.	Optison	57
84.	Oticin	54
85.	Otiprio	56
86.	Oti-sone	52
87.	Otobione	54
88.	Otrivin	52
89.	Pavulon	50
90.	Pentran	54
91.	Photofrin	53
92.	Pileran	52
93.	Piperine	50
94.	Prodrin	51
95.	Rice bran	60
96.	Ridiprin	54
97.	Roxiprin	51
98.	Sebizon	54
99.	Sebulon	53
100.	Septin	53
101.	Sudodrin	55
102.	Sudrine	56
103.	Sultrin	52
104.	Suphedrin	55
105.	Suprane	52

106.	Suprofen	51
107.	Syprine	50
108.	Tabloid	50
109.	Tab-profen	54
110.	Tabradol	50
111.	Tacrine	55
112.	Teebacin	50
113.	Tegison	50
114.	Teldrin	60
115.	Tembrav	51
116.	Terocin	52
117.	Tetracon	54
118.	Tiadilon	53
119.	Ticon	56
120.	Tigan	51
121.	Tilarin	58
122.	Tildren	67
123.	Tin-ben	54
124.	Tiorfan	52
125.	Tobralcon	54
126.	Triaprin	54
127.	Triban	54
128.	Tridrane	53
129.	Tussigon	54
130.	Tymtran	60
131.	Vicoprin	52
132.	Vivarin	52
133.	Vydren	51
134.	Zactran	50
135.	Zetran	54
136.	Zutripro	52

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/s/

LISSA C OWENS
07/06/2015

LUBNA A MERCHANT
07/06/2015

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:	June 25, 2015
Application Type and Number:	NDA 207930
Product Name and Strength:	Utibron Neohaler (Indacaterol and Glycopyrrolate) Capsules for Inhalation, 27.5 mcg/12.5 mcg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Novartis Pharmaceuticals
Panorama #:	2015-81167
DMEPA Primary Reviewer:	Lissa C. Owens, PharmD
DMEPA Team Leader:	Kendra Worthy, PharmD
DMEPA Associate Director:	Lubna Merchant, PharmD, MS

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The proposed proprietary name, (b) (4) was previously reviewed under IND 076377 and found unacceptable due to orthographic and phonetic similarity to the currently marketed product, (b) (4). The Applicant submitted a request for reconsideration of the proposed proprietary name, (b) (4), on December 31, 2014 in which we maintained our objection to the name (b) (4).

Thus, the Applicant submitted the name, Utibron Neohaler, for review on May 1, 2015.

1.2 PRODUCT INFORMATION

The following product information is provided in the May 1, 2015 proprietary name submission.

- Intended Pronunciation: oo-TEE-bron NEE-o-hail-er
- Active Ingredient: Indacaterol and Glycopyrrolate
- Indication of Use: Long-term twice daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema
- Route of Administration: Oral Inhalation
- Dosage Form: Inhalation powder hard capsules for pulmonary administration using a single-dose dry powder inhaler
- Strength: 27.5 mcg/12.5 mcg
- Dose and Frequency: One inhalation twice daily
- How supplied: 10 blister cards, each containing 6 capsules; Neohaler inhaler consists of a cap and a base.
- Storage: Should not be stored above 25°C. Should be stored in the original package to protect from moisture. Must be kept out of the reach and sight of children.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of 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 indicated in their submission that the name Utibron was (b) (4)

The Applicant also indicated in their submission the proprietary name Neohaler has been assessed as acceptable for the inhaler in conjunction with Arcapta Neohaler (Indacaterol). The same device name has also been provisionally approved for Seebri Neohaler (glycopyrrolate), for which the NDA was also submitted in December 2014 (submitted under NDA 207923). The inhaler provided in the fixed-dose combination drug product Utibron Neohaler is identical to that used in both single-ingredient products Arcapta Neohaler and Seebri Neohaler, except for color and markings.

As stated, 'Neohaler' is used with the currently marketed product, Arcapta Neohaler (Indacaterol inhalation powder). However, we do not anticipate any confusion between Arcapta Neohaler and Utibron Neohaler given the root names are different. The applicant did not provide data to support that the proposed modifier is understood by health care practitioners and patients; however, the naming convention to use a modifier to represent a specific device has been used before (e.g Advair Diskus and Flovent Diskus). The Neohaler device is not available on its own and we do not anticipate that the modifier 'Neohaler' will be written on its own without the root name.

We note that modifiers may sometimes be omitted. If the modifier Neohaler is omitted, there is no other Utibron 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 'Neohaler' during our sound alike and look alike searches. Therefore, we do not find the modifier, Neohaler, misleading or vulnerable to confusion and find it acceptable for this product.

¹USAN stem search conducted on May 12, 2015.

2.2.4 *FDA Name Simulation Studies*

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

2.2.5 *Comments from Other Review Disciplines at Initial Review*

In response to the OSE, May 12, 2015 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.

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 $\geq 50\%$ retrieved from our POCA search² 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 $\geq 70\%$	5
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	241
Low similarity name pair: combined match percentage score $\leq 49\%$	0

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

Our analysis of the 246 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.8 *Communication of DMEPA’s Analysis at Midpoint of Review*

DMEPA communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) via e-mail on June 15, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DPARP on June 22, 2015, they stated no additional concerns with the proposed proprietary name, Utibron Neohaler.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

² POCA search conducted on May 28, 2015.

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, Utibron Neohaler, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your May 1, 2015 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 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 $\geq 70\%$).

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 do not share a common strength or dose.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of 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>

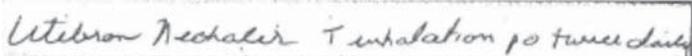
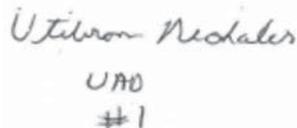
<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> • 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?
--	--

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. Utibron Neohaler Study (Conducted on April 21, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
<p>Medication Order:</p> 	<p>Utibron Neohaler UAD #1</p>
<p>Outpatient Prescription:</p> 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Utibron Neohaler

As of Date 6/3/2015

247 People Received Study
78 People Responded

Study Name: Utibron Neohaler

INTERPRETATION	Total	31	21	26	TOTAL
	OUTPATIENT	VOICE	INPATIENT		
BUTOBAN INHALER	0	1	0		1
DUDIBRON NEOHALER	0	1	0		1
EUTABRAUN NEOHALER	0	1	0		1
LITIBRAM NEOHALER	0	0	1		1
LITIBRAN NEOHALER	0	0	1		1
LITIBRON NEHALER	0	0	1		1
LITIBRON NEOHALER	0	0	2		2
LITIBRON NEOHALIR	0	0	1		1
ODABRAN NEOHALOR	0	1	0		1
OODABRON NEOHALER	0	1	0		1
OODEBRON NEO-HALER	0	1	0		1
OOTEBRAUN NEOHALER	0	1	0		1
OUDOBRAUN INHALER	0	1	0		1
OUDOBRON NEOHALER	0	1	0		1
UDABRON NEOHALER	0	2	0		2
UDEBRAND	0	1	0		1
UDEBRON NEOHALER	0	2	0		2
UDIBROM INHALER	0	1	0		1
UDIBRON NEOHALER	0	1	0		1
UDOBRON NEOHALER	0	1	0		1
ULTIBRON NIOHALER	1	0	0		1
UTABRON NEOHALER	0	1	0		1
UTABRON NUHALER	0	1	0		1
UTABROWN NEOHALER	0	1	0		1
UTIBRAN NEOHALER	0	0	5		5
UTIBROM NEOHALER	1	0	0		1
UTIBRON	2	0	0		2
UTIBRON (CAN'T READ SECOND WORD)	1	0	0		1
UTIBRON INHALER	4	0	0		4
UTIBRON NEDALER	1	0	0		1
UTIBRON NEOHALER	15	1	14		30
UTIBRON NEOHALIR	0	0	1		1

UTIBRON NICHALER	1	0	0	1
UTIBRON NIOHALER	1	0	0	1
UTIBRUN NEOHALER	1	0	0	1
UTILRON NEOHALER	1	0	0	1
VTIBRON MEDHALER	1	0	0	1
VTIBRON NEOHALER	1	0	0	1

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

No.	Proposed name: Utibron Neohaler Established name: Indacaterol and Glycopyrrolate Dosage form: Capsules containing dry powder for oral inhalation Strength(s): 27.5 mcg/12.5 mcg Usual Dose: 1 capsule twice daily	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	Utibron***	100	Name is the subject of this review
2.	Quibron	76	Name discontinued under the ANDA. Actual name is Quibron-T and Quibron-T/SR. There is no overlap or numerical similarity in strength, dose and frequency.
3.	Timpron	72	Found in Rx Norm. No information found in common drug references
4.	(b) (4)	72	Name denied based on orthographic and phonetic similarity to (b) (4)
5.	Uni-Tren	72	Found in Rx Norm. No information found in common drug references

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.	Name	POCA Score (%)
1.	Uniferon	67
2.	Dibromm DM	66
3.	Ibren	64
4.	Ibrin	63
5.	Quibron-T	63

6.	Antiben	60
7.	Uni-pro	60
8.	Femiron	58
9.	Lupron	57
10.	Axiron	56
11.	Nitrong	56
12.	Tiopronin	56
13.	Ultraprin	56
14.	Unipen	56
15.	Utimox	56
16.	Utrona-C	56
17.	Zemuron	56
18.	Enduron	55
19.	Decadron	54
20.	(b) (4)	54
21.	Metastron	54
22.	Unipres	54
23.	Utira	54
24.	Vitron-C	54
25.	Didronel	53
26.	Intron A	53
27.	Nu-iron	53
28.	Nu-iron 150	53
29.	Betaseron	52

30.	Boron	52
31.	Ceron	52
32.	Etidronate	52
33.	Folvron	52
34.	Mivacron	52
35.	Phenetron	52
36.	Un-aspirin	52
37.	Encron	51
38.	Ibrance	51
39.	Betaprone	50
40.	Calphron	50
41.	Debrox	50
42.	Estrone	50
43.	Iron	50
44.	Iron 300	50
45.	Mol-iron	50
46.	Quibron T-SR	50
47.	Quibron-T/SR	50
48.	Sylatron	50
49.	Trex brom	50
50.	Unisom	50
51.	Unithroid	50

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: Utibron Neohaler Established name: Indacaterol and Glycopyrrolate Dosage form: Capsules containing dry powder for oral inhalation Strength(s): 27.5 mcg/12.5 mcg Usual Dose: 1 capsule twice 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.	Xibrom	64	<p>When compared to the root name, the prefix, infix, and suffix, of this name pair have sufficient orthographic differences.</p> <p>When compared to the modifier, the prefixes of this name pair have sufficient orthographic differences.</p> <p>When compared to the root name, the first and second syllables of this name pair sound different.</p> <p>When compared to the modifier, the first and second syllables of this name pair sound different.</p>
2.	Isochron	56	<p>When compared to the modifier, the infix and suffix of this name pair have sufficient orthographic differences.</p> <p>When compared to the modifier, Redihaler contains an extra syllable.</p>
3.	Mepron	56	<p>When compared to the modifier, the infix and suffix of this name pair have sufficient orthographic differences.</p> <p>When compared to the modifier, Ritalin-SR contains an extra syllable.</p>
4.	Pseubrom	56	<p>When compared to the root name, the prefix, infix, and suffix, of this name pair have sufficient orthographic differences.</p> <p>When compared to the root name, the first and second syllables of this name pair sound different.</p> <p>When compared to the modifier, Redihaler contains an extra</p>

			syllable.
5.	Librium	54	When compared to the root name, the prefix, infix, and suffix have sufficient orthographic differences. When compared to the root name, Carvedilol has extra syllables
6.	Saluron	51	When compared to the root name, the prefix, infix, and suffix, of this name pair have sufficient orthographic differences. When compared to the modifier, the prefixes of this name pair have sufficient orthographic differences. When compared to the root name, Utibron contains an extra syllable. When compared to the modifier, the first and second syllables of this name pair sound different.
7.	Alosetron	50	When compared to the modifier, the infix and suffix of this name pair have sufficient orthographic differences. When compared to the modifier, the second, third, and fourth 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	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.	Simron	68	Product discontinued with no generics available
2.	Dibrom	68	Product discontinued with no generics available

3.	Asbron	67	Product discontinued with no generics available
4.	Accurbron	64	Product discontinued with no generics available
5.	Eutron	64	Product discontinued with no generics available
6.	Uniparin	64	No information found in common drug references
7.	Uretron	64	Product discontinued with no generics available
8.	Butibufen	61	No information found in common drug references
9.	Asbron G	60	Product discontinued with no generics available
10.	ED bron G	60	No information found in common drug references
11.	Equibron G	60	Product discontinued with no generics available
12.	EQUI-bron G	60	No information found in common drug references
13.	Fepron	60	No information found in common drug references
14.	Ukidan	60	No information found in common drug references
15.	Ultrabrom	60	Product discontinued with no generics available
16.	Uniprim	60	Product is only available as a powder for horses.
17.	Actron	59	Product discontinued with no generics available
18.	(b) (4)	59	Name withdrawn by Applicant. Approved under 'Xtandi'
19.	Pacitron	58	No information found in common drug references
20.	Uridon	58	Product discontinued with no generics available

21.	Uticort	58	Product discontinued with no generics available
22.	Danthron	56	Product discontinued with no generics available
23.	Imferon	56	No information found in common drug references
24.	Securon	55	Product discontinued with no generics available
25.	Tibolone	55	No information found in common drug references
26.	Unburn	55	No information found in common drug references
27.	Chibroxin	54	Product discontinued with no generics available
28.	Dibrom SR	54	No information found in common drug references
29.	Disobrom	54	Product discontinued with no generics available
30.	Pancron	54	No information found in common drug references
31.	DURA ron	53	No information found in common drug references
32.	Lentaron	53	No information found in common drug references
33.	Timpron 250 EC	53	No information found in common drug references
34.	Timpron 500 EC	53	No information found in common drug references
35.	Trilitron	53	Product discontinued with no generics available
36.	Actibine	52	Product discontinued with no generics available
37.	Anhydron	52	Product discontinued with no generics available
38.	Betaferon	52	No information found in common drug references
39.	Biostron	52	No information found in

			common drug references
40.	Lufenuron	52	Product is a veterinary powder
41.	UNI bronchial	52	No information found in common drug references
42.	Uni-lan	52	Product discontinued with no generics available
43.	Uni-tann	52	Product discontinued with no generics available
44.	Fipronil	51	No information found in common drug references
45.	Dipyron	50	Product discontinued with no generics available
46.	Genetron 12	50	No information found in common drug references
47.	U-tri-lone	50	No information found in common drug references

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

No.	Name	POCA Score (%)
1.	Abatren	55
2.	Acticon	52
3.	Acuprin 81	60
4.	Addaprin	53
5.	Aleudrin	52
6.	Alidrin	58
7.	Altafrin	54
8.	Amidrine	51
9.	Ampitrin	54
10.	Anefrin	50
11.	Antagon	50
12.	A-phedrin	54

13.	Aspirin	50
14.	Ativan	54
15.	Betadren	58
16.	Bindren	57
17.	Bran	52
18.	Bridion	50
19.	Budeprion	54
20.	Bufferin	51
21.	Butabarb	51
22.	Butamben	56
23.	Butrans	52
24.	Calabren	50
25.	Caprin	52
26.	Citroma	52
27.	Cuprofen	51
28.	Cyrcin	50
29.	Cytadren	58
30.	Differin	52
31.	Diprivan	50
32.	Ditropan	52
33.	Dutoprol	50
34.	Ecotrin	56
35.	Ecpirin	50
36.	Edecrin	52
37.	Emblon	50
38.	Entaprin	58
39.	Epidrin	65
40.	Epifrin	60
41.	Epipram	52
42.	Estybon	57
43.	Eumydrin	60

44.	Fetrin	54
45.	Fibercon	56
46.	Fostimon	52
47.	Fucidin	51
48.	Ibifon 600	58
49.	Ibuprin	62
50.	Ibuprofen	52
51.	Ibuprohm	50
52.	Ic-green	55
53.	Imbrilon	52
54.	Imigran	58
55.	Imuran	50
56.	Innopran	56
57.	Isibloom	55
58.	Isovorin	52
59.	Iver-on	58
60.	Kutapressin	50
61.	Leukeran	52
62.	Lipidro	50
63.	Liquiprin	50
64.	Medipren	54
65.	Mestinon	50
66.	Metandren	50
67.	Midrin	58
68.	Miniprin	52
69.	Minirin	50
70.	Minitran	52
71.	Mitaban	52
72.	Mitran	56
73.	Nuprin	56
74.	Nutropin	50

75.	Oat bran	65
76.	Obredon	54
77.	Octodrine	50
78.	Ocu-phrin	58
79.	Ocu-pred	50
80.	Ocu-trol	50
81.	Opilon	53
82.	Opticrom	58
83.	Optison	57
84.	Oticin	54
85.	Otiprio	56
86.	Oti-sone	52
87.	Otobione	54
88.	Otrivin	52
89.	Pavulon	50
90.	Pentran	54
91.	Photofrin	53
92.	Pileran	52
93.	Piperine	50
94.	Prodrin	51
95.	Rice bran	60
96.	Ridiprin	54
97.	Roxiprin	51
98.	Sebizon	54
99.	Sebulon	53
100.	Septtrin	53
101.	Sudodrin	55
102.	Sudrine	56
103.	Sultrin	52
104.	Suphedrin	55
105.	Suprane	52

106.	Suprofen	51
107.	Syprine	50
108.	Tabloid	50
109.	Tab-profen	54
110.	Tabradol	50
111.	Tacrine	55
112.	Teebacin	50
113.	Tegison	50
114.	Teldrin	60
115.	Tembrav	51
116.	Terocin	52
117.	Tetracon	54
118.	Tiadilon	53
119.	Ticon	56
120.	Tigan	51
121.	Tilarin	58
122.	Tildren	67
123.	Tin-ben	54
124.	Tiorfan	52
125.	Tobralcon	54
126.	Triaprin	54
127.	Triban	54
128.	Tridrane	53
129.	Tussigon	54
130.	Tymtran	60
131.	Vicoprin	52
132.	Vivarin	52
133.	Vydren	51
134.	Zactran	50
135.	Zetran	54
136.	Zutripro	52

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/s/

LISSA C OWENS
06/25/2015

KENDRA C WORTHY
06/26/2015

LUBNA A MERCHANT
06/28/2015

PROPRIETARY NAME RECONSIDERATION 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*****

****This document contains proprietary drug use data obtained by FDA under contract. The drug use data/information cannot be released to the public/non-FDA personnel without contractor approval obtained through the FDA/CDER Office of Surveillance and Epidemiology.****

Date of This Review:	March 12, 2015
Application Type and Number:	NDA 207930
Product Name and Strength:	(b) (4) (Indacaterol and Glycopyrrolate) Capsules for Inhalation, 27.5 mcg/12.5 mcg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Novartis Pharmaceuticals
Submission Date:	December 31, 2014
Panorama #:	2014-46578
DMEPA Primary Reviewer:	Lissa C. Owens, PharmD
DMEPA Team Leader:	Kendra Worthy, PharmD
DMEPA Associate Director:	Lubna Merchant, PharmD, MS
DMEPA Deputy Director:	Todd Bridges, RPh

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1 INTRODUCTION

This review responds to a December 31, 2014, request from Novartis to reconsider the proposed proprietary name, (b) (4) for NDA 207930.

1.1 PRODUCT INFORMATION

The following product information is provided in the December 31, 2014 proprietary name submission.

- Intended Pronunciation: (b) (4)
- Active Ingredient: Indacaterol and Glycopyrronium
- Indication of Use: Long-term twice daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema
- Route of Administration: Oral Inhalation
- Dosage Form: Inhalation powder hard capsules for pulmonary administration using a single-dose dry powder inhaler
- Strength: 27.5 mcg/12.5 mcg
- Dose and Frequency: One inhalation twice daily
- How Supplied: 10 blister cards, each containing 6 capsules; Neohaler inhaler consists of a cap and a base.
- Storage: Should not be stored above 25°C. Should be stored in the original package to protect from moisture. Must be kept out of the reach and sight of children.

2 REGULATORY HISTORY

The proposed proprietary name, (b) (4) was previously reviewed under IND 076377 and found unacceptable¹ due to orthographic and phonetic similarity to the currently marketed product, (b) (4). The Applicant was informed of our decision in writing on August 19, 2014.² The Applicant submitted a request for reconsideration of the proposed proprietary name, (b) (4) on December 31, 2014.

(b) (4)

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In summary, based on our evaluation of the information documented in our previous reviews along with the information provided as part of your reconsideration request for the proposed name [REDACTED] (b) (4), we conclude that the data submitted does not address our previous safety concerns regarding the potential for confusion between [REDACTED] (b) (4) and your proposed name, [REDACTED] (b) (4) for this product. Therefore, we maintain our objection to the use of this proposed proprietary name.

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/s/

LISSA C OWENS
03/12/2015

KENDRA C WORTHY
03/12/2015

LUBNA A MERCHANT
03/12/2015

TODD D BRIDGES
03/13/2015