

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**205636Orig1s000**

**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\*\*\***

---

<b>Date of This Review:</b>	July 16, 2014
<b>Application Type and Number:</b>	NDA 205636
<b>Product Name and Strength:</b>	ProAir RespiClick (Albuterol Sulfate) Inhalation Powder 90 mcg per actuation
<b>Product Type:</b>	Single Ingredient Product
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	Teva Pharmaceuticals
<b>Submission Date:</b>	May 5, 2014
<b>Panorama #:</b>	2014-17311
<b>DMEPA Primary Reviewer:</b>	Lissa C. Owens, PharmD
<b>DMEPA Associate Director:</b>	Lubna Merchant, M.S., PharmD

---

## Contents

1	INTRODUCTION.....	1
1.1	Product Information .....	1
2	RESULTS .....	2
2.1	Promotional Assessment .....	2
2.2	Safety Assessment.....	2
3	CONCLUSIONS .....	5
3.1	Comments to the Applicant.....	5
4	REFERENCES .....	6
	APPENDICES .....	7

## 1 INTRODUCTION

This review evaluates the proposed proprietary name, ProAir RespiClick, 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 submitted an external name study, conducted by [REDACTED] <sup>(b) (4)</sup> for this product.

### 1.1 PRODUCT INFORMATION

The following product information is provided in the May 5, 2014 proprietary name submission.

<b>Table 1. Relevant Product Information for ProAir RespiClick (Albuterol Sulfate) and ProAir HFA (Albuterol Sulfate)</b>		
<b>Product Name</b>	ProAir RespiClick	ProAir HFA
<b>Initial Approval Date</b>	N/A	2004
<b>Active Ingredient</b>	Albuterol Sulfate	Albuterol Sulfate
<b>Indication</b>	Long-term once daily maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), and for reducing COPD exacerbations.	Long-term once daily maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), and for reducing COPD exacerbations.
<b>Route of Administration</b>	Oral Inhalation	Oral Inhalation
<b>Dosage Form</b>	Inhalation Powder	Inhalation Aerosol
<b>Strength</b>	90 mcg per actuation	90 mcg per capsule
<b>Dose and Frequency</b>	2 inhalations every 4 to 6 hours or 2 inhalations 15 to 30 minutes before exercise	2 inhalations every 4 to 6 hours or 2 inhalations 15 to 30 minutes before exercise
<b>How Supplied</b>	Dry powder inhaler in boxes of one	Pressurized aluminum canister with a red plastic actuator and white dust cap each in boxes of one
<b>Storage</b>	15°C to 25°C (59°F to 77°F)	15°C to 25°C (59°F to 77°F)

## 2 RESULTS

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

### 2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Pulmonary, Allergy, and Rheumatology Products (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<sup>1</sup>.

#### 2.2.2 *Components of the Proposed Proprietary Name*

The proposed proprietary name, ProAir RespiClick, is comprised of two words: the root name 'ProAir' and the modifier 'RespiClick'. The Applicant indicated in their submission that the proposed name, ProAir RespiClick, is a new addition to the ProAir® product line. The registered tradename RespiClick® provides differentiation from the press-and breathe HFA metered-dose inhalation product lines and is related to the patented technology utilized in this multi-dose dry-powder, breath-actuated device delivery system. The RespiClick® name was coined based on the click sound that is made each time the cap is opened to prepare for a dose.

We have evaluated whether or not the proposed name requires the modifier, evaluated the appropriateness of the chosen modifier 'RespiClick', and considered if this product should utilize a totally different proprietary name to help distinguish the product presentation from the existing product line. Our evaluation of this issue is discussed in Section 2.2.8.

#### 2.2.3 *FDA Name Simulation Studies*

101 practitioners participated in DMEPA's prescription studies. The interpretations did overlap with one currently marketed product 'ProAir' which was found in the voice study. Eighteen (outpatient: n=1, voice: n=9, inpatient: n=8) participants interpreted the name correctly as 'ProAir RespiClick', Eleven (voice: n=1, inpatient: n=10) participants interpreted the name as 'ProAir Respi Click', and Eight (inpatient: n=8) participants interpreted the name as Pro Air Respi Click. Appendix B contains the results from the verbal and written prescription studies.

---

<sup>1</sup>USAN stem search conducted on July 1, 2014.

#### 2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, May 16, 2014 e-mail, the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

#### 2.2.5 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) on May 16, 2014 using the criteria in Table 1, and then individually reviewed each case. We limited our analysis to cases that described errors possibly associated with name confusion. We used the NCC MERP Taxonomy of Medication Errors to code the type and factors contributing to the errors when sufficient information was provided by the reporter.<sup>2</sup>

<b>Table 3: FAERS Search Strategy</b>	
<b>Date Range</b>	<b>January 3, 2012 to May 16, 2014</b>
<b>Product</b>	ProAir
<b>Event (MedDRA Terms)</b>	<b>Medication Errors [HLGT] Product Packaging Issues [HLT] Product Label Issues [HLT] Product Quality Issues [HLT]</b>

The FAERS database search identified 175 cases. After individual review, none of the cases were relevant as they did not involve name confusion with ProAir.

#### 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 search organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified by (b) (4)

<b>Table 1. POCA Search Results</b>	<b>Number of Names</b>
Highly similar name pair: combined match percentage score $\geq 70\%$	2
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	65
Low similarity name pair: combined match percentage score $\leq 49\%$	5

<sup>2</sup> The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Taxonomy of Medication Errors. Website <http://www.nccmerp.org/pdf/taxo2001-07-31.pdf>.

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

Our analysis of the 72 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through G.

### ***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 25, 2014. At that time we also requested additional information or concerns that could inform our review. DPARP did not state any additional concerns with the proposed proprietary name, ProAir RespiClick.

### ***2.2.9 FMEA of the Modifier "RespiClick" for this product***

The Applicant proposes to use the modifier 'RespiClick' to differentiate the proposed Inhalation Powder from the currently marketed, ProAir HFA formulation.

The differences between the proposed formulation and the current marketed formulation are listed in Table 1 in section 1.1.

Although, there are several similarities between the proposed and marketed ProAir products, the dosage form and formulation differ and may cause wrong formulation errors or a delay in therapy if the same proprietary name is used. Given the need to distinguish the proprietary nomenclature of these products and the Applicant's proposal to use the ProAir name with the addition of a modifier, we considered the following:

- (1) Whether a modifier could adequately distinguish the two products,
- (2) Whether the modifier proposed is appropriate,
- (3) Whether marketing the product under a unique name is appropriate.

### ***Safety assessment of the modifier***

It is not uncommon for modifiers to be used to denote a specific formulation or packaging configuration (e.g., Advair Diskus and Advair HFA) as part of a product line extension. The applicant states that the modifier 'RespiClick' denotes the breath-actuated device delivery system and is based on the click sound that is made each time the cap is opened to prepare for a dose. The device is not currently marketed.

Given the applicant's proposal to use a modifier, we evaluated the potential risk of confusion within the ProAir product line. Our postmarketing surveillance of ProAir did not identify any name confusion with the existing ProAir product. We note that by adding a modifier to 'ProAir', the existing dosage form (Inhalation Spray), are further differentiated from the Inhalation Powder formulation. If a prescription is written for 'ProAir RespiClick, it is unlikely ProAir HFA will be dispensed. Thus, the name offers a distinguishing factor that is not currently seen within the current product line.

Additionally, the modifier 'Respiclick' has not been previously marketed, does not have any intended meaning, nor is the Respiclick device available on its own. Additionally, we did not identify any names that can be confused with 'Respiclick' during our sound alike and look alike searches. However, we also note that omission and oversight of a

modifier is cited in literature<sup>2</sup> as a common cause of medication error. Postmarketing experience shows that the introduction of product line extensions result in medication errors if the modifier is omitted and the product characteristics are similar or overlap. We note that in this instance a delay in therapy may occur.

***Safety of using a unique name to market this product***

An alternative to using a modifier to distinguish this product from the currently marketed product is to use a totally different root name. However, introducing a total new proprietary name for this product also carries a risk of medication errors. Specifically, marketing the new product under a unique name may lead to additional medication errors such as therapeutic duplication and overdoses. These errors may have greater associated safety risks than the omission or oversight of the modifier. Therefore, for the aforementioned reasons listed DMEPA finds that the proprietary name ‘ProAir RespiClick,’ although not free from the risk of error, offers a safer approach to naming this product.

**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, ProAir Respiclick, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your May 5, 2014 submission are altered, the name must be resubmitted for review.

---

<sup>2</sup> Lesar TS. Prescribing Errors Involving Medication Dosage Forms. *J Gen Intern Med.* 2002; 17(8): 579-587.

## 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](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.<sup>3</sup>

#### **\*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?

<sup>3</sup> National Coordinating Council for Medication Error Reporting and Prevention.  
<http://www.nccmerp.org/about/MedErrors.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  $\geq 70\%$ .
  - 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. 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  $\geq 70$  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  $\geq 70\%$ ).**

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).			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
<b>Y/N</b>	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>	<b>Y/N</b>	Do the names have different number of syllables?
<b>Y/N</b>	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>	<b>Y/N</b>	Do the names have different syllabic stresses?
<b>Y/N</b>	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?	<b>Y/N</b>	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
<b>Y/N</b>	Is there different number or placement of cross-stroke or dotted letters present in the names?	<b>Y/N</b>	Across a range of dialects, are the names consistently pronounced differently?
<b>Y/N</b>	Do the infixes of the name appear dissimilar when scripted?		
<b>Y/N</b>	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 have a higher potential for confusion and should be evaluated further (see Step 2).</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>For any combination drug products, 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"> <li>○ 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.</li> <li>○ Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.</li> <li>○ Similar sounding doses: 15 mg is similar in sound to 50 mg</li> </ul>
<p>Step 2</p>	<p>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 <b>with</b> overlapping or similar strengths or doses.</p>

<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names begin with different first letters?</li> </ul> <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"> <li>• Are the lengths of the names dissimilar* when scripted?</li> </ul> <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> <li>• 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?</li> <li>• Is there different number or placement of cross-stroke or dotted letters present in the names?</li> <li>• Do the infixes of the name appear dissimilar when scripted?</li> <li>• Do the suffixes of the names appear dissimilar when scripted?</li> </ul>	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names have different number of syllables?</li> <li>• Do the names have different syllabic stresses?</li> <li>• Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?</li> <li>• Across a range of dialects, are the names consistently pronounced differently?</li> </ul>
--	--

**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 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. ProAir RespiClick Study (Conducted on May 16, 2014)**

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u> <i>ProAir RespiClick 11 inhalations</i> <i>every 4 to 6 hrs</i></p>	<p>ProAir RespiClick #1 UAD</p>
<p><u>Outpatient Prescription:</u> <i>Pro Air RespiClick</i> <i>UAD</i> <i>#1</i> <i>Dr. Ose</i></p>	

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

268 People Received Study  
101 People Responded

Study Name: ProAir Respiclick

	<b>Total</b>	<b>35</b>	<b>34</b>	<b>32</b>	
<b>INTERPRETATION</b>	<b>OUTPATIENT</b>	<b>VOICE</b>	<b>INPATIENT</b>	<b>TOTAL</b>	
POR AIR RESPICLID	1	0	0	1	
PRE AIR RESPI CLICK	0	0	1	1	
PRO ACI RETPI CLICK	0	0	1	1	
PRO AIR RESPI CLICK	0	0	8	8	
PRO AIR RESPICHECK	1	0	0	1	
PRO AIR RESPICHL	1	0	0	1	
PRO AIR RESPICIEL	1	0	0	1	
PRO AIR RESPICLICK	7	0	0	7	
PRO AIR RESPICLICL	1	0	0	1	
PRO AIR RESPICLIEL	3	0	0	3	
PRO AIR RESPICLIL	4	0	0	4	
PRO AIR RESPICLISH	1	0	0	1	
PRO AIR RESPICLUL	2	0	0	2	
PRO AIR RESPICULE	1	0	0	1	
PRO AIR RESPIDIAL	1	0	0	1	
PRO AIR RESPIDIL	3	0	0	3	
PRO AIR RESPIDUL	2	0	0	2	
PRO AIR RESPIQUICK	0	1	0	1	
PRO AIR RESPIRBID	1	0	0	1	
PRO AIR RESPITLIL	1	0	0	1	
PRO AIR RESPITUL	1	0	0	1	
PRO AIRE RESPIQUIK	0	1	0	1	
PROAIR	0	1	0	1	
PROAIR RESCUE CLICK	0	1	0	1	

PROAIR RESICLIP	0	1	0	1
PROAIR RESPI CLICK	0	1	10	11
PROAIR RESPI CLICK II INHALATIONS	0	0	1	1
PROAIR RESPICLICK	1	9	8	18
PROAIR RESPI-CLICK	0	3	0	3
PRO-AIR RESPI-CLICK	0	1	0	1
PROAIR RESPICLIK	0	1	0	1
PRO-AIR RESPI-CLIK	0	1	0	1
PROAIR RESPICLIQUE	0	1	0	1
PROAIR RESPIDIAL	1	0	0	1
PROAIR RESPIDIL	1	0	0	1
PROAIR RESPIQUICK	0	7	0	7
PROAIR RESPIQUIK	0	1	0	1
PROAIR RESPIT	0	1	0	1
PROAIR RESPUCLICK	0	1	0	1
PROAIRE RESPIQUICK	0	1	0	1
PROERASPLIC	0	1	0	1
PROTEI RESPICLICK	0	0	1	1
PROTIC RESPICLICK	0	0	1	1
PROTIR RESPI CLICK	0	0	1	1

**Appendix C:** Moderately Similar Names (i.e., 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.	Pegasys Proclick***	62
2.	Respigam	58
3.	Respi-Tann	58
4.	Rapiflux	56

5.	Respbid	56
6.	Retacrit***	56
7.	Brevivbloc	55
8.	Respa-1 <sup>st</sup>	54
9.	Respi-Tann G	54
10.	Aristopak	53
11.	Respaire-120 SR	52
12.	Respaire-60 SR	52
13.	Respa-PE	52
14.	Respi-Tann Pd	52
15.	RespiVent-D	52
16.	Risperdal	52
17.	Adrenaclick	50
18.	Despec-SF	50
19.	Prepopik	50
20.	Rescula	50
21.	Resectisol	50
22.	Rocephin Kit	50
23.	Versacloz	50

**Appendix D:** Moderately Similar Names (i.e., combined POCA score is  $\geq 50\%$  to  $\leq 69\%$ ) with overlap or numerical similarity in Strength and/or Dose

No.	<b>Proposed name: ProAir Respiclick</b> <b>Strength(s):90 mcg</b> <b>Usual Dose:2 inhalations every 4-6 hours or 2 inhalations 30 minutes prior to exercise</b>	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
1.	Respa C&C	60	The suffix of this name pair have sufficient orthographic differences  The name contains extra syllables
2.	Respahist	58	The infix and suffix of this name pair have sufficient orthographic differences  The third syllable of this name pair sound different
3.	Respirol	58	The infix of this name pair have sufficient orthographic differences  The third syllable of this name pair sound different
4.	Rest Simply	55	The infix and suffix of this name pair have sufficient orthographic differences  The name contains an extra syllable
5.	Restasis	54	The infix and suffix of this name pair have sufficient orthographic differences  The second and third syllables of this name pair sound different
6.	Rectasol-HC	52	The infix and suffix of this name pair have sufficient orthographic differences  The name contains extra syllables
7.	Respa-BR	50	The infix and suffix of this name pair have sufficient orthographic differences  The name contains extra syllables
8.	Respahist II	50	The infix and suffix of this name pair have sufficient orthographic differences  The name contains extra syllables
9.	Resporal	50	The infix and suffix of this name pair have sufficient orthographic differences

			The third syllable of this name pair sound different
10.	Tri-Sprintec	50	The prefix, infix, and suffix of this name pair have sufficient orthographic differences The first, second, and third syllables of the name pair sound different

**Appendix E:** Low Similarity Names (i.e., combined POCA score is  $\leq 49\%$ )

No.	Name	POCA Score (%)
1.	Combivent Respimat	$\leq 49\%$
2.	Easy Click	$\leq 49\%$
3.	Remeron	$\leq 49\%$
4.	Topi Click	$\leq 49\%$
5.	Risperdone	$\leq 49\%$

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

No.	Name	POCA Score (%)	Failure preventions
1.	Proair Respiclick***	100	Name is the subject of this review
2.	Respillin	71	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
3.	(b) (4)		
4.	(b) (4)		

	(b) (4)		
5.	(b) (4)		
6.	Respivent	58	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
7.	ProAir (b) (4)***	58	Name denied by OPDP and resubmitted as ProAir Respiclick
8.	Respimat	58	Product is a device not a drug
9.	Lastolic	57	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
10.	Despec-PD	56	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
11.	Respiram	56	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
12.	(b) (4)		
13.	Rescufolin	54	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
14.	Resperal	54	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases

15.	(b) (4)		
16.	Trispec Dex	54	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
17.	(b) (4)		
18.	(b) (4)		
19.	Pre Folic	53	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
20.	Pro-Air Albuterol	53	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
21.	Respicort	53	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
22.	Respa-GF	53	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
23.	(b) (4)		
24.	(b) (4)		
25.	Prostaphlin	50	Product discontinued with

			no generics available.
26.	Arpicolin	50	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
27.	Proteus Mirabilis	50	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
28.	Respa-SA	50	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
29.	Trispec PSE	50	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
30.	Reteplase	50	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
31.	Revive Plus	50	Product identified in Rx Norm. Unable to find product characteristics in commonly used drug databases
32.	Prestalia***	50	Product identified Names entered by Safety Evaluator. Unable to find product characteristics in commonly used drug databases
33.	Repatha Sureclick***	50	Product identified Names entered by Safety Evaluator. Unable to find product characteristics in commonly used drug databases
34.	(b) (4)		

35.



(b) (4)

(b) (4)

-----  
**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
-----

/s/  
-----

LISSA C OWENS  
07/16/2014

LUBNA A MERCHANT  
07/16/2014