

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

209203Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	January 23, 2017
Application Type and Number:	IND 119031 NDA 209203
Product Name and Strength:	Duzallo (lesinurad and allopurinol) tablets 200 mg/200 mg and 200 mg/300 mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Ardea Biosciences, Inc.
Panorama #:	2016-9521365 (IND) 2016-11240362 (NDA)
DMEPA Primary Reviewer:	Madhuri R. Patel, PharmD
DMEPA Associate Director (Acting):	Mishale Mistry, PharmD, MPH

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Duzallo, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by (b) (4) for this product.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, (b) (4)***, on February 12, 2016 under IND 119031. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, (b) (4)*** unacceptable due to (b) (4)

Thus, the Applicant submitted the name, Duzallo, for review on August 5, 2016 under IND 119031 and on November 8, 2016 under NDA 209203.

1.2 PRODUCT INFORMATION

The following product information is provided in the August 5, 2016 and November 8, 2016 proprietary name submissions.

- Intended Pronunciation: Dew-ZAL-oh
- Active Ingredient: Lesinurad and Allopurinol
- Indication of Use: Treatment of hyperuricemia associated with gout (b) (4)
- Route of Administration: Oral
- Dosage Form: Tablet
- Strength: 200 mg/200 mg; 200 mg/300 mg
- Dose and Frequency: Recommended starting dose is the 200 mg /300 mg strength once daily in the morning. The recommended dose for the patients with moderate renal impairment (creatinine clearance [CrCL] of (b) (4)-59 mL/min) is lesinurad/allopurinol FDC 200 mg/ 200 mg.
- How Supplied: 5-count, 30-count, and 90-count bottles
- Storage: Room temperature
- Container and Closure Systems: n/a
- Reference Listed Drug: n/a

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 name^a.

2.2.2 *Components of the Proposed Proprietary Name*

The Applicant did not provide a derivation or intended meaning for the proposed name, Duzallo, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 *FDA Name Simulation Studies*

68 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.

2.2.4 *Comments from Other Review Disciplines at Initial Review*

In response to the OSE, August 26, 2016 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 *Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Table 1 lists the number of names with the combined orthographic and phonetic score of $\geq 55\%$ retrieved from our POCA search^b and also includes names identified from by (b) (4). These names are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	2
Moderately similar name pair:	73

^a USAN stem search conducted on January 9, 2017.

^b POCA search conducted on December 22, 2016 in version 4.0.

combined match percentage score $\geq 55\%$ to $\leq 69\%$	
Low similarity name pair: combined match percentage score $\leq 54\%$	46

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

Our analysis of the 121 names contained in Table 1 determined 121 names will not pose a risk for confusion as described in Appendices C through H.

2.2.7 Communication of DMEPA’s Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) via e-mail on January 13, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DPARP on January 17, 2017, they stated no additional concerns with the proposed proprietary name, Duzallo.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Michael Sinks, OSE project manager, at 240-402-2684.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your November 8, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

3. *Electronic Drug Registration and Listing System (eDRLS) database*

The electronic Drug Registration and Listing System (eDRLS) was established to support the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

APPENDICES

Appendix A

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

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. ^c

^c National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there medical and/or coined abbreviations in the proprietary name?
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
Y/N	Are there inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

- b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:
- Highly similar pair: combined match percentage score $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 54\%$.

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 does not share a
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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 z and f), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name
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	<p>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
Step 2	<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 with 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? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as <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 $\leq 54\%$).

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. Duzallo Study (Conducted on August 19, 2016)

Handwritten Medication Order/Prescription	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Duzallo 200/300mg tab po once daily</i></p>	<p>Duzallo 200/300mg tablet</p> <p>Take one tablet by mouth once daily every morning. Dispense #30</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Duzallo 200/300mg</i> <i>T tab PO QAM</i> <i>Disp #30</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Duzallo					310 People Received Study 68 People Responded
Total	25	16	27		
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL	
DUNPALLO	1	0	0	1	
DUNZALLO	2	0	0	2	
DURZALLO	0	0	1	1	
DUSALLOW	0	1	0	1	
DUVELLO	0	1	0	1	
DUYALLO	3	0	0	3	
DUZALLO	19	2	24	45	
DUZALO	0	9	0	9	
DUZALTO	0	0	2	2	

DUZAOLO	0	1	0	1
DUZELLO	0	2	0	2

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

No.	Proposed name: Duzallo Established name: Lesinurad and Allopurinol Dosage form: Tablet Strength(s): 200 mg/200 mg; 200 mg/300 mg Usual Dose: 1 tablet once 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.	Duzallo***	100	Subject of this review
2.	(b) (4) ***	78	Proposed proprietary name for NDA (b) (4) found unacceptable by DMEPA (OSE# 2008-464). NDA (b) (4) approved under new proprietary name (b) (4).

Appendix D: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
3.	Durezol	61
4.	D-Tal	56
5.	Duralex	56

Appendix E: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Duzallo Established name: Lesinurad and Allopurinol Dosage form: Tablet Strength(s): 200 mg/200 mg; 200 mg/300 mg Usual Dose: 1 tablet once daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
6.	Dioval 40	65	The suffixes of this name pair have sufficient orthographic differences. Dioval 40 contains a number string ('40') and if included in the prescription adds additional orthographic differences. The second and third syllables of this name pair sound different.

No.	Proposed name: Duzallo Established name: Lesinurad and Allopurinol Dosage form: Tablet Strength(s): 200 mg/200 mg; 200 mg/300 mg Usual Dose:1 tablet once daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
7.	Duraflu	65	<p>The 'z' vs 'r' in the third position of the names and the cross-stroke 'f' in the 5th position for Duraflu provides sufficient orthographic differences.</p> <p>The second syllables, the first sounds of the third syllables ('f' vs 'l'), and the last sounds of the third syllables ('o' vs 'u') of this name pair sound different.</p> <p>Strength: 200 mg/200 mg and 200 mg/300 mg vs. 325 mg/20 mg/200 mg/60 mg</p>
8.	Doral	64	<p>The lengths of the names differ by 2 letters. The additional upstroke letter in the suffix for Duzallo*** provide sufficient orthographic differences.</p> <p>Duzallo*** name contains an extra syllable. The last syllables of this name pair sound different.</p>
9.	Duo-Vil	64	<p>The infixes and the additional upstroke letter in the last position of Duo-Vil provide sufficient orthographic differences.</p> <p>The second and third syllables of this name pair sound different.</p>
10.	Nuzole	64	<p>The first letters of this name pair and the additional upstroke letter in the 6th position in Duzallo*** provide sufficient orthographic differences.</p> <p>Duzallo*** contains an extra syllable. The first sounds of the first syllables ('d' vs 'n') and the second sound of the second syllable ('al' vs 'ol') of this name pair sound different.</p>
11.	Tussall	64	<p>The infixes and the 'o' in the last position of Duzallo provide sufficient orthographic differences.</p> <p>Duzallo*** name contains an extra syllable. The last syllables of this name pair sound different.</p>
12.	Diulo	63	<p>The lengths of the names differ by 2 letters. The infixes and the additional upstroke letter in the suffix for Duzallo*** provide sufficient orthographic differences.</p> <p>The last sound of the first syllables ('i' vs 'u') and the second syllables of this name pair sound different.</p>

No.	Proposed name: Duzallo Established name: Lesinurad and Allopurinol Dosage form: Tablet Strength(s): 200 mg/200 mg; 200 mg/300 mg Usual Dose:1 tablet once daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
13.	(b) (4)***	63	The (b) (4) of (b) (4)*** provide sufficient orthographic differences. The first syllables and the last sounds of the third syllables ('(b) (4)' vs 'o') of this name pair sound different.
14.	Duraclon	62	The infixes and suffixes provide sufficient orthographic differences. The second syllables and the last sound of the last syllables ('n' vs 'o') of this name pair sound different.
15.	D-Val	62	The lengths of the names differ by 3 letters. The infixes and suffixes of this name pair have sufficient orthographic differences. Duzallo*** name contains an extra syllable. The last syllables of this name pair sound different.
16.	Fazaclo	62	The first letters of this name pair and the additional upstroke letter in the 5 th position in Duzallo*** provide sufficient orthographic differences. The first syllables ('Du' vs. 'Fa') and the first sounds of the third syllables ('l' vs 'c') of this name pair sound different.
17.	(b) (4)***	62	The first letters of this name pair have sufficient orthographic differences. Duzallo*** name contains an extra syllable. The first syllables ('Du' vs. (b) (4)) and last syllables of this name pair sound different. Strength: 200 mg/200mg and 200 mg/300mg vs. (b) (4)
18.	Livalo	62	The prefixes, infixes, and the double upstroke letters in the 5 th and 6 th position in Duzallo*** provide sufficient orthographic differences. The first and second syllables of this name pair sound different.
19.	Durlaza	61	The infixes and suffixes of this name pair have sufficient orthographic differences. The last sounds of the first syllables ('u' vs 'r') and third syllables of this name pair sound different.

No.	Proposed name: Duzallo Established name: Lesinurad and Allopurinol Dosage form: Tablet Strength(s): 200 mg/200 mg; 200 mg/300 mg Usual Dose:1 tablet once daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
20.	Dulera	60	The infixes and suffixes of this name pair have sufficient orthographic differences.. The second and third syllables of this name pair sound different.
21.	Duralone	60	The suffixes of this name pair provide sufficient orthographic differences. The first sounds of the second syllables ('r' vs 'z') and the last sounds of the last syllables ('n' vs. 'o') of this name pair sound different.
22.	Xyzal	60	The prefixes and suffixes of this name pair have sufficient orthographic differences. Duzallo*** name contains an extra syllable. The first syllables of this name pair sound different.
23.	Durasal	59	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
24.	Dalalone	57	The infixes and suffixes of this name pair have sufficient orthographic differences.. The first syllables and the last sound of the third syllables ('o' vs. 'ne') of this name pair sound different.
25.	(b) (4) ***	57	The infixes and suffixes of this name pair have sufficient orthographic differences. The last sounds of the first syllables ((b) (4) vs 'u') and second syllables of this name pair sound different.
26.	Danazol	57	The suffixes of this name pair have sufficient orthographic differences. The last sounds of the first syllables ('an' vs. 'uz') and third syllables of this name pair sound different.
27.	Nullo	57	Duzallo*** has the letter string 'Duz' at the beginning of the name which provides sufficient orthographic differences. Duzallo*** name contains an extra syllable. The second syllables of this name pair sound different.

No.	Proposed name: Duzallo Established name: Lesinurad and Allopurinol Dosage form: Tablet Strength(s): 200 mg/200 mg; 200 mg/300 mg Usual Dose:1 tablet once daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
28.	Docucal	56	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair sound different.</p>
29.	Dofsol-A	56	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The last sounds of the first syllables ('of' vs 'u') and second syllables of this name pair sound different.</p>
30.	Dovaril	56	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair sound different.</p>
31.	Adderall	56	<p>The prefixes and infixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
32.	Adderall 10	56	<p>The prefixes and infixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Adderall 10 name contains a number string that is not present in Duzallo***.</p>
33.	Adderall 12.5	56	<p>The prefixes and infixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Adderall 12.5 name contains a number string that is not present in Duzallo***.</p>
34.	Adderall 15	56	<p>The prefixes and infixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Adderall 15 name contains a number string that is not present in Duzallo***.</p>
35.	Adderall 20	56	<p>The prefixes and infixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Adderall 20 name contains a number string that is not present in Duzallo***.</p>

No.	Proposed name: Duzallo Established name: Lesinurad and Allopurinol Dosage form: Tablet Strength(s): 200 mg/200 mg; 200 mg/300 mg Usual Dose:1 tablet once daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
36.	Adderall 30	56	The prefixes and infixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different. Adderall 30 name contains a number string that is not present in Duzallo***.
37.	Adderall 5	56	The prefixes and infixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different. Adderall 5 name contains a number string that is not present in Duzallo***.
38.	Adderall 7.5	56	The prefixes and infixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different. Adderall 7.5 name contains a number string that is not present in Duzallo***.

Appendix F: Low Similarity Names (e.g., combined POCA score is $\leq 54\%$)

No.	Name	POCA Score (%)
39.	Doxil	54
40.	Lovaza	54
41.	Dulcolax	52
42.	Natelle	52
43.	Puralube	52
44.	Zevalin	52
45.	Bensal	51
46.	Lo/Ovral	50
47.	Lo/Ovral-28	50
48.	Midol	50
49.	Vivelle	50
50.	Xolido	50
51.	Advil	49
52.	Bravelle	49
53.	Gonal F	48
54.	Neoral	48

No.	Name	POCA Score (%)
55.	Xarelto	48
56.	Bosulif	47
57.	Glofil-125	46
58.	Myzilra	46
59.	Novarel	46
60.	Norel AD	45
61.	Boroleum	44
62.	Dilacor	44
63.	Gazyva	44
64.	Novolin	44
65.	Novolin 70/30	44
66.	Sosol	44
67.	Ulo	44
68.	Tridil	43
69.	Betalin 12	42
70.	Novolin N	42
71.	Toviaz	42
72.	Valchlor	42
73.	Buspar	41
74.	Duracillin A.S.	41
75.	Prosol	41
76.	Bicillin	40
77.	Covera	40
78.	Divalproex	40
79.	Duramorph	40
80.	Boniva	38
81.	Tisseel	38
82.	Innovar	36
83.	Dyazide	35
84.	Xofigo	35

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
85.	No Dolo	68	Discontinued product with no active generics.
86.	Doxal	65	International product formerly marketed in Austria and marketed in Russia, Finland (doxepin hydrochloride), and Brazil (pyridoxine hydrochloride/thiamine hydrochloride).

No.	Name	POCA Score (%)	Failure preventions
87.	Duphalac	63	Discontinued lactulose product with no generic equivalents available.
88.	Disal	62	Veterinary product.
89.	Docal	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
90.	Duraflor	62	International product marketed in Canada.
91.	Corzall	62	Discontinued carbetapentane/pseudoephedrine product with no generic equivalents available.
92.	Tusal	62	Discontinued product with no active generics.
93.	Dexall	62	Discontinued dexbrompheniramine maleate/dextromethorphan hydrobromide/phenylephrine hydrochloride product with no active generics.
94.	Dopa, DI	60	Product is not a drug. It stands for (+/-)-3,4-Dihydroxyphenylalanine.
95.	Benz-all	60	Product is not a drug. It is a disinfectant for medical, dental and veterinary equipment.
96.	Nasal La	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
97.	Daonil	58	International product formerly marketed in Finland, Israel, Netherlands, Norway, Austria, and Denmark and marketed in Belgium, Argentina, Australia, Brazil, Chile, France, Greece, Hong Kong, India, Indonesia, Ireland, Italy, Japan, Malaysia, Mexico, New Zealand, Philippines, Portugal, South Africa, Singapore, Spain, Switzerland, Thailand, United Kingdom, and Venezuela.
98.	Qdall	57	Discontinued chlorpheniramine/pseudoephedrine product with no generic equivalents available.
99.	Dura Ron	56	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
100.	Qdall Ar	56	Discontinued chlorpheniramine product with no generic equivalents available.

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

No.	Name	POCA Score (%)
101.	Sudal	62

No.	Name	POCA Score (%)
102.	Sudal 12	62
103.	Zazole	62
104.	Zonalon	62
105.	(b) (4) ***	61
106.	Nucala	60
107.	(b) (4) ***	59
108.	Nadolol	58
109.	Nodolor	58
110.	Sulfo-Lo	58
111.	Zidoval	58
112.	Adacel	56
113.	Nidazol	56
114.	Nuflor	56
115.	Nuvileo	56
116.	Savella	56
117.	Vazol	56
118.	Xodol	56
119.	Zyflo	56
120.	Norel La	55
121.	Vazol D	55

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/s/

MISHALE P MISTRY on behalf of MADHURI R PATEL
01/23/2017

MISHALE P MISTRY
01/23/2017