

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

211911Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME 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)

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

Date of This Review:	December 17, 2019
Application Type and Number:	NDA 211911
Product Name and Strength:	Durysta (bimatoprost (b) (4) implant, 10 mcg
Product Type:	Single Ingredient Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Allergan
Panorama #:	2019-31589115-1
DMEPA Safety Evaluator:	Melina Fanari, R.Ph.
DMEPA Team Leader:	Otto L. Townsend, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name Durysta, which was found conditionally acceptable under NDA 211911 on July 29, 2019.^a We internally initiated this review to capture additional names not previously identified in our previous review. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

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

Our POCA search^b identified 110 names with the combined score of $\geq 55\%$ or individual orthographic or phonetic score of $\geq 70\%$. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 8 names not previously analyzed. These names are included in Table 1 below.

2.1.2 *Names Retrieved for Review Organized by Name Pair Similarity*

Table 1 lists the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	0
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	8
Low similarity name pair: combined match percentage score $\leq 54\%$	0

^a Fanari, M. Proprietary Name Review for Durysta (N211911). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Jun 29. Panorama No.: 2019-31589115.

^b POCA search conducted on December 4, 2019 in version 4.3.

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

Our analysis of the 8 names contained in Table 1 determined none of the names will pose a risk for confusion with Durysta as described in Appendices C through H.

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Durysta, is acceptable.

4 REFERENCE

1. *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.

APPENDICES

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

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 (%)
1.	Therastat	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: Durysta Established name: bimatoprost Dosage form: intracameral implant; preloaded in a Novadur drug delivery system Strength(s): 10 mcg Usual Dose: 1 implant (b) (4)	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
2.	(b) (4) ***	57	<p>This name pair has sufficient orthographic and phonetic differences.</p> <p>Orthographically, the names begin with different first (b) (4) letters. Additionally, the suffixes (b) (4) provide some differentiation. (b) (4) *** ends with (b) (4) whereas, Durysta ends with the cross-stroke letter ‘t’ followed by the round letter ‘a’, which gives the suffixes of the names different shapes when scripted.</p> <p>Phonetically, all three syllables [(1st: (b) (4) vs dur), (onset of the 2nd: (b) (4) vs ‘is), and (3rd: (b) (4) vs tah)] sound different.</p>

Appendix F: Low Similarity Names (e.g., combined POCA score is $\leq 54\%$)- 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
3.	(b) (4) ***	64	Proposed proprietary name for IND 047857 found to be unacceptable (RCM 2016-11005567 dated 2/2/2017). Alternative proposed proprietary name Lucemyra was found to be acceptable (RCM 2017-13576754 dated 7/26/2017). NDA 209229 was approved under the proprietary name Lucemyra.
4.	(b) (4) ***	60	Proposed proprietary name for BLA 125683 found to be unacceptable. BLA 125683 was approved under alternative name, Xembify.
5.	Nd Stat	55	Name identified in Rx Norm database. Product deactivated and no generic equivalents are available.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion^c.

No.	Name	POCA Score (%)
6.	Tukysa***	56
7.	Sulster	55
8.	Tavist Da	55

^c Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MELINA N FANARI
12/17/2019 03:02:14 PM

OTTO L TOWNSEND
12/17/2019 03:40:13 PM

PROPRIETARY NAME REVIEW

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

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Date of This Review:	July 29, 2019
Application Type and Number:	NDA 211911
Product Name and Strength:	Durysta (bimatoprost (b) (4) implant, 10 mcg
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Allergan
Panorama #:	2019-31589115
DMEPA Safety Evaluator:	Melina Fanari, R.Ph.
DMEPA Team Leader:	Otto L. Townsend, PharmD

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Allergan previously submitted the proposed proprietary name, Durysta*** on July 25, 2016 under IND 108324. We found the name, Durysta*** acceptable on December 30, 2016.^a

Thus, Allergan submitted the name, Durysta, for review under NDA 211911 on May 10, 2019.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on May 10, 2019.

- Intended Pronunciation: dur 'is tah
- Active Ingredient: bimatoprost
- Indication of Use: Reduction of intraocular pressure in patients with ocular hypertension or open-angle glaucoma
- Route of Administration: ophthalmic (intracameral)
- Dosage Form: intracameral implant; preloaded in a Novadur drug delivery system
- Strength: 10 mcg
- Dose and Frequency: 1 implant (b) (4) into anterior chamber of the affected eye
- How Supplied: Single-use applicator with implant pre-loaded that is packaged in an aluminum foil pouch.
- Storage: Store refrigerated 2°C - 8°C (36°F - 46°F)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Durysta would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Transplant and Ophthalmology Products (DTOP) concurred with the findings of OPDP's assessment for Durysta.

^a Patel, M. Proprietary Name Review for Durysta (IND 108324). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 Dec 30. Panorama No. 2016-9105162.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Durysta.

2.2.1 *United States Adopted Names (USAN) Search*

There is no USAN stem present in the proposed proprietary name^b.

2.2.2 *Components of the Proposed Proprietary Name*

Allergan did not provide a derivation or intended meaning for the proposed proprietary name, Durysta, 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.

We note bimatoprost is currently marketed by the same manufacturer under the dual proprietary names, Lumigan and Latisse. The approval of the proposed product, Durysta, would represent an additional proprietary name introduced to the market for this active ingredient from the same manufacturer. We considered this in our previous review^a and determined the use of a different proprietary name for this intracameral implant dosage form of bimatoprost would likely help minimize medication errors associated with the wrong route of administration since Lumigan is intended for administration of solution into the eye as drops, Latisse is for topical use only, and Durysta for intracameral injection of an implant. Thus, we maintain our non-objection to the use of a third proprietary name for bimatoprost.

2.2.3 *Comments from Other Review Disciplines at Initial Review*

In response to the OSE, May 28, 2019 e-mail, the Division of Transplant and Ophthalmology Products (DTOP) did not forward any comments or concerns relating to Durysta at the initial phase of the review.

2.2.4 *FDA Name Simulation Studies*

Sixty-three practitioners participated in DMEPA's prescription studies for Durysta. 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 *Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Our POCA search^c identified 102 names with the combined score of $\geq 55\%$ or individual orthographic or phonetic score of $\geq 70\%$. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We also evaluated

^b USAN stem search conducted on May 20, 2019.

^c POCA search conducted on May 20, 2019 in version 4.3.

previously identified names taking into account the change in (b) (4)

. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. Therefore, we identified 26 names not previously analyzed. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	4
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	21
Low similarity name pair: combined match percentage score $\leq 54\%$	1

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

Our analysis of the 26 names contained in Table 1 determined none of the names will pose a risk for confusion with Durysta 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 Transplant and Ophthalmology Products (DTOP) via e-mail on July 29, 2019. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Transplant and Ophthalmology Products (DTOP) on July 29, 2019, they stated no additional concerns with the proposed proprietary name, Durysta.

3 CONCLUSION

The proposed proprietary name, Durysta, is acceptable.

If you have any questions or need clarifications, please contact Abby Olagundoye, OSE project manager, at 301-796-3982.

3.1 COMMENTS TO ALLERGAN

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

If any of the proposed product characteristics as stated in your submission, received on May 10, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. *USAN Stems* (<https://www.ama-assn.org/about/united-states-adopted-names-approved-stems>)

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 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. ^d

^d 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 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 55% 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 are further evaluated to identify the presence of attributes that are known to cause name confusion.
 - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names^c. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
 - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information 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) may be limited when the strength or dose overlaps. DMEPA reviews 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

^c Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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 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 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 $\geq 55\%$ 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 with overlapping or similar strengths or doses.</p>

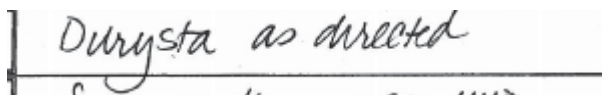
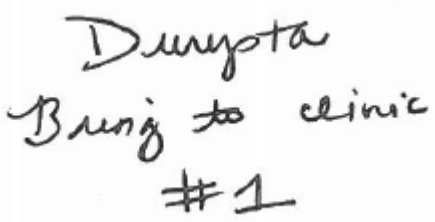
<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* 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 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 ≤54%).

Names with low similarity 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.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Durysta Study (Conducted on May 28, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
<p>Medication Order:</p> 	<p>Durysta Bring to Clinic #1</p>
<p>Outpatient Prescription:</p> 	

FDA Prescription Simulation Responses (Aggregate Report)

<p>Study Name: Durysta</p> <p style="text-align: right;">221 People Received Study 63 People Responded</p>				
Total	21	22	20	63
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
DARIFTA	0	1	0	1
DARISTA	0	1	0	1
DERISTA	0	1	0	1
DORISTA	0	2	0	2
DUREISTA	0	1	0	1
DUREPTA	2	0	0	2
DURESTA	0	1	0	1
DURISTA	0	13	0	13
DURYSTA	19	1	20	39
STIRISTA	0	1	0	1

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

No.	Proposed name: Durysta Established name: bimatoprost Dosage form: intracameral implant; preloaded in a Novadur drug delivery system Strength(s): 10 mcg Usual Dose: 1 implant (b) (4)	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.	Durysta***	100	Name subject to this review
2.	Dryptal	72	International product formerly marketed in Czech, Ireland, United Kingdom, and Hong Kong.
3.	Uristat	72	Durysta*** has a downstroke letter in the 4 th position which is not present in Uristat. Uristat has upstroke letters in the last position which is absent in Durysta***. The onsets of the first syllables ('D' vs. 'U') and the end of the rimes of the third syllables ('a' vs. 't') of this name pair sound different.
4.	Duratest	70	Durysta*** has a downstroke letter in the 4 th position which is not present in Duratest. In addition, Duratest has an additional upstroke letter 't' in the infix that is absent in Durysta. The second syllables ('y' vs. 'a') and the third syllables ('ta' vs. 'test') of this name pair sound different.

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 (%)
5.	Hydrostat	60

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: Durysta Established name: bimatoprost Dosage form: intracameral implant; preloaded in a Novadur drug delivery system Strength(s): 10 mcg Usual Dose: 1 implant (b) (4)	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.	Daurismo	62	This name pair has sufficient orthographic and phonetic differences.
7.	Duratuss DM	56	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
8.	Norisc	51

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
9.	(b) (4) ***	62	Proposed proprietary name under IND (b) (4) found to be unacceptable (RCM # (b) (4) dated (b) (4)). A subsequent proposed proprietary name for this product; (b) (4) was also found to be unacceptable (RCM (b) (4) dated (b) (4)).
10.	(b) (4) ***	60	Proposed proprietary name under CBER IND (b) (4) found to be unacceptable (letter to Applicant dated (b) (4)). A subsequent name has not been submitted for this IND.
11.	Duratuss HD	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
12.	(b) (4) ***	58	Proposed proprietary name withdrawn by the Applicant on (b) (4) for IND (b) (4) (RCM (b) (4)).

No.	Name	POCA Score (%)	Failure preventions
13.	Tustan	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
14.	Zadstat	58	International product formally marketed in Israel and the UK.
15.	Duratuss CS	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
16.	Sustac	56	International product marketed in Hungary.
17.	ND-STAT	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion^f.

No.	Name	POCA Score (%)
18.	Qtrypta	64
19.	(b) (4) ***	60
20.	(u) (4) ***	60
21.	(b) (4) ***	58
22.	(b) (4) ***	57
23.	Alustra	56
24.	Isturisa***	56
25.	Tri-Sudo	56
26.	Lustra	55

^f Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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/s/

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