CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215019Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM
Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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:	November 10, 2021
Application Type and Number:	NDA 215019
Product Name and Strength:	Dartisla ODT (glycopyrrolate) orally disintegrating tablets, 1.7 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Edenbridge Pharmaceuticals LLC (Edenbridge)
PNR ID #:	2021-1044724143
DMEPA 1 Safety Evaluator:	Sherly Abraham, R.Ph.
DMEPA 1 Team Leader:	Idalia E. Rychlik, Pharm.D.
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, Pharm.D.

1 INTRODUCTION

This memorandum is to assess the proposed proprietary name, Dartisla ODT. The root name 'Dartisla' was found conditionally acceptable under NDA 215019 and IND 135178 on May 20, 2021.[a] Thus, Edenbridge submitted the name, Dartisla ODT, under NDA 215019 for review on August 20, 2021. We note that all product characteristics remain the same.

1.1 REGULATORY HISTORY

Balto Therapeutics previously submitted the proposed proprietary name, (b) (4)*** on July 14, 2020. However, we found the name, (b) (4)*** unacceptable due to OPDP objection under IND 135178 on December 16, 2020.[b] The Office of Prescription Drug Promotion (OPDP) objected to the proposed proprietary name, (b) (4), because as proposed it created a misleading impression regarding the efficacy of the drug.

Balto Therapeutics submitted the proposed proprietary name, Dartisla***, for review on March 5, 2021. We found the name, Dartisla*** conditionally acceptable under OSE Review Panorama IDs# 2021-1044723857 and 2021- 1044623860 on May 20, 2021.[a] However, we recommended Balto consider the use of an appropriate modifier (e.g., ODT) for their proposed proprietary name to help convey the 'orally disintegrating' nature of their product and notify us of their decision.

On June 29, 2021, the ownership of NDA 215019 was transferred from Balto Therapeutics to Edenbridge Pharmaceuticals, LLC.[c] On August 20, 2021, Edenbridge withdrew the proposed proprietary name, Dartisla***and submitted the proposed name with modifier, Dartisla ODT, for our evaluation.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Dartisla ODT would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) and the Division of Gastroenterology (DG) concurred with the findings of OPDP's assessment for Dartisla ODT.

2.2 SAFETY ASSESSMENT OF THE ROOT NAME 'DARTISLA***'

For re-assessment of the proposed proprietary root name Dartisla***, we evaluated the previously identified names of concern considering any lessons learned from recent post-

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[a]Abraham, S. Proprietary Name Review for Dartisla*** (NDA 215019 and IND 135178). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 May 20. PNR ID No. 2021-1044723857 and 2021-1044623860.

(b) (4)

[c] Administrative/Change of Applicant proposed under NDA 215019 available in EDR via: \\CDSESUB1\evsprod\nda215019\0009\m1\us\cover-letter-ownership-transfer-nda-eden.pdf

marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The September 14, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Dartisla ODT.

2.3 SAFETY ASSESSMENT OF THE MODIFIER 'ODT'

The proposed modifier, ODT, is currently utilized in the marketplace.[d] It is typically used to convey the meaning "orally disintegrating tablet" for products designed to disintegrate or dissolve rapidly on contact with saliva[e]. Provided the Office of Pharmaceutical Quality (OPQ) determines that the product meets the criteria for an orally disintegrating tablet, the modifier may help to communicate the orally disintegrating characteristic of the tablet.

We note that the reference listed drug (RLD) for Dartisla ODT is Robinul forte regular tablet (NDA 12827) and the reference standard (RS) is glycopyrrolate regular tablet (ANDA 40653 Par Pharmaceutical, Inc). Additionally, there are multiple currently marketed generic glycopyrrolate products in regular tablets. Dartisla ODT proposes a new dosage form, orally disintegrating tablet, which is a different formulation from that of the RLD, RS, and currently available generic glycopyrrolate tablets. Additionally, Dartisla ODT has some overlapping product characteristics (overlapping dose, route of administration, and frequency of administration) with currently marketed glycopyrrolate tablets, which may increase the risk of the product being confused as a regular tablet, leading to wrong technique of administration errors.

Although we acknowledge that modifiers may be omitted or overlooked[f], when used, it may provide an additional measure to emphasize and communicate the intended method of administration for the product. It may also help distinguish the new dosage form (orally disintegrating tablet) of Dartisla ODT from currently marketed glycopyrrolate regular tablets, which may reduce the potential for errors related to wrong administration technique. Thus, in this case, we find that the modifier 'ODT' is appropriate for this product.

2.4 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Gastroenterology (DG) on October 27, 2021. DG stated no additional concerns with the proposed proprietary name, Dartisla ODT.

If you have further questions or need clarifications, please contact Alvis Dunson, OSE project manager, at 301-796-6400.

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[d] ISMP's List of Products with Drug Name Suffixes [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2010 [cited 2021 SEP 14]. https://www.ismp.org/sites/default/files/attachments/2018-04/drugnamesuffixes.pdf

[e] Guidance for Industry: Orally Disintegrating Tablets. Food and Drug Administration. 2008. Available from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070578.pdf.

[f] Lesar TS. Prescribing errors involving medication dosage forms. J Gen Intern Med. 2002 Aug;17(8):579-87.

3 CONCLUSION

Our assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we find that the proposed proprietary name, Dartisla ODT, is acceptable.

3.1 COMMENTS TO EDENBRIDGE PHARMACEUTICALS LLC

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

If any of the proposed product characteristics as stated in your submission, received on August 20, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCE

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

USAN Stems List contains all the recognized USAN stems.

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/

SHERLY ABRAHAM
11/10/2021 02:19:29 PM

IDALIA E RYCHLIK
11/10/2021 02:34:09 PM

MISHALE P MISTRY
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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:	May 20, 2021
Application Type and Number:	NDA 215019 and IND 135178
Product Name and Strength:	Dartisla (glycopyrrolate) orally disintegrating tablets, 1.7 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Balto Therapeutics, LLC (Balto Therapeutics)
PNR ID #:	2021-1044723857 and 2021- 1044623860
DMEPA Safety Evaluator:	Sherly Abraham, R.Ph.
DMEPA Team Leader:	Idalia E. Rychlik, Pharm.D.
DMEPA Deputy Director:	Danielle Harris, Pharm.D., BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Dartisla, 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. Balto Therapeutics did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Balto Therapeutics previously submitted the proposed proprietary name, (b) (4)*** on July 14, 2020. However, we found the name, (b) (4)*** unacceptable due to OPDP objection under IND 135178 on December 16, 2020.[a] Office of Prescription Drug Promotion (OPDP) objected to the proposed proprietary name, (b) (4), because as proposed it created a misleading impression regarding the efficacy of the drug.

Thus, Balto Therapeutics submitted the name, Dartisla, for review on March 5, 2021.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 5, 2021 and prescribing information received on February 26, 2021.

- Intended Pronunciation: Där-tis-lə
- Active IngredientActive IngredientActive Ingredient: glycopyrrolate
- Indication of Use: Dartisla indicated for use (b) (4) (b) (4)
- Route of Administration: oral
- Dosage Form: orally disintegrating tablets
- Strength: 1.7 mg
- Dose and Frequency: Initiate dosing at one ODT two or three times daily (b) (4) (b) (4) with a maximum recommended daily dose is 6.8 mg

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

(b) (4)

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

2.2 SAFETY ASSESSMENT

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

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

Balto Therapeutics did not provide a derivation or intended meaning for the proposed proprietary name, Dartisla, in their submission. This proprietary name is comprised of a single word. We note that Dartisla ends with the letter string '-la', an abbreviation for the modifier 'long acting'. In accessing the acceptability of including the modifier '-la' we considered whether there are any currently marketed proprietary names that begin with the letters 'Dartis' and note that this letter string does not overlap with any currently marketed products; therefore, in the event that the modifier, '-la' were to be omitted from a prescription order, the letter string would not pose a risk for confusion with any other currently marketed products. Beyond this abbreviation, we note that Dartisla does not contain any additional components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On March 18, 2021March 18, 2021, the Division of Gastroenterology (DG) did not forward any comments or concerns relating to Dartisla at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-one (n=81) practitioners participated in DMEPA's prescription studies for Dartisla. 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 prescription simulation studies.

[b] USAN stem search conducted on March 15, 2021.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 197 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. 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 ≥70%	4
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	177
Low similarity name pair: combined match percentage score ≤54%	16

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

Our analysis of the 197 names contained in Table 1 determined none of the names will pose a risk for confusion with Dartisla 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 Gastroenterology (DG). At that time we also requested additional information or concerns that could inform our review. On May 18, 2021, the Division of Gastroenterology (DG) stated no additional concerns with the proposed proprietary name, Dartisla.

3 CONCLUSION

The proposed proprietary name, Dartisla, is acceptable.

If you have any questions or need clarifications, please contact Alvis Dunson, Project manager, at 301-796-6400.

3.1 COMMENTS TO BALTO THERAPEUTICS, LLC

[c] POCA search conducted on March 16, 2021 in version 4.4.

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

If any of the proposed product characteristics as stated in your submission, received on March 5, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

In addition, we have the following comments related to our review:

We recommend you also consider the use of an appropriate modifier (e.g., ODT) with your proposed proprietary name to help convey the 'orally disintegrating' nature of your product. While not required, a modifier may help distinguish your orally disintegrating product from currently marketed glycopyrrolate regular tablets. Dartisla has some overlapping product characteristics (overlapping dose, dosage form, and frequency of administration) with currently marketed glycopyrrolate tablets, which may increase the risk of your product being confused as a regular tablet leading to medication errors. The addition of a modifier, e.g. ODT, to your proprietary name may provide an additional measure to emphasize and communicate the intended method of administration for the product, which may reduce the potential for errors related to wrong administration technique. Therefore, we request you to consider including the modifier ODT to your proposed name and notify us of your determination.

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. 6F[d]

[d] National Coordinating Council for Medication Error Reporting and Prevention. https://www nccmerp.org/about-medication-errors Last accessed 10/05/2020.

*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 ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤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 names7F[e]. 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).

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

- 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.

   Four 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, verbal pronunciation of the drug name or during computerized provider order entry. 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 vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is **≥** 70%).

Answer the questions in the checklist below. Affirmative answers to 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? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		

Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths 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. For single strength products, also consider circumstances where the strength may not be expressed. 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. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • 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	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.

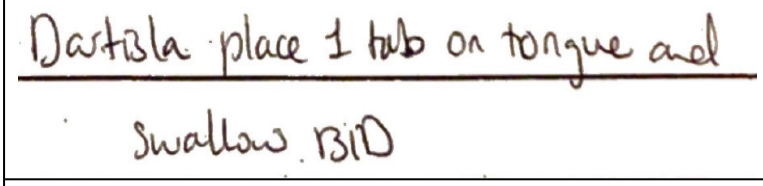
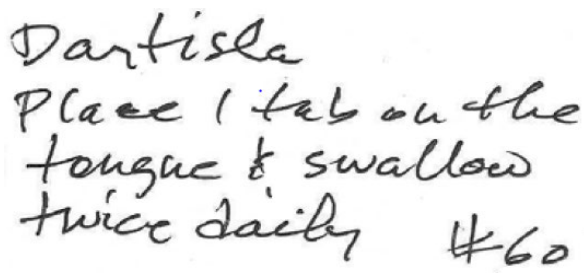
	Orthographic Checklist (Y/N to each question)	Phonetic Checklist (Y/N to each question)
	• Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	• Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is **≤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. Dartisla Study (Conducted on March 19, 2021)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Dartisla Place 1 tab on the tongue and swallow twice daily #60
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Dartisla	

209 People Received Study
81 People Responded

Study Name: Dartisla

Total	21	18	26	16	
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
CARTISLA	1	0	0	0	1
DARLISTA	0	0	1	0	1
DARTISLA	20	18	2	7	47
DARTIZLA	0	0	16	0	16
DARTLIZA	0	0	1	0	1
DARTYZLA	0	0	2	0	2
DASTBLA	0	0	0	1	1

DASTIBLA	0	0	0	1	1
DASTILA	0	0	0	1	1
DASTISLA	0	0	0	5	5
DASTIZLA	0	0	0	1	1
DELTIZLA	0	0	1	0	1
DERTISMA	0	0	1	0	1
NARTIZLA	0	0	1	0	1
TARLIZLA	0	0	1	0	1

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

No.	Proposed name: Dartisla Established name: glycopyrrolate Dosage form: orally disintegrating tablets Strength(s): 1.7 mg Usual Dose: one orally disintegrating tablet two or three times 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.	Dartisla	100	Proposed name is the subject of the review.
2.	Partuss-LA	81	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available as per Redbook.
3.	Carticel	70	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available as per Redbook.
4.	Gardasil	70	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available as per Redbook.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose-N/A

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

No.	Proposed name: Dartisla Established name: glycopyrrolate Dosage form: orally disintegrating tablets Strength(s): 1.7 mg Usual Dose: one orally disintegrating tablet two or three times daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	Barbital	66	This name pair has sufficient orthographic and phonetic differences.
2.	Darcalma	66	This name pair has sufficient orthographic and phonetic differences.
3.	Sarclisa	66	This name pair has sufficient orthographic and phonetic differences.
4.	Duratuss DA	65	This name pair has sufficient orthographic and phonetic differences.
5.	Tearisol	64	This name pair has sufficient orthographic and phonetic differences.
6.	Cartilade	64	This name pair has sufficient orthographic and phonetic differences.
7.	Artiss	64	Both names start with different letters, (D vs. A). The name pair differs by two letters. Dartisla has an additional syllable. The beginning of the first syllables ('duh ar' vs. 'ar') have some phonetic differences. In addition to the orthographic and phonetic differences, the following product characteristics may help to minimize the risk of error: Dartisla is available as orally disintegrating tablet administered orally as one tablet (or 1.7 mg) two or three times daily whereas Artiss is available as topical solution applied topically as a thin layer topically to the dry, surgically prepared wound surface or as directed, as needed. There is no overlap in dose of both products and the frequency of administration needs to be specified for Dartisla. Furthermore, there is no overlap in dosage form or route of

No.	Proposed name: Dartisla Established name: glycopyrrolate Dosage form: orally disintegrating tablets Strength(s): 1.7 mg Usual Dose: one orally disintegrating tablet two or three times 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
			administration between the products (if included on a prescription/medication order). When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case
8.	Marlissa	63	This name pair has sufficient orthographic and phonetic differences.
9.	Drizalma	62	This name pair has sufficient orthographic and phonetic differences.
10.	Atripla	62	This name pair has sufficient orthographic and phonetic differences.
11.	Ed A-Hist LA	62	This name pair has sufficient orthographic and phonetic differences.
12.	Durasal	61	This name pair has sufficient orthographic and phonetic differences.
13.	Dristan	61	This name pair has sufficient orthographic and phonetic differences.
14.	Certiva	60	This name pair has sufficient orthographic and phonetic differences.
15.	Dermatol 10	60	This name pair has sufficient orthographic and phonetic differences.
16.	Fortical	60	This name pair has sufficient orthographic and phonetic differences.
17.	Duratest	60	This name pair has sufficient orthographic and phonetic differences.
18.	Xartemis	60	This name pair has sufficient orthographic and phonetic differences.
19.	Cartia	60	This name pair has sufficient orthographic and phonetic differences.
20.	Dermasarra	59	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Dartisla Established name: glycopyrrolate Dosage form: orally disintegrating tablets Strength(s): 1.7 mg Usual Dose: one orally disintegrating tablet two or three times 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
21.	Drisdol	59	This name pair has sufficient orthographic and phonetic differences.
22.	Smart San	59	This name pair has sufficient orthographic and phonetic differences.
23.	Derifil	58	This name pair has sufficient orthographic and phonetic differences.
24.	Daptacel	58	This name pair has sufficient orthographic and phonetic differences.
25.	Derma Stat	58	This name pair has sufficient orthographic and phonetic differences.
26.	Duratuss	58	This name pair has sufficient orthographic and phonetic differences.
27.	Durysta	58	This name pair has sufficient orthographic and phonetic differences.
28.	Darbid	58	This name pair has sufficient orthographic and phonetic differences.
29.	Daurismo	58	This name pair has sufficient orthographic and phonetic differences.
30.	Dicarbosil	58	This name pair has sufficient orthographic and phonetic differences.
31.	Disipal	58	This name pair has sufficient orthographic and phonetic differences.
32.	Patisiran	58	This name pair has sufficient orthographic and phonetic differences.
33.	Risdiplam	58	This name pair has sufficient orthographic and phonetic differences.
34.	Diltia	58	This name pair has sufficient orthographic and phonetic differences.
35.	Dilatrate-SR	58	This name pair has sufficient orthographic and phonetic differences.
36.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.
37.	Aristada	58	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Dartisla Established name: glycopyrrolate Dosage form: orally disintegrating tablets Strength(s): 1.7 mg Usual Dose: one orally disintegrating tablet two or three times 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
38.	Duratuss G	57	This name pair has sufficient orthographic and phonetic differences.
39.	(b) (4) ***	57	This name pair has sufficient orthographic and phonetic differences.
40.	Delatest	57	This name pair has sufficient orthographic and phonetic differences.
41.	Normiflo	56	This name pair has sufficient orthographic and phonetic differences.
42.	Dermasav	56	This name pair has sufficient orthographic and phonetic differences.
43.	Deltalin	56	This name pair has sufficient orthographic and phonetic differences.
44.	Ddavp Nasal	56	This name pair has sufficient orthographic and phonetic differences.
45.	Duratuss PE	56	This name pair has sufficient orthographic and phonetic differences.
46.	Drituss HD	56	This name pair has sufficient orthographic and phonetic differences.
47.	Droxia	56	This name pair has sufficient orthographic and phonetic differences.
48.	Dasetta 1/35	56	This name pair has sufficient orthographic and phonetic differences.
49.	Dasetta 7/7/7	56	This name pair has sufficient orthographic and phonetic differences.
50.	Cartia XT	56	This name pair has sufficient orthographic and phonetic differences.
51.	Dornase alfa	56	This name pair has sufficient orthographic and phonetic differences.
52.	Lantrisul	56	This name pair has sufficient orthographic and phonetic differences.
53.	Diastat	56	This name pair has sufficient orthographic and phonetic differences.
54.	Larotid	56	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Dartisla Established name: glycopyrrolate Dosage form: orally disintegrating tablets Strength(s): 1.7 mg Usual Dose: one orally disintegrating tablet two or three times 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
55.	Lamisil AT	56	This name pair has sufficient orthographic and phonetic differences.
56.	Dura-Tap PD	55	This name pair has sufficient orthographic and phonetic differences.
57.	Duratuss HD	55	This name pair has sufficient orthographic and phonetic differences.
58.	Daraprim	55	This name pair has sufficient orthographic and phonetic differences.
59.	Di-Dak-Sol	55	This name pair has sufficient orthographic and phonetic differences.
60.	(b) (4) ***	55	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
1.	Arctic Blast	54
2.	Disal	54
3.	Dovaril	54
4.	Ritalin LA	54
5.	Deapril-St	53
6.	Abrilada	52
7.	Tandearil	52
8.	Ilaris	50
9.	Sandril	50
10.	(b) (4) ***	49
11.	(b) (4) ***	49
12.	Dialar	49
13.	Alprostadil	48
14.	Aralast	48
15.	Sandostatin Lar	48
16.	(b) (4) ***	47

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

No.	Name	POCA Score (%)	Failure preventions
1.	Dermasil	66	International product marketed in Israel per Micromedex database.
2.	Adalat LA	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Sarisol	64	Brand discontinued with no generic equivalents available. ANDA 084723 withdrawn FR effective 03/14/1996.
4.	Dritail	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Decortisyl	62	International product formerly marketed in United Kingdom and Ireland per Micromedex database.
6.	(b) (4) ***	62	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
7.	Diuresal	60	International product formerly marketed in Switzerland per Micromedex database.
8.	Darvocet A500	60	Product withdrawn from the market due to safety concerns (contained propoxyphene).
9.	Durasal Ii	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	Dactil	60	International product formerly marketed in United Kingdom and Japan per Micromedex database.
11.	(b) (4) ***	58	Proposed proprietary name for IND (b) (4) was found unacceptable by DMEPA ((b) (4)). The applicant proposed a new proprietary name, (b) (4) *** which is currently under review.
12.	Darpaz	57	Name identified in RxNorm database. Identified in Martindale Drug Products as a formerly marketed product which is discontinued or no longer actively marketed. Unable to find product characteristics in commonly used drug databases.
13.	Dermestril 100	57	International product marketed in Belgium Portugal, Germany, Czech Republic, Hungary, China, France, and Italy.

No.	Name	POCA Score (%)	Failure preventions
14.	Dermestril 25	57	International product marketed in Belgium Portugal, Germany, Czech Republic, Hungary, China, France, and Italy.
15.	Dermestril 50	57	International product marketed in Belgium Portugal, Germany, Czech Republic, Hungary, China, France, and Italy.
16.	Verticalm	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
17.	Direct Black 19	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
18.	Dryptal	56	International product formerly marketed in United Kingdom and other countries per Micromedex database.
19.	Darutoside	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
20.	Trisilane	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
21.	Dilcardia SR	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
22.	Duraflor	55	International product marketed in Canada per Micromedex database.
23.	Dofsol-A	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
24.	(b) (4) ***	55	Proposed proprietary name for NDA 210598 was found unacceptable by DMEPA (OSE #2017-18929786). NDA 210598 is approved under the proprietary name, Yupelri.
25.	Aridil	55	International product formerly marketed in United Kingdom and Japan per Micromedex database.
26.	(b) (4) ***	55	Proposed proprietary name for IND 105004 found unacceptable by DMEPA (OSE# 2016-7853541) dated 10/03/2016. BLA 761061 approved under proprietary name, Tremfya.

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 (%)
1.	Anatuss La	66
2.	Marsilid	64
3.	Modisal La	64
4.	Nardil	64
5.	Parsidol	64
6.	(b) (4)***	63
7.	Bar-Test	63
8.	Farbital	62
9.	Serpasil	61
10.	Cardizem La	60
11.	Farnesal	60
12.	Fortesta	60
13.	Gastrese-La	60
14.	Maltitol	60
15.	Sarkosyl	60
16.	Sildaflo	60
17.	Tricosal	60
18.	Tri-Nasal	60
19.	Triphasil-21	60
20.	Triphasil-28	60
21.	Vaprisol	60
22.	Vitadil 2A	60
23.	Vitadil 5A	60
24.	Atropisol	59
25.	Sorbid Sa	59
26.	(b) (4)***	59
27.	Zorblisa***	59
28.	Baratol	58
29.	Carbiset	58
30.	Cardinol	58
31.	Carlesta	58
32.	Cortastat La	58
33.	Farnesol	58

[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

No.	Name	POCA Score (%)
34.	Garasol	58
35.	Marcillin	58
36.	Masti-Clear	58
37.	Nostrilla	58
38.	Pan-Mist La	58
39.	Parasal	58
40.	Portalac	58
41.	Santex La	58
42.	Sarisol No. 1	58
43.	Sarisol No. 2	58
44.	Terrasil	58
45.	Torisel	58
46.	Trital Sr	58
47.	Allersol A	57
48.	(b) (4) ***	57
49.	Granisol	57
50.	(b) (4) ***	57
51.	Lortuss Lq	57
52.	Pharmasal	57
53.	Trapidil	57
54.	Adcortyl	56
55.	Bacti-Stat	56
56.	Barstatin 100	56
57.	Brotizolam	56
58.	Cataflam	56
59.	Cortastat	56
60.	Cortastat 10	56
61.	(b) (4) ***	56
62.	Largactil	56
63.	Nasahist La	56
64.	Nasatab La	56
65.	Permitil	56
66.	Seradex La	56
67.	Tafinlar	56
68.	Tavist Da	56
69.	Taytulla	56
70.	Tildiem La	56
71.	Trinessa	56
72.	Tri-Vi-Sol	56
73.	Versiclear	56

No.	Name	POCA Score (%)
74.	Vertab Sr	56
75.	Vertavis	56
76.	Vistaril	56
77.	Brisdelle	55
78.	Calcilat	55
79.	Carbastat	55
80.	Carbatuss-Cl	55
81.	Inderide La	55
82.	Inderide La 120/50	55
83.	Inderide La 160/50	55
84.	Inderide La 80/50	55
85.	Karbinal	55
86.	Para-Time S. R.	55
87.	Pharbetol	55
88.	Tarceva	55
89.	Testro-L.A.	55
90.	Veltassa	55
91.	Virasal	55

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