CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

219373Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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 28, 2025
Application Type and Number:	NDA 219373
Product Name, Dosage Form, and Strength:	Lopressor (metoprolol tartrate) Oral Solution, 10 mg/mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Rubicon Research Private Limited (Rubicon)
PNR ID #:	2024-1044726093
DMEPA 2 Safety Evaluator:	Christina Topper, PharmD, BCPS
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS
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1 INTRODUCTION

This review evaluates the proposed proprietary name, Lopressor, 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. Rubicon did not submit an external name study for this proposed proprietary name.

1.1 BACKGROUND AND REGULATORY HISTORY

Lopressor (metoprolol tartrate) tablets were approved on August 7, 1978 under NDA 017963. It is currently indicated for the treatment of hypertension, angina pectoris and myocardial infarction. Lopressor is currently marketed as 50 mg and 100 mg tablets (see Table 1).

Rubicon proposes NDA 219373 metoprolol tartrate oral solution, 10 mg/mL, intended to be marketed for the treatment of the same approved indications as the currently approved tablets. We note that Lopressor is an existing proprietary name approved for Metoprolol Tartrate Oral Tablet formulation of Validus Pharmaceuticals LLC. The proposed product will be distributed by Validus Pharmaceuticals LLC upon approval.

Thus, Rubicon submitted the proposed proprietary name, Lopressor, for the new dosage form under NDA 219373 on November 8, 2024.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on 11/8/2024[a] for Lopressor (metoprolol tartrate) oral solution and the Prescribing Information for Lopressor (metoprolol tartrate) tablets.

Table 1. Relevant Product Information for Lopressor (metoprolol tartrate)

Application Number	**Lopressor [proposed] NDA 219373**	**Lopressor (NDA 017963)[b]**
Initial Approval Date	N/A	August 07, 1978
Intended pronunciation:	Lo-pres-sor	
Active ingredient:	metoprolol tartrate	
Indication:	Treatment of: • Hypertension • Angina Pectoris • Myocardial Infarction	
Dosage Form:	Oral solution	Tablets

[a] Request for Proprietary Name Review (Metoprolol tartrate NDA 219373). Thane (India): Rubicon Research Private Limited; 2024 NOV 08. Available from: \\CDSESUB1\EVSPROD\nda219373\0007\m1\us\proprietary-name-request-metoprolol-os.pdf.

[b] Lopressor (metoprolol tartrate) [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. DEC 2023 [cited 2025 JAN 7]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/017963Orig1s076lbl.pdf.

Table 1. Relevant Product Information for Lopressor (metoprolol tartrate)		
Strength:	10 mg/mL	50 mg and 100 mg
Route of administration:	Oral	

Table 1. Relevant Product Information for Lopressor (metoprolol tartrate)	
Dose and frequency:	Administer once daily with food or after a meal. Titrate at weekly or longer intervals as needed and tolerated. Hypertension • Individualize the dosage of Lopressor tablets. Lopressor tablets should be taken with or immediately following meals. • The usual initial dosage is 100 mg daily in single or divided doses. Adjust dosage at weekly (or longer) intervals until optimum blood pressure reduction is achieved. In general, the maximum effect of any given dosage level will be apparent after 1 week of therapy. The effective dosage range of Lopressor tablets is 100 mg to 450 mg per day. Dosages above 450 mg per day have not been studied. While once-daily dosing can maintain a reduction in blood pressure throughout the day, lower doses (especially 100 mg) may not maintain a full effect at the end of the 24-hour period. Larger or more frequent daily doses may be required. Measure blood pressure near the end of the dosing interval to determine whether satisfactory control is being maintained throughout the day. Angina Pectoris • The dosage of Lopressor tablets should be individualized. Lopressor tablets should be taken with or immediately following meals. • The usual initial dosage is 100 mg daily, given in two divided doses. Gradually increase the dosage at weekly intervals until optimum clinical response has been obtained or there is a pronounced slowing of the heart rate. The effective dosage range of Lopressor tablets is 100 to 400 mg per day. Dosages above 400 mg per day have not been studied. If treatment is to be discontinued, reduce the dosage gradually over a period of 1 – 2 weeks. Myocardial Infarction • See prescribing information of intravenous metoprolol for dosage instructions for intravenous therapy. • In patients who tolerate the full intravenous dose, initiate Lopressor tablets, 50 mg every 6 hours, 15 minutes after the last intravenous dose of metoprolol and continue for 48 hours. In the case of intolerance, reduce dose to 25 mg and administer for 48 hours. Titrate, based on tolerability, to a maintenance dosage of 100 mg twice daily. Continue therapy for at least 3 months. Although the efficacy of Lopressor beyond 3 months has not been conclusively established, data from studies with other beta-blockers suggest that treatment should be continued for 1 to 3 years.

Table 1. Relevant Product Information for Lopressor (metoprolol tartrate)		
How Supplied:	Lopressor (metoprolol tartrate) oral solution contains 10 mg/mL of Metoprolol Tartrate. It is a clear, colorless solution and is supplied in the bottle of: • 300 mL, White, Opaque, HDPE Bottle - NDC 30698-464-30. • 300 mL white, opaque, HDPE bottle NDC 30698-464-30 (10 mg/mL) with child-resistant cap along with a 10 mL calibrated oral dosing syringe. The bottle and the dosing syringe are placed in a carton.	Lopressor (metoprolol tartrate) tablets • Tablets 50 mg – capsule shaped, biconvex, pink, scored (imprinted LOPRESSOR on one side and 458 twice on the scored side); Bottles of 100; NDC 30698-458-01 • Tablets 100 mg – capsule shaped, biconvex, light blue, scored (imprinted LOPRESSOR on one side and 459 twice on the scored side); Bottles of 100; NDC 30698-459-01
Storage:	Store at 77°F (25°C); excursions permitted to 59° to 86°F (15° to 30°C) [See USP Controlled Room Temperature]. Protect from heat. Dispense in a tight, light-resistant container (USP).	Store at 77°F (25°C); excursions permitted to 59° to 86°F (15° to 30°C) [See USP Controlled Room Temperature]. Protect from moisture and heat. Dispense in a tight, light-resistant container (USP).

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Lopressor would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Lopressor. The Division of Cardiology and Nephrology (DCN) concurred with the findings of OPDP's assessment for Lopressor.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

There is no USAN stem present in the proposed proprietary name.[c]

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Rubicon did not provide a derivation or intended meaning for the proposed proprietary name, Lopressor, in their submission. This proprietary name is comprised of a single word that contains the letter string "es", which is the medical abbreviation for 'extended-release' formulation and the letter string "or" which is the medical abbreviation for 'operating room'. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the location of the letter string "es" in the infix of the name is unlikely to be separated from the surrounding letters in a manner that would lead to confusion in this case.

As the letter string "or" is located at the end of a proprietary name we evaluated the potential risk of misinterpreting the proposed proprietary name, Lopressor, as "[drug name similar to Lopress] OR" and did not identify any concern.[d] We note the letter string 'or' is not listed on ISMP's List of Error Prone Abbreviations, Symbols, or Dose Designations.[e] Additionally, we note that the terminal letter string 'or' is common in drug nomenclature for currently marketed drug products (e.g., Caldolor, Valchlor, Ketochlor, etc.). Thus in this case, we do not object to the inclusion of the letter strings "es" and "or".

Beyond these abbreviations, we did not identify any other components (i.e., a modifier, dosage form, etc.) that can contribute to medication error.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Cardiology and Nephrology (DCN) did not forward any comments or concerns relating to Lopressor at the initial phase of the review.

2.2.4 EVALUATION OF A SINGLE PROPRIETARY NAME FOR MULTIPLE DOSAGE FORMS

We note that the newly proposed oral solution formulation shares the same active ingredient, indications for use, frequency of administration, route of administration, and recommended dosing as the currently approved Lopressor tablets.

Rubicon indicates "*a liquid oral dosage form of Metoprolol Tartrate Oral Solution, 10 mg/mL is desirable for patients who cannot swallow a solid tablet or capsule such as geriatric, mentally ill, physically severely ill, or incapacitated patients, in-tubated (NG-tube, OG-tube, PEG-tube, etc.), disabled and non-co-operative patients as it can be easily dispensed as milliliters of solution using an oral syringe. A liquid dosage form is also useful in geriatric patients where small doses of the medication may be required."*

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[c] USAN stem search conducted on January 7, 2025.

[d] POCA search conducted on January 7, 2025.

Based on our understanding of the prescribing information and the assertion by Rubicon that "the proposed drug product, Metoprolol Tartrate Oral Solution, 10 mg/mL is targeted to be therapeutically equivalent to the tablet product.", both the tablet and oral solution are equivalent on a mg-per-mg basis at the time of this review.

It is a common and accepted practice to have a product line with multiple dosage forms managed under one proprietary name (e.g. Renvela and Pradaxa).

The difference in the product characteristics between the two dosage formulations for Lopressor may be managed through labels and labeling.

2.2.5 COMMUNICATION OF DMEPA'S DETERMINATION

On January 28, 2025, DMEPA 2 communicated our determination to the Division of Cardiology and Nephrology (DCN).

3 CONCLUSION

The proposed proprietary name, Lopressor, is conditionally acceptable.

3.1 COMMENTS TO RUBICON RESEARCH PRIVATE LIMITED

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

If any of the proposed product characteristics as stated in your submission, received on 11/8/2024 are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. United States Adopted Names (USAN) Stems

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-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 https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms).

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).

Purple Book

The Purple Book is an online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service (PHS) Act. See Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or.

Division of Medication Errors Prevention and Analysis pending proprietary name requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis.

5 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, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD 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 ONPD 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 3*. 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.[f]

*Table 3. 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.

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

*Table 3. 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 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, Cerner RxNorm, Purple Book, 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 4-6) 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 4).
- 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[9]. 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 5).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) 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 also conducts 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), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) 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-

[9] 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

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.

Additionally, other review disciplines opinions such as OPQ 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 Safety Evaluator 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 4. 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.			
Orthographic Checklist		Phonetic Checklist	
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>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">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</td></tr>
<tr><td>Step 2</td><td colspan="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 with overlapping or similar strengths or doses.</td></tr>
<tr><td></td><td>Orthographic 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</td><td>Phonetic Checklist (Y/N to each question)
• 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?</td></tr>
</table>

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	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?	

Table 6. 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.

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/

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