CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210737Orig1s000
210737Orig2s000

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:	August 20, 2019
Application Type and Number:	NDA 210737
Product Name and Strength:	RediTrex (b) (4) Injection, 7.5 mg/0.3 mL, 10 mg/0.4 mL, 12.5 mg/0.5 mL, 15 mg/0.6 mL, 17.5 mg/0.7 mL, 20 mg/0.8 mL, 22.5 mg/0.9 mL and 25 mg/mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Cumberland Pharmaceuticals Inc.
Panorama #:	2019-33597603
DMEPA Primary Reviewer:	Teresa McMillan, PharmD
DMEPA Team Leader:	Idalia Rychlik, PharmD
DMEPA Associate Director:	Mishale Mistry, PharmD, MPH

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, RediTrex, which was found unacceptable under NDA 210737 on November 28, 2018.[a] The proposed proprietary name, RediTrex, was found to be vulnerable to medication errors due to confusion with another [redacted] under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, RediTrex, was dependent upon which underlying application was approved first.

We note that the goal date for NDA 210737 is September 5, 2019, whereas the underlying application for [redacted] Therefore, if the proposed proprietary name, RediTrex, is granted approval under NDA 210737 on or before September 5, 2019, this application approval will precede approval of the application with the conflicting proposed name, [redacted]***.

Thus, Cumberland Pharmaceuticals Inc. resubmitted the proposed proprietary name, RediTrex, for review.

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA 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 proposed proprietary name. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The August 13, 2019 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Finally, DMEPA evaluated the status of the underlying application of the conflicting name, [redacted]***, and determined that if NDA 210737 for RediTrex is approved on or before the September 5, 2019, this application approval will precede approval of the application with the conflicting proposed name, [redacted]*** given the underlying application for [redacted]***

Based upon our safety assessment of the proposed proprietary name, RediTrex, the application goal date for NDA 210737, and the status of the underlying application for [redacted]***, we find RediTrex conditionally acceptable.

2.2 COMMUNICATION OF DMEPA'S ANALYSIS

DMEPA communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) via e-mail on August 13, 2019.

3 CONCLUSIONS

We conclude that the proposed proprietary name, RediTrex, is acceptable.

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[a] Griffis, M. Proprietary Name Review for RediTrex (NDA 210737). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 NOV 28. Panorama No. 2018-25692069.

If you have any questions or need clarifications, please contact Saharat Patanavanich, OSE project manager, at 240-402-0139.

3.1 COMMENTS TO CUMBERLAND PHARMACEUTICALS INC.

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

If any of the proposed product characteristics as stated in your submission, received on August 2, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

If your application receives a complete response, please submit a new request for review of your proposed proprietary name when you respond to the application deficiencies.

4 REFERENCES

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

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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)

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

Date of This Review:	July 9, 2019
Application Type and Number:	NDA 210737
Product Name and Strength:	(b) (4) (methotrexate) Injection, 7.5 mg/0.3 mL, 10 mg/0.4 mL, 12.5 mg/0.5 mL, 15 mg/0.6 mL, 17.5 mg/0.7 mL, 20 mg/0.8 mL, 22.5 mg/0.9 mL and 25 mg/mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Cumberland Pharmaceuticals Inc.
Panorama #:	2019-31379544
DMEPA Safety Evaluator:	Teresa McMillan, PharmD
DMEPA Team Leader:	Idalia E. Rychlik, PharmD
DMEPA Associate Director:	Mishale Mistry, PharmD, MPH

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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)

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

Date of This Review:	November 28, 2018
Application Type and Number:	NDA 210737
Product Name and Strength:	Reditrex (methotrexate) injection 7.5 mg/0.3 mL, 10 mg/0.4 mL, 12.5 mg/0.5 mL, 15 mg/0.6 mL, 17.5 mg/0.7 mL, 20 mg/0.8 mL, 22.5 mg/0.9 mL and 25 mg/mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Rx
Applicant/Sponsor Name:	Cumberland Pharmaceuticals, Inc.
Panorama #:	2018-25692069
DMEPA Safety Evaluator:	Melina Griffis, R.Ph
DMEPA Team Leader:	Sarah K. Vee, PharmD
DMEPA Associate Director:	Mishale Mistry, PharmD, MPH

Contents

1 INTRODUCTION

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

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on September 4, 2018.

- Intended Pronunciation: re-dee-treks
- Active Ingredient: methotrexate
- Indication of Use: treatment of severe, active rheumatoid arthritis (RA) and polyarticular juvenile idiopathic arthritis (pJIA), who are intolerant of or had an inadequate response to first-line therapy. Symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy.
- Route of Administration: subcutaneous
- Dosage Form: injection
- Strength: 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 22.5 mg and 25 mg
- Dose and Frequency:
    - RA: 7.5 mg once weekly
    - pJIA: 10 mg/m^2 once weekly
    - Psoriasis: 10 mg to 25 mg once weekly

  Adjust dose gradually to achieve an optimal response.
- How Supplied: Sterile solution for subcutaneous injection available as prefilled syringe presentation, in cartons of 4.
- Storage: Store between 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). Protect from light (keep in carton until the time to use).

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Cumberland Pharmaceuticals indicated in their submission that the proposed name, Reditrex, combines "Redi", a shorter form of the word "Ready" with "Trex", taken from the generic "Methotrexate". This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, September 18, 2018 e-mail, the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Thirty-seven practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[b] identified 246 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.

[a] USAN stem search conducted on September 18, 2018

[b] POCA search conducted on September 18, 2018 in version 4.2.

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. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	17
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	221
Low similarity name pair: combined match percentage score ≤54%	7

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

We determined 244 of the 245 names will not pose a risk for confusion as described in Appendices C through H. However, the proposed name could be confused with (b) (4)***. The rationale for the risk of confusion is described below.

Reditrex vs (b) (4)***

The proposed proprietary name, Reditrex, may be confused with another pending proposed proprietary name, (b) (4)

Orthographically, Reditrex (b) (4) owever, considering the orthographic similarities in the rest of the names, these differences may be overlooked.

The similarity of this name pair is further supported by the FDA Phonetic and Orthographic Computer Analysis (POCA) software, which calculates a combined phonetic and orthographic score of 60% (orthographic only score of 66%) for this name pair, which suggests that the names are moderately similar and may pose a risk for confusion.[c]

In addition to the orthographic similarities, Reditrex and (b) (4)*** share overlapping product characteristics, which can further increase the potential for wrong drug errors. The products overlap in strength (b) (4) Furthermore, both products share similar dosage forms (b) (4) and routes of administration (b) (4). We

[c] POCA search conducted on August 14, 2018, 2018, POCA tool updated to incorporate a revised orthographic algorithm.

acknowledge that Reditrex and (b) (4)*** have differences in frequency of administration and indication. However, we are concerned that these differences may not prevent confusion between this name pair as we are aware of postmarketing reports of errors involving confusion between similarly named drug products, despite differences in frequency of administration and indications. For example, name confusion has been reported between Narcan (naloxone) and Norcuron (vecuronium) despite their differences in frequency and indication.[d]

Therefore, based on the totality of the information considered above, we find that the proposed names Reditrex and (b) (4)*** cannot safely co-exist in the market.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) via e-mail on November 28, 2018. At that time, we also requested additional information or concerns that could inform our review. DPARP did not have any comments in response to the email.

3 CONCLUSION

The proposed proprietary name is not acceptable from a safety perspective. The proposed name is vulnerable to name confusion with (b) (4)***. Therefore, the decision to deny the name will be communicated to the Applicant via letter (See *3.1).*

If you have further questions or need clarifications, please contact Saharat Patanavanich, OSE project manager, at 240-402-0139

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Reditrex, and have concluded that this name is unacceptable for the following reasons:

The proposed proprietary name, Reditrex, could result in medication errors due to confusion with another product that is also under review. Therefore, the ultimate acceptability of your proposed proprietary name, Reditrex, is dependent upon which underlying application is approved first. If another product is approved prior to your product, with a name that would be confused with your proposed name Reditrex, you will be requested to submit another name.

[d] Institute for Safe Medication Practices. Paralyzed by mistakes: Look-alike drug names. ISMP Med Saf Alert Acute Care. 2016;21(12):2.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

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. [e]

b.

***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)).

[e] National Coordinating Council for Medication Error Reporting and Prevention. http://www.nccmerp.org/aboutMedErrors.html. Last accessed 10/11/2007.

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.

c. 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 names[f]. 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 a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

d. 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

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

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.

e. 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.			
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 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 **with** overlapping or similar strengths or doses.

	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 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?	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?

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. Reditrex Study (Conducted on October 4, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Redi Trex 12.5 mg subcutaneously once weekly Outpatient Prescription: Patient _____ Date _____ Address _____ ℞ Redi Trex 10mg once weekly in the abdomen or thigh #4 MEDWATCH 1-800-FDA-1088 Refill(s):_____ Dr. _____ dse DEA No._____ Address _____	Reditrex Inject 10 mg once weekly in abdomen or thigh Dispense #4

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

306 People Received Study
37 People Responded

Study Name: Reditrex

Total	9	14	14	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
READITRAX	0	1	0	1
READITREX	0	4	0	4
READY TREX	0	2	0	2

READYTREX	0	3	0	3
READY-TREX	0	1	0	1
REDI TREX	1	0	6	7
REDITRACKS	0	1	0	1
REDITREX	8	2	7	17
RIDIJREX	0	0	1	1

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

No.	**Proposed name:** Reditrex **Established name:** methotrexate **Dosage form:** Injection **Strength(s):** 7.5 mg/0.3mL, 10 mg/0.4 mL, 12.5 mg/0.5 mL, 15 mg/0.6 mL, 17.5 mg/0.7 mL and 20 mg/0.8 mL, 22.5 mg/0.9 mL, and 25 mg/mL **Usual Dose:** RA-7.5 mg once weekly; Psoriasis 10 mg- 25 mg once weekly; pJIA-10 mg/m2 once weekly *Mark all proposed PNs with ****	**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.	Didrex	76	The length of the names differs by 2 letters. The prefixes of this name pair ('Di-"vs 'Re') provide some orthographic differences. Didrex contain one less syllable and the first syllables ('Di' vs 'Re') of the names provide some phonetic differences. The following differences in product characteristics may also help to mitigate the risk of errors: • Strength: Didrex is available in a 50 mg tablet vs. Reditrex is available in strengths of 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg or 25 mg. A strength must be included on a prescription for Reditrex, and there is no overlap in strength. • Frequency of Administration: Didrex is taken 1 to 3 times daily vs. Reditrex is administered once weekly. Therefore, due to the above-mentioned factors we find this name pair acceptable.
2.	Imitrex	76	Orthographically, the prefixes of this name pair ('Im'vs 'Red') differ. In addition, Reditrex has an additional upstroke letter 'd' not present in Imitrex. Phonetically, the first syllables ('Im' vs 'Re') and second syllables ('i' vs. 'di') of the names sound different. The following differences in product characteristics may also help to mitigate the risk of errors:

No.	**Proposed name:** Reditrex **Established name:** methotrexate **Dosage form:** Injection **Strength(s):** 7.5 mg/0.3mL, 10 mg/0.4 mL, 12.5 mg/0.5 mL, 15 mg/0.6 mL, 17.5 mg/0.7 mL and 20 mg/0.8 mL, 22.5 mg/0.9 mL, and 25 mg/mL **Usual Dose:** RA-7.5 mg once weekly; Psoriasis 10 mg- 25 mg once weekly; pJIA-10 mg/m2 once weekly *Mark all proposed PNs with ****	**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.**
			• Imitrex is available in 3 dosage forms (injection, tablet, and spray) which will be required on a prescription or order and help to differentiate between the products. • Although there is an overlap in dosage form (injection), Imitrex injection is only available in 4 mg and 6 mg which doesn't overlap with the available strengths of Reditrex injection. The strength would be required on a prescription or order for both products, which would help to differentiate between them. • Imitrex is administered as a one-time dose that can be repeated once in a 24-hour period vs. Reditrex is administered once weekly, therefore there is no overlap in frequency of administration. Therefore, due to the above-mentioned factors we find this name pair acceptable.
3.	Betatrex Deactivated according to RedBook however generics available.	74	The infixes ('ta' vs. 'di') provide some orthographic differences. The first syllables ('Be' vs 'Re') and ending sounds of the second syllables ('ta' vs. 'di') of the names provide some phonetic differences. The following differences in product characteristics may also help to mitigate the risk of errors: • Dosage Form: Betatrex is available as a cream, ointment or lotion vs. Reditrex will be available as an injection. The dosage form of Betatrex would be specified on a medication order/prescription and there is no overlap between dosage forms of Betatrex and Reditrex.

No.	**Proposed name:** Reditrex **Established name:** methotrexate **Dosage form:** Injection **Strength(s):** 7.5 mg/0.3mL, 10 mg/0.4 mL, 12.5 mg/0.5 mL, 15 mg/0.6 mL, 17.5 mg/0.7 mL and 20 mg/0.8 mL, 22.5 mg/0.9 mL, and 25 mg/mL **Usual Dose:** RA-7.5 mg once weekly; Psoriasis 10 mg- 25 mg once weekly; pJIA-10 mg/m2 once weekly *Mark all proposed PNs with ****	**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.**
			• Strength: Betatrex is available in a 0.1% concentration vs. Reditrex is available in doses of 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg or 25 mg. The strength of Reditrex would be specified on a medication order/prescription and there is no overlap in strength. • Dose: The usual dose for Betatrex would be apply to affected skin area or use as directed vs. RediTrex would be 7.5 mg to 25 mg. There is no overlap in dose. • Frequency of Administration: Betatrex is applied 1 to 3 times daily vs. Reditrex is administered once weekly. Therefore, due to the above-mentioned factors we find this name pair acceptable.
4.	Dobutrex Deactivated according to RedBook however generics available.	73	The prefixes/infixes of this name pair ('obu' vs 'edi') provide some orthographic differences. The first syllables ('Do' vs 'Re') and second syllable ('bu' vs 'di') of the names provide some phonetic differences. The following differences in product characteristics may also help to mitigate the risk of errors: • Dose & Frequency of Administration: Dobutrex is infused at 2.5 to 15 mcg/kg/min but can be up to 40 mcg/kg/min vs. Reditrex is administered as a fixed dose once weekly. Thus, the dose and frequency for Dobutrex can vary depending on the patient's weight and response vs. Reditrex, which is a fixed dose and frequency.

No.	**Proposed name:** Reditrex **Established name:** methotrexate **Dosage form:** Injection **Strength(s):** 7.5 mg/0.3mL, 10 mg/0.4 mL, 12.5 mg/0.5 mL, 15 mg/0.6 mL, 17.5 mg/0.7 mL and 20 mg/0.8 mL, 22.5 mg/0.9 mL, and 25 mg/mL **Usual Dose:** RA-7.5 mg once weekly; Psoriasis 10 mg- 25 mg once weekly; pJIA-10 mg/m2 once weekly *Mark all proposed PNs with ****	**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.**
			Therefore, due to the above-mentioned factors we find this name pair acceptable.
5.	Tetrex	73	Discontinued drug product with no available generics.
6.	(b) (4) ***	72	Proposed proprietary name for NDA 204824 found to be unacceptable (OSE 2017-13281208). Alternative name Otrexup PFS** was found to be acceptable (OSE 2018-24383803)
7.	Peditex	72	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
8.	Penetrex	72	Discontinued drug product with no available generics
9.	Sitrex	72	Discontinued drug product with no available generics
10.	Isotrex	71	Foreign product
11.	(b) (4) ***	71	(b) (4) proprietary name for NDA 204824 found to be unacceptable (OSE 2016-10878619).
12.	Diaprex	70	Discontinued drug product with no available generics
13.	Esidrix Deactivated according to RedBook however generics available.	70	The prefixes of this name pair ('Es' vs 'Re') provide some orthographic differences. In addition, Reditrex contains an additional upstroke letter 't'. The first ('E' vs 'Re') and second syllables ('sid' vs. 'di') of the names provide some phonetic differences. The following differences in product characteristics may also help to mitigate the risk of errors:

No.	**Proposed name:** Reditrex **Established name:** methotrexate **Dosage form:** Injection **Strength(s):** 7.5 mg/0.3mL, 10 mg/0.4 mL, 12.5 mg/0.5 mL, 15 mg/0.6 mL, 17.5 mg/0.7 mL and 20 mg/0.8 mL, 22.5 mg/0.9 mL, and 25 mg/mL **Usual Dose:** RA-7.5 mg once weekly; Psoriasis 10 mg- 25 mg once weekly; pJIA-10 mg/m2 once weekly *Mark all proposed PNs with ****	**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.**
			• Frequency of Administration: Esidrex is taken 1 to 2 times daily vs. Reditrex is administered once weekly. Therefore, due to the above-mentioned factors we find this name pair acceptable.
14.	(b) (4) ***	70	(b) (4)
15.	Regimex	70	Regimex contains a downstroke letter 'g' in the third position where Reditrex contains an upstroke letter 'd'. Reditrex also contains the upstroke letter 't' in the suffix which provides orthographic differences. The beginning of the second ('g' vs. 'd') and third syllables ('m' vs. 'tr') provide some phonetic differences.

No.	**Proposed name:** Reditrex **Established name:** methotrexate **Dosage form:** Injection **Strength(s):** 7.5 mg/0.3mL, 10 mg/0.4 mL, 12.5 mg/0.5 mL, 15 mg/0.6 mL, 17.5 mg/0.7 mL and 20 mg/0.8 mL, 22.5 mg/0.9 mL, and 25 mg/mL **Usual Dose:** RA-7.5 mg once weekly; Psoriasis 10 mg- 25 mg once weekly; pJIA-10 mg/m2 once weekly *Mark all proposed PNs with ****	**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.**
			The following differences in product characteristics may also help to mitigate the risk of errors: • Frequency of Administration: Regimex is taken once to three times daily vs. Reditrex is administered once weekly. Therefore, due to the above-mentioned factors we find this name pair acceptable.
16.	Rheumatrex Deactivated according to RedBook however generics available.	70	The length of the names differs by 2 letters. The prefixes ('Rh' vs. 'Re') and infixes ('euma' vs 'di') of this name pair provide some orthographic differences. The second syllables ('ma' vs. 'di') of the names provide some phonetic differences.
17.	Trintex	70	Discontinued drug product with no available generics

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

No.	**Name** *Mark all proposed PNs with ****	**POCA Score (%)**
18.	Triatex	67
19.	Codeprex	66
20.	Dandrex	66
21.	Prodenrx	66
22.	Rotarix	66
23.	Benzedrex	65
24.	Vincrex	66
25.	Diurex	65
26.	Pediarix	65
27.	Medidex	65
28.	Mytrex	64

No.	Name *Mark all proposed PNs with ****	POCA Score (%)
29.	Retacrit	64
30.	Tretin X	64
31.	Mifeprex	63
32.	Regranex	63
33.	Tricitrates	63
34.	Valtrex	63
35.	Denorex	62
36.	Pemetrexed	62
37.	Redutemp	62
38.	Retisert	62
39.	Semprex-D	62
40.	Celebrex	62
41.	Delta Tritex	61
42.	Medipred	61
43.	Migrex	61
44.	Niferex	61
45.	Niferex-150	61
46.	Ridiprin	61
47.	Feridex	61
48.	Cardiotek Rx	60
49.	Iferex	60
50.	Mytrex A	60
51.	Mytrex F	60
52.	Readi-Cat 2	60
53.	Ryanodex	60
54.	Stridex	60
55.	Tobrex	60
56.	Zephrex	60
57.	Alphatrex	59
58.	Eprex	59
59.	Meditest	59
60.	Rhinoflex	59
61.	Robitet 500	59
62.	Trezix	59
63.	Dutrebis	58
64.	Hiprex	58
65.	Isoditrate	58
66.	Medipren	58
67.	Nitrek	58
68.	Red Yeast Rice	58
69.	Rembrandt	58
70.	Ridifed	58
71.	Ritifed	58

No.	Name *Mark all proposed PNs with ****	POCA Score (%)
72.	Peridex	58
73.	(b) (4) ***	60
74.	(b) (4) ***	58
75.	Rybix ODT	58
76.	Cefditoren	57
77.	Relexxii	57
78.	Rescriptor	57
79.	Predator	55

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:** Reditrex **Established name:** methotrexate **Dosage form:** Injection **Strength(s):** 7.5 mg/0.3 mL, 10 mg/0.4 mL, 12.5 mg/0.5 mL, 15 mg/0.6 mL, 17.5 mg/0.7 mL and 20 mg/0.8 mL, 22.5 mg/0.9 mL, and 25 mg/mL **Usual Dose:** RA-7.5 mg once weekly; Psoriasis 10 mg- 25 mg once weekly; pJLA-10 mg/m2 once weekly *Mark all proposed PNs with ****	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**
80.	Cleviprex	67	This name pair has sufficient orthographic and phonetic differences.
81.	Fanatrex	66	This name pair has sufficient orthographic and phonetic differences.
82.	Orgatrax	64	This name pair has sufficient orthographic and phonetic differences.
83.	Matrex	61	This name pair has sufficient orthographic and phonetic differences.
84.	Abitrexate	60	This name pair has sufficient orthographic and phonetic differences.
85.	Mitozytrex	60	This name pair has sufficient orthographic and phonetic differences.
86.	Orenitram	60	This name pair has sufficient orthographic and phonetic differences.
87.	Predicort RP	60	This name pair has sufficient orthographic and phonetic differences.
88.	Reprexain	59	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Reditrex **Established name:** methotrexate **Dosage form:** Injection **Strength(s):** 7.5 mg/0.3 mL, 10 mg/0.4 mL, 12.5 mg/0.5 mL, 15 mg/0.6 mL, 17.5 mg/0.7 mL and 20 mg/0.8 mL, 22.5 mg/0.9 mL, and 25 mg/mL **Usual Dose:** RA-7.5 mg once weekly; Psoriasis 10 mg- 25 mg once weekly; pJLA-10 mg/m2 once weekly *Mark all proposed PNs with ****	**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**
89.	Robitet	59	This name pair has sufficient orthographic and phonetic differences.
90.	Prednicot	58	This name pair has sufficient orthographic and phonetic differences.
91.	Reteplase	58	This name pair has sufficient orthographic and phonetic differences.
92.	Fluotrex	58	This name pair has sufficient orthographic and phonetic differences.
93.	Zerit XR	58	This name pair has sufficient orthographic and phonetic differences.
94.	Pediapred	57	This name pair has sufficient orthographic and phonetic differences.
95.	Rapiflux Deactivated according to RedBook however generics available	57	The upstroke letter 'd' vs. 'downstroke letter 'p' in the third position of the name pair and the additional upstroke letter 'l' in the 6th position of Rapiflux provide some orthographic differences. The third syllables ('trex' vs 'flux') of the names provide some phonetic differences. The following differences in product characteristics may also help to mitigate the risk of errors: • Frequency of Administration: Rapiflux is dosed once daily vs. Reditrex is administered once weekly. Therefore, due to the above-mentioned factors we find this name pair acceptable.

No.	**Proposed name:** Reditrex **Established name:** methotrexate **Dosage form:** Injection **Strength(s):** 7.5 mg/0.3 mL, 10 mg/0.4 mL, 12.5 mg/0.5 mL, 15 mg/0.6 mL, 17.5 mg/0.7 mL and 20 mg/0.8 mL, 22.5 mg/0.9 mL, and 25 mg/mL **Usual Dose:** RA-7.5 mg once weekly; Psoriasis 10 mg- 25 mg once weekly; pJLA-10 mg/m2 once weekly *Mark all proposed PNs with ****	**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**
96.	Pediatex CT	56	The letter 'a' between the letter string 'd-i' in Pediatex provides some orthographic differences. The root name Pediatex has an additional syllable. The third syllables ('trex' vs. 'a') sound different. Pediatex is available in multiple formulations therefore, the modifier (CT) will be included on a prescription/order. The modifier CT also provides orthographic and phonetic differences. The following differences in product characteristics may also help to mitigate the risk of errors: • Frequency of Administration: Pediatex CT is given 3 to 4 times daily vs. Reditrex is administered once weekly. Therefore, due to the above-mentioned factors we find this name pair acceptable.

No.	**Proposed name:** Reditrex **Established name:** methotrexate **Dosage form:** Injection **Strength(s):** 7.5 mg/0.3 mL, 10 mg/0.4 mL, 12.5 mg/0.5 mL, 15 mg/0.6 mL, 17.5 mg/0.7 mL and 20 mg/0.8 mL, 22.5 mg/0.9 mL, and 25 mg/mL **Usual Dose:** RA-7.5 mg once weekly; Psoriasis 10 mg- 25 mg once weekly; pJLA-10 mg/m2 once weekly *Mark all proposed PNs with ****	**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**
97.	Regitine	56	Reditrex has an upstroke letter 'd' in the third position whereas Regitine has a downstroke letter 'g' which provide some orthographic differences. The third syllables ('trex' vs 'tine') of the names provide some phonetic differences. The following differences in product characteristics may also help to mitigate the risk of errors: • Frequency of Administration/Setting of Use: Regitine is given prior to or during surgery or prevention of dermal necrosis associated with norepinephrine administration vs. Reditrex is administered once weekly. Therefore, due to the above-mentioned factors we find this name pair acceptable.
98.	Risedronate	56	This name pair has sufficient orthographic and phonetic differences.
99.	Veripred	56	This name pair has sufficient orthographic and phonetic differences.
100.	Sorbitrate	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 (%)
101.	Sterexidine	48(O71)
102.	Predair	50(O70)
103.	Digiter	52(O70)
104.	Mitride	52(O70)

No.	Name	POCA Score (%)
105.	Predate-50	52(O70)
106.	Erex	54(P71)
107.	Rexavite	54(O72)

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
108.	Pediatex 12	68	Discontinued drug product with no available generics
109.	Centrax	66	Discontinued drug product with no available generics
110.	Pedipirox-4	66	Discontinued drug product with no available generics
111.	Evitex	65	Veterinary Product
112.	Redux	65	Discontinued drug product with no available generics
113.	(b) (4) ***	64	Proposed proprietary name for (b) (4) found to be unacceptable (b) (4) no new proprietary name has been submitted for review.
114.	Robadex	64	Discontinued drug product with no available generics
115.	Virac Rex	64	Discontinued drug product with no available generics
116.	Vitrax	63	Discontinued drug product with no available generics
117.	Kantrex	62	Discontinued drug product with no available generics
118.	Lincorex	62	Veterinary Product
119.	Medinex	62	Foreign product
120.	Neutrexin	62	Discontinued drug product with no available generics
121.	Pediatex 12D	62	Discontinued drug product with no available generics
122.	Pediatex D	62	Discontinued drug product with no available generics
123.	Predicort-50	62	Discontinued drug product with no available generics
124.	Repronex	62	Discontinued drug product with no available generics

No.	Name	POCA Score (%)	Failure preventions
125.	Rondex	62	Discontinued drug product with no available generics
126.	Trimetrexate	62	Discontinued drug product with no available generics
127.	Ritodrine	61	Discontinued drug product with no available generics
128.	Dietrim ES	60	Discontinued drug product with no available generics
129.	Renormax	60	This name pair has sufficient orthographic and phonetic differences.
130.	Tussirex	60	Discontinued drug product with no available generics
131.	Aridex-D	58	Discontinued drug product with no available generics
132.	Imrex	58	Name identified in RxNorm database. Unable to find product in commonly used drug databases
133.	Tenkorex	60	Name identified in RxNorm database. Unable to find product in commonly used drug databases
134.	Re Dualvit F	58	Discontinued drug product with no available generics
135.	Retre-Gel	58	Discontinued drug product with no available generics
136.	Rinatec	58	Foreign product
137.	Raltitrexed	69	Foreign product
138.	Relifex	68	Foreign product
139.	(b) (4) ***	62	(b) (4)
140.	Pediatex TD	57	Discontinued drug product with no available generics
141.	Polistirex	57	Name only part of the established name/active ingredient for several products (i.e. Delsym) (e.g., chlorpheniramine polistirex, dextromethorphan polistirex etc.)?
142.	Revex	57	Discontinued drug product with no available generics
143.	Trichlorex	57	Discontinued drug product with no available generics
144.	Radiogenix***		(b) (4)

No.	Name	POCA Score (%)	Failure preventions
145.	Radish Extract	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
146.	Rapi-ject	56	Discontinued 510K cleared device
147.	(b) (4) ***	56	Proposed proprietary name for NDA (b) (4) found unacceptable ((b) (4) ; application received a Complete Response (CR).
148.	Ridactate	56	Discontinued drug product with no available generics
149.	Rymed-TR	56	Discontinued drug product with no available generics
150.	Ex-Dec-Tr	55	Name identified in RxNorm database. Unable to find product in commonly used drug databases
151.	Rideril	55	Discontinued drug product with no available generics
152.	Betadex	58	Foreign product
153.	Fematrix 40	69	Foreign product
154.	Fematrix 80	69	Foreign product

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

No.	Name	POCA Score (%)
155.	Aeroseb-Dex	55
156.	Ami-Tex	58
157.	Arimidex	66
158.	Atoperox	56
159.	Biothrax	56
160.	Bitex	59
161.	Breathrx	64
162.	Brintellix	62
163.	Britlofex	59
164.	Brontex	60
165.	Cetavlex	56
166.	Cidaflex	58
167.	Ciprodex	58
168.	Cortidex	63

[g] 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 (%)
169.	Crantex	62
170.	Debrox	59
171.	Degarelix	56
172.	Dextrates	58
173.	Dextrose 25%	55
174.	Dextrose 50%	55
175.	Dextrose 50%	55
176.	Dextrose 60%	55
177.	Digex	56
178.	Dilatrate	58
179.	Dilatrate-Sr	55
180.	Dilatrate-Sr	55
181.	Dilex	56
182.	Divaproex	65
183.	Doxytex	56
184.	(b) (4) ***	56
185.	Eltroxin	56
186.	Entex	56
187.	Entex Er	55
188.	Entre-S	56
189.	Epidiolex	56
190.	Eprinex	55
191.	Erbitux	64
192.	Ferndex	55
193.	Ferriprox	63
194.	Fertinex	60
195.	Imrex	58
196.	Keratex	56
197.	Kerledex	58
198.	Latrix	58
199.	Lead Tetroxide	55
200.	Liotrix	64
201.	Lymerix	58
202.	Matrix	58
203.	Medrox	60
204.	Med-Rx	60
205.	Metenix	55
206.	Metrovex	62
207.	Mintex	55
208.	Mite Extract	56
209.	Myrbetriq	58
210.	Pedtrace-4	58
211.	Pentrax	62

No.	Name	POCA Score (%)
212.	Phenytex	56
213.	Precedex	67
214.	Premesis Rx	58
215.	Preservex	60
216.	Previcox	60
217.	Prevident	58
218.	Pri-Dextra	56
219.	Prodrox	57
220.	Proferdex	60
221.	Protex	56
222.	Protex D	55
223.	Septra Ds	56
224.	Septra Ds	56
225.	Stiedex	58
226.	Sudatex	60
227.	Temetex	59
228.	Terbinex	60
229.	Tetroxy	62
230.	Tivorbex	56
231.	Tobradex	56
232.	Trianex	58
233.	Trifexis	58
234.	Trilipix	58
235.	Trimpex	63
236.	Trimpex 200	63
237.	Trintellix	64
238.	Trisenox	60
239.	Trispec Dex	62
240.	Trokendi Xr	58
241.	Uni-Tex	58
242.	Unit-Tex	58
243.	Vortex	55
244.	Zostrix	60

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