CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

1255456Orig1s000

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:	January 23, 2018
Application Type and Number:	BLA 125545
Product Name and Strength:	Retacrit ("Epoetin Hospira"*) Injection 2,000 units/mL, 3,000 units/mL, 4,000 units/mL, 10,000 units/mL, and 40,000 units/mL
Total Product Strength:	2,000 units/mL, 3,000 units/mL, 4,000 units/mL, 10,000 units/mL, and 40,000 units/mL
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Hospira
Panorama #:	2017-19145298
DMEPA Safety Evaluator:	Nicole Garrison, PharmD, BCPS
DMEPA Team Leader:	Hina Mehta, PharmD

* Retacrit has been developed as a proposed biosimilar to US-licensed Epogen/Procrit (epoetin alfa). Since the proper name for Retacrit has not yet been determined "Epoetin Hospira" is used throughout this review as the nonproprietary name for this product.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Retacrit, which was found conditionally acceptable under BLA 125545 on March 17, 2017.[a] We note that all product characteristics remain the same. The Applicant previously submitted an external name study, conducted by (b) (4) for this product, which was reviewed under OSE# 2015-47422[b].

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Hematology Products (DHP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 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 December 11, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on January 5, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DHP on January 22, 2018, they stated no additional concerns with the proposed proprietary name, Retacrit.

3 CONCLUSIONS

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

If you have any questions or need clarifications, please contact Wana Manitpisitkul, PharmD, OSE project manager, at 240-402-4156.

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[a] Garrison, N. Proprietary Name Review for Retacrit (BLA 125545). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); Insert Date as 2017 Mar 17. Panorama No. 2016-11762660.

[b] Vora, N. Proprietary Name Review for Retacrit (BLA 125545). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 Apr 3. OSE RCM No.: 2015-47422.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your November 17, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

NICOLE B GARRISON
01/23/2018

HINA S MEHTA
01/24/2018

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:	March 17, 2017
Application Type and Number:	BLA 125545
Product Name and Strength:	Retacrit ("Epoetin Hospira"*) Injection 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL, and 40,000 units/mL
Total Product Strength:	2000 units/mL, 3000 units/mL, 40000 units/mL, 10,000 units/mL, and 40,000 units/mL
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Hospira
Panorama #:	2016-11762660
DMEPA Primary Reviewer:	Nicole Garrison, PharmD, BCPS
DMEPA Team Leader:	Hina Mehta, PharmD

*Retacrit has been developed as a proposed biosimilar to US-licensed Epogen/Procrit (epoetin alfa). Since the proper name for Retacrit has not yet been determined, "Epoetin Hospira" is used throughout this review as the nonproprietary name for this product.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Retacrit, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant previously submitted an external name study, conducted by (b) (4) for this product, which was reviewed under OSE# 2015-47422. Subsequently, the Applicant submitted a gap search addendum to the previous report dated July 22, 2013.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Retacrit on January 16, 2015. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Retacrit acceptable in OSE# 2015-47422[a]; however, the application received a Complete Response (CR) on August 13, 2015. On December 22, 2016, the Applicant submitted a response to the CR letter. Thus, the Applicant submitted the name, Retacrit, for review.

1.2 PRODUCT INFORMATION

The following product information is provided in the December 22, 2016 proprietary name submission.

- Intended Pronunciation: Ret- Ə-krit
- Active Ingredient: Epoetin alfa
- Indication of Use:
    - For the treatment of anemia due to Chronic Kidney Disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion
    - For the treatment of anemia due to zidovudine administered at ≤ 4200 mg/week in HIV-infected patients with endogenous serum erythropoietin levels of ≤ 500 mUnits/mL
    - For the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy
    - Reduction of allogenic RBC transfusions among patients with perioperative hemoglobin > 10 to ≤ 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery
- Route of Administration: Intravenous and subcutaneous
- Dosage Form: Injection

[a] Vora, N. Proprietary Name Review for Retacrit (BLA 125545). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 Apr 3. OSE RCM No.: 2015-47422.

- Strength: 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL, and 40,000 units/mL
- Dose and Frequency:

Treatment of anemia due to Chronic Kidney Disease (CKD) in patients on dialysis and not on dialysis

- Adult patients: 50 to 100 units/kg 3 times weekly intravenously or subcutaneously.
- Pediatric patients: 50 units/kg 3 times weekly or intravenously is recommended. The intravenous route is recommended for patients on hemodialysis.

Treatment of anemia due to Zidovudine in HIV-infected patients

- The recommended starting dose in adult patients is 100 units/kg as an intravenous or subcutaneous injection 3 times per week.

Treatment of anemia due to chemotherapy in patients with cancer

- Adults: 150 units/kg subcutaneously 3 times per week until completion of a chemotherapy course or 40,000 units subcutaneously weekly for 4 weeks.
- Pediatric patients (5 to 18 years): 600 units intravenously weekly until completion of a chemotherapy course.

Treatment of anemic patients (hemoglobin > 10 to <13 g/dL) scheduled to undergo elective, noncardiac, nonvascular surgery to reduce the need for allogeneic blood transfusions

- The recommended regimens are 300 units/kg per day subcutaneously for 15 days total: administered daily for 10 days before surgery, on the day of surgery, and for 4 days after surgery. Alternatively, 600 units/kg can be administered subcutaneously in 4 doses on 21, 14, and 7 days before surgery and on the day of surgery.

- How Supplied: Single-dose, preservative-free vial: 1 mL of solution contains 2000, 3000, 4000, 10,000, or 40,000 units of epoetin alfa
- Storage: Store at 36°F to 46°F (2°C to 8°C). Do not freeze. Do not shake. Protect from light; store Retacrit in the carton until use. Do not use Retacrit that has been shaken or frozen.
- Reference Listed Drug: Epogen/Procrit BLA 103234

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Hematology Products (DHP) 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[b].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Retacrit, is derived from Hospira's biosimilar epoetin product currently marketed in Europe. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Eighty-three practitioners participated in DMEPA's prescription studies. In the voice study, one participant misinterpreted Retacrit for "Feratecrit," which is a close variation to the marketed product Ferrlecit (NDA 020955). Another participant in the voice study misinterpreted Retacrit for "Redecrit," which is a close variation to the marketed product, Edecrin (NDA 016092 and NDA 016093). Despite the misinterpretation in the FDA Rx Study, we do not think that the name pairs Retacrit and Ferrlecit or Retacrit and Edecrin, have the potential for confusion in the actual use environment for following reasons (See Appendix E for additional evaluation of both name pairs):

Retacrit vs. Ferrlecit

Retacrit and Ferrlecit (Combined POCA 50%) have sufficient orthographic and phonetic differences. Orthographically, the prefixes ('Ret' vs. 'Ferr') differ due to the upstroke letter in the 3rd position of Retacrit. The infixes ('a' vs. 'le') differ due to the upstroke letter 'l' in Ferrlecit. The first ('Ret' vs. 'Ferr') and second ('a' vs. 'le') syllables of this name pair have notable phonetic differences when spoken. Retacrit and Ferrlecit differ in terms of dose (weight-based vs. 125 mg once weekly) and strength (2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL vs. 62.5 mg/mL).

Retacrit vs. Edecrin

Retacrit and Edecrin (Combined POCA 62%) have sufficient orthographic and phonetic differences. Orthographically, Retacrit has two upstroke letters in the 3rd and 8th position (letter "t"), whereas Edecrin has one upstroke in the second position (letter "d"). The first sounds of the first syllable ('R' vs. 'E') and the ending sounds of the third syllables ('cri*t*' vs. 'cri*n*') sound different. Retacrit and Edecrin differ in terms of strength (2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL vs. 25 mg and 50 mg).

Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 17, 2017 e-mail, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

[b] USAN stem search conducted on January 4, 2017.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names retrieved from our POCA search[c] and also includes names identified from the FDA Prescription Simulation Study. These names are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	6
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	383
Low similarity name pair: combined match percentage score ≤54%	27

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

Our analysis of the 416 names contained in Table 1 determined 416 names will not pose a risk for confusion as described in Appendices C through H.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on March 10, 2017. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DHP on March 15, 2017, they stated no additional concerns with the proposed proprietary name, Retacrit.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Sue Kang, OSE project manager, at 301-796-4216.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 22, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

[c] POCA search conducted on January 23, 2017 in version 4.0.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

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

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

APPENDICES

Appendix A

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

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [d]

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

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥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[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.,

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

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.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

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

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

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

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

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

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 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	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation,

	upstroke/downstroke letters present in the names?		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

<table>
<tr><td></td><td colspan="2">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 rowspan="2">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 <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><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 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</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>
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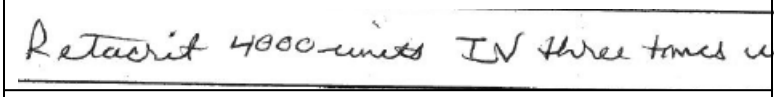
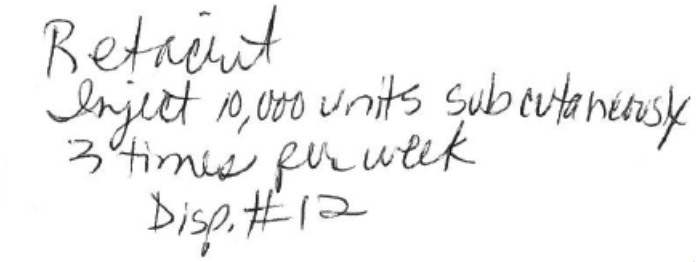
	scripted?	

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. Retacrit Study (Conducted on January 11, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Retacrit 4000 units IV three times	Retacrit Inject 10,000 units subcutaneously 3 times per week Disp. # 12
Outpatient Prescription:  Retacrit Inject 10,000 units subcutaneously 3 times per week Disp. #12	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

297 People Received Study

83 People Responded

Study Name: Retacrit

Total	27	22	34	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
FERATECRIT	0	1	0	1
RADICRIST	0	1	0	1
REACRIT	0	0	1	1
REDACRIT	0	1	0	1
REDECRIT	0	1	0	1
REDICRIT	0	8	0	8
REDIKRIT	0	1	0	1

RETACIAT	1	0	0	1
RETACRIT	24	4	32	60
RETICRET	0	1	0	1
RETICRIT	0	2	0	2
RETOCRIT	2	2	1	5

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

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):** 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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.	Retacrit***	100	Subject of this review

* Retacrit has been developed as a proposed biosimilar to US-licensed Epogen/Procrit (epoetin alfa). Since the proper name for Retacrit has not yet been determined, "Epoetin Hospira" is used throughout this review as the nonproprietary name for this product.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):** 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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.**
2.	Cetacort	76	This name pair begins with different letters ('c' vs. 'r') providing adequate orthographic differences. Retacrit contains the dotted letter "i" in the seventh position which is absent from Cetacort. Additionally, Retacrit ends with different letter strings ('rit' vs. 'ort'). The first (Re- vs. Ce-) and third (-crit vs. –cort) syllables of this name pair sound different. Additionally, the first letter 'R' in Retacrit further distinguishes this name pair as it has a post-alveolar approximant sound. Cetacort and Retacrit differ in terms of: Dose: apply to the affected area up to 3 to 4 times daily vs. weight-based Strength: 0.5% and 1% vs. 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL A strength must be specified for the dispensing of Cetacort and a dose must be specific for the dispensing of Retacrit, thus providing differentiating product characteristics.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):** 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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.**
3.	Resicort	74	Resicort is an anti-inflammatory lotion for veterinary use, which differs from Retacrit, which is an erythropoiesis-stimulating factor for human use.
4.	Retisert	72	This name pair has different infixes ('i' vs. 'a') and ends with different suffixes ('sert' vs. 'crit'). Retisert has upstroke dotted letter in the fourth position while Retacrit has an upstroke dotted letter in the seventh position. The second and third syllables of this name pair have notable differences when spoken ('i' vs. 'a' and 'sert' vs. 'crit'). Retisert differs from Retacrit in terms of: Dose: 1 implant vs. weight-based A dose must be specified when dispensing Retacrit, thus providing differentiating product characteristics. Strength: 0.59 mg vs. 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL Dosage form: insert vs. injection Route of administration: ophthalmic vs. intravenous and subcutaneous

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):** 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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.**
5.	Readi-Cat 2	71	This name pair has different infixes ('adi' vs. 'ta') and ends with different suffixes ('cat' vs. 'crit'). Readi-Cat 2 contains a modifier which is absent from Retacrit. The second and third syllables of this name pair have notable differences when spoken ('di' vs. 'ta' and 'cat' vs. 'crit'). Readi-Cat 2 has 4 syllables and Retacrit has 3 syllables. Readi-Cat 2 differs from Retacrit in terms of: Strength: 2% vs. 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL. Route of administration: oral vs. intravenous and subcutaneous A dose must be specified when dispensing Retacrit, thus providing differentiating product characteristics.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):** 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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.**
6.	Predacort 50	70	This name pair has different infixes ('da' vs. 'ta') and ends with different suffixes ('cort' vs. 'crit'). The first and third syllables of this name pair have notable differences when spoken ('Pre' vs. 'Ret' and 'cort' vs. 'crit'). Predacort 50 has 5 syllables and Retacrit has 3 syllables. Predacort 50 differs from Retacrit in terms of: Dose: 1 drop vs. weight-based A dose must be specified when dispensing Retacrit, thus providing differentiating product characteristics. Strength: 1% vs. 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL Route of administration: ophthalmic vs. intravenous and subcutaneous

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):** 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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.**
7.	Rectacreme	70 (Ortho - 78)	This product was identified in RxNorm, however it is listed with a modifier Rectacreme HC. Rectacreme HC is listed as discontinued per RedBook with no generic equivalents available.
8.	Uritact	70 (Ortho - 77)	This product was identified in RxNorm, however it is listed with modifiers as Uritact DS and EC. Uritact DS and EC are discontinued per RedBook and there are no generic equivalents available.

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	POCA Score (%)
1.	Cetapred	69 (phonetic- 72)
2.	Rotarix	68 (ortho- 70)
3.	Triacort	66 (ortho- 75)
4.	React	66 (ortho- 85)
5.	Restasis	65
6.	Cetiri-D	64 (ortho- 70)
7.	Cotacort	64
8.	Rectacreame	64 (ortho- 76)
9.	(b) (4) ***	64 (ortho- 73)
10.	Rotateq	64
11.	Zetacet	64 (ortho- 70)
12.	critic-Aid	62

No.	Name	POCA Score (%)
13.	Rectacaine	62 (ortho- 81)
14.	Rectacreme Hc	62 (ortho – 72)
15.	Rice Bran	62
16.	Recticare	62 (ortho- 79)
17.	Betatrex	61
18.	Estra-C	61 (ortho-71)
19.	Texacort	61 (ortho-72)
20.	Acticort	61
21.	Acticort 100	61
22.	Britaject	60 (ortho- 74)
23.	Rabavert	60
24.	Rena-Vite	60 (ortho- 72)
25.	Entocort	60
26.	Retavase	60
27.	Reteplase	60
28.	Triacet	60 (ortho- 77)
29.	Estrace	60 (ortho- 70)
30.	Rectiv	60 (ortho- 71)
31.	Triatex	60 (ortho- 70)
32.	(b) (4)***	60
33.	Dixarit	59
34.	Lacrisert	59 (ortho-74)
35.	Duetact	58
36.	Ramiprilat	58
37.	(b) (4)***	58
38.	Cetaderm	58
39.	Ertaczo	58
40.	Instacort	58
41.	Instacort 10	58
42.	Orabrite	58 (ortho- 72)
43.	Ravicti	58 (ortho- 70)
44.	Rhinatate	58
45.	Rt Capsin	58
46.	Theracort	58 (ortho-71)
47.	Metaglip	57
48.	Riociguat	57
49.	Retin-A Micro	57 (ortho – 74)
50.	Tretin X	57
51.	Triacetin	57 (ortho- 71)
52.	Renacidin	56
53.	Reumacetin	56
54.	Rhinaris	56
55.	Trital Sr	56

No.	Name	POCA Score (%)
56.	Delta Tritex	56 (ortho- 71)
57.	Racemistat	56 (ortho- 72)
58.	Ragwitek	56
59.	Raphtre	56
60.	R-Tannate	56
61.	Vaseretic	56
62.	Relagard	55
63.	Retapamulin	55
64.	Retin-A	55 (ortho-71)
65.	Arnica Extract	55 (ortho-74)
66.	Emerita	55 (ortho- 70)
67.	Nicorette	55
68.	Noritate	55
69.	Reticare Wipes	58 (ortho-71)
70.	Ceretec	53 (ortho-70)
71.	Arthriten	52 (ortho-71)
72.	Brethaire	49 (ortho-71)

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:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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.	Letairis	66 (ortho-72)	The prefixes and suffixes of this name pair have sufficient orthographic differences. The third syllable of this name pair sound different. Letairis has 4 syllables and Retacrit has 3 syllables.

* Retacrit has been developed as a proposed biosimilar to US-licensed Epogen/Procrit (epoetin alfa). Since the proper name for Retacrit has not yet been determined, "Epoetin Hospira" is used throughout this review as the nonproprietary name for this product.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
2.	Rectacort-Hc	66 (ortho-79)	The suffixes of this name pair have sufficient orthographic differences. Retacort-Hc has 11 letters, whereas Retacrit has 8 letters, giving it a shorter length when scripted. The third syllable of this name pair sound different. Rectacort-Hc has 4 syllables and Retacrit has 3 syllables. Retacrit differs from Rectacort-HC in terms of: Dose: 1 suppository vs. weight-based dosing Strength: 25 mg vs. 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL Dosage Form: suppository vs. injection Route of administration: rectal vs. intravenous and subcutaneous
3.	Ridactate	66 (ortho-71)	The infixes and suffixes of this name pair have sufficient orthographic differences. Ridactate has 3 upstrokes and Retacrit has 2 upstrokes. The second and third syllables of this name pair sound different.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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**
4.	Refacto	65 (ortho-73)	The suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
5.	Procrit	64 (ortho-70)	The prefixes of this name pair have sufficient orthographic differences. Procrit has 2 syllables and Retacrit has 3 syllables. The first syllable of this name pair sound different. Furthermore, these two products are highly similar and even if Procrit was administered instead of Retacrit, it would be acceptable since Procrit is the reference product for Retacrit. Thus, Procrit and Retacrit are both dosed the same and used for the same patient population.
6.	(b) (4)***	64	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
7.	Rescriptor	64 (ortho-72)	The infixes, and suffixes of this name pair have sufficient orthographic differences. Rescriptor has 10 letters and Retacrit has 8 letters, giving it a shorter length when scripted. The first, second and third syllables of this name pair sound different.
8.	(b) (4) ***	64	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
9.	Edecrin	62	Retacrit and Edecrin have sufficient orthographic and phonetic differences. Orthographically, Retacrit has two upstroke letters in the 3rd and 8th position (letter "t"), whereas Edecrin has one upstroke in the second position (letter "d"). The first sounds of the first syllable ('R' vs. 'E') and the ending sounds of the third syllables ('cri*t*' vs. 'cri*n*') sound different. Retacrit and Edecrin differ in terms of: Strength: 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL vs. 25 mg and 50 mg

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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**
10.	Methacort 40	62 (ortho-74)	The prefixes and infixes of this name pair have sufficient orthographic differences. Additionally, Retacrit has 2 upstrokes, whereas Methacort 40 has 3 upstrokes. The first syllable of this name pair sound different. Methacort 40 has 4 syllables and Retacrit has 3 syllables.
11.	Methacort 80	62 (ortho-74)	The prefixes and suffixes of this name pair have sufficient orthographic differences. Additionally, Retacrit has 2 upstrokes, whereas Methacort 80 has 3 upstrokes. The first syllable of this name pair sound different. Methacort 80 has 4 syllables and Retacrit has 3 syllables.
12.	(b) (4)***	62	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
13.	Restoril	62	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different. Restoril differs from Retacrit in terms of: Strength: 15 mg, 22.5 mg, 30 mg, and 7.5 mg vs. 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL Route of administration: oral vs. intravenous and subcutaneous Dosage form: capsule vs. injection
14.	Retet	62 (ortho-79)	The suffixes of this name pair have sufficient orthographic differences. Retacrit has 8 letters, whereas Retet has 5 letters, giving it a shorter length when scripted. The third syllable of this name pair sound different. Retet has 2 syllables and Retacrit has 3 syllables.
15.	Vanatrip	62 (phonetic-70)	The prefixes and suffixes of this name pair have sufficient orthographic differences. Additionally, Retacrit has 2 upstrokes, whereas Vanatrip has 1 upstroke and 1 downstroke. The first, second and third syllables of this name pair sound different.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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**
16.	Ritalin	61	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
17.	Raciran	60	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Additionally, Retacrit has 2 upstrokes, whereas Raciran does not have an upstroke. The first, second and third syllables of this name pair sound different.
18.	Ridiprin	60 (phonetic-75)	The prefixes and suffixes of this name pair have sufficient orthographic differences. Additionally, Retacrit has 2 upstrokes, whereas Ridiprin has 1 upstroke and 1 downstroke. The first and third syllables of this name pair sound different.
19.	Rituxan	60	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
20.	Tracrium	60 (ortho-72)	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
21.	Acetadrink	60	The prefixes and suffixes of this name pair have sufficient orthographic differences. Acetadrink has 10 letters, whereas Retacrit has 8 letters, giving it a shorter length when scripted. The first and third syllables of this name pair sound different.
22.	Acitretin	60 (ortho-71)	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
23.	Aricept	60 (ortho-73)	The prefixes, infixes, suffixes of this name pair have sufficient orthographic differences. Additionally, Retacrit has 2 upstrokes, whereas Aricept has 1 downstroke. The first, second, and third syllables of this name pair sound different.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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**
24.	Citrate	60 (ortho-70)	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllable of this name pair sound different. Citrate has 2 syllables and Retacrit has 3 syllables.
25.	Rucaparib	60	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Additionally, Retacrit has 2 upstrokes, whereas Rucaparib has 1 downstroke and 1 upstroke. All syllables of this name pair sound different. Rucaparib has 4 syllables and Retacrit has 3 syllables.
26.	Pentacarinat	59 (ortho-78)	The prefixes and suffixes of this name pair have sufficient orthographic differences. Pentacarinat has 12 letters, whereas Retacrit has 8 letters, giving it a shorter length when scripted. First and third syllable of this name pair sound different. Pentacarinat has 5 syllables and Retacrit has 3 syllables.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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**
27.	Reclast	58	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllable of this name pair sound different. Reclast has 2 syllables and Retacrit has 3 syllables.
28.	Retaine	58 (ortho-77)	The suffixes of this name pair have sufficient orthographic differences. Additionally, Retacrit has 2 upstrokes, whereas Retaine has 1 upstroke. The second syllable of this name pair sound different. Retaine has 2 syllables and Retacrit has 3 syllables. Retaine differs from Retacrit in terms of: Dose: 1 to 2 drops vs. weight-based dosing Strength: 5% vs. 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL Dosage form: solution vs. injection Route of administration: ophthalmic vs. intravenous and subcutaneous

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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**
29.	Retaine Pm	58	The suffixes of this name pair have sufficient orthographic differences. Additionally, Retacrit has 2 upstrokes, whereas Retaine has 1 upstroke. The second syllable of this name pair sound different. Retaine Pm has 4 syllables and Retacrit has 3 syllables. Retaine Pm differs from Retacrit in terms of: Dose: apply a small amount vs. weight-based dosing Strength: 20%-80% vs. 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL Dosage form: ointment vs. injection Route of administration: ophthalmic vs. intravenous and subcutaneous
30.	Rexavite	58 (ortho-72)	The infixes and suffixes of this name pair have sufficient orthographic differences. Additionally, Retacrit has 2 upstrokes, whereas Rexavite has 1 upstroke. The second and third syllables of this name pair sound different.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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**
31.	Rizatriptan	58	The prefixes, infixes, suffixes of this name pair have sufficient orthographic differences. Rizatriptan has 11 letters, whereas Retacrit has 8 letters, giving it a shorter length when scripted. The first, second and third syllables of this name pair sound different. Rizatriptan has 4 syllables and Retacrit has 3 syllables.
32.	Robitet	58	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
33.	Robitet 500	58	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different. Robitet 500 has 4 syllables and Retacrit has 3 syllables.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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**
34.	Grape Extract	58 (ortho-70)	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Additionally, Grape Extract has 12 letters, whereas Retacrit has 8 letters, giving it a shorter length when scripted. The first, second and third syllables of this name pair sound different.
35.	Oracit	58 (ortho-79)	The prefixes of this name pair have sufficient orthographic differences. Additionally, Retacrit has 8 letters, whereas Oracit has 6 letters, giving it a shorter length when scripted. The first syllables of this name pair sound different.
36.	Rimactane	58	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.
37.	Secretin	58	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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.	Ethacrynate	57 (ortho-71)	The prefixes and suffixes of this name pair have sufficient orthographic differences. Additionally, Ethacrynate has 11 letters, whereas Retacrit has 8 letters, giving it a shorter length when scripted. The first and third syllables of this name pair sound different. Ethacrynate has 4 syllables and Retacrit has 3 syllables.
39.	Res-Q-Dent	57	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.
40.	Rifater	57	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
41.	Rytary	57	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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**
42.	Recothrom	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
43.	Repan Cf	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different. Repan Cf has 4 syllables and Retacrit has 3 syllables.
44.	Respa-1St	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
45.	Respahist	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
46.	Respi-Tann	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.

No.	Proposed name: Retacrit Established name: "Epoetin Hospira*" Dosage form: Injection Strength(s):2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL Usual Dose: Anemia due to Chronic Kidney Disease: Adults 50 to 100 units/kg IV or SQ three times a week. Pediatric: 50 units/kg IV or SQ weekly Anemia due to chemotherapy: Adults: 150 to 300 units/kg three times a week. Adults: 40,000 to 60,000 units SQ weekly for 4 weeks. Pediatric: 600 to 900 units/kg IV weekly	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
47.	(b) (4)***	56	The suffixes of this name pair have sufficient orthographic differences. (b) (4)
48.	Rhinocort	56	The prefixes, infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
49.	Ribatab	56	The prefixes, infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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**
50.	Roxicet	56	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
51.	Vistacot	56	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
52.	Meritate	56	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
53.	Oretic	56 (ortho-71)	The prefixes and suffixes of this name pair have sufficient orthographic differences. Additionally, Retacrit has 8 letters, whereas Oretic has 6 letters, giving it a shorter length when scripted. The first and third syllables of this name pair sound different.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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**
54.	Remicade	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
55.	Retrovir	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
56.	(b) (4) ***	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
57.	Vaseretic 10-25	56	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different. Vaseretic 10-25 has 6 syllables and Retacrit has 3 syllables.
58.	Vaseretic 5-12.5	56	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different. Vaseretic 5-12.5 has 7 syllables and Retacrit has 3 syllables.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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**
59.	Ramipril	55	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.
60.	Ascriptin	55	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.
61.	etanercept	55	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different. Etanercept has 4 syllables and Retacrit has 3 syllables.
62.	Metaprel	55	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
63.	Red Yeast Rice	55	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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**
64.	Revitaderm 40	55	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different. Revitaderm 40 has 5 syllables and Retacrit has 3 syllables.
65.	Rifamate	55	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.
66.	R-Tannic-S A/D	55	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The third syllable of this name pair sounds different. R-Tannic-S A/D has 6 syllables and Retacrit has 3 syllables.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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**
67.	Ferrlecit	50 (Ortho-71)	Retacrit and Ferrlecit have sufficient orthographic and phonetic differences. Orthographically, the prefixes ('Ret' vs. 'Ferr') differ due to the upstroke letter in the 3rd position of Retacrit. The infixes ('a' vs. 'le') differ due to the upstroke letter 'l' in Ferrlecit. The first ('Ret' vs. 'Ferr') and second ('a' vs. 'le') syllables of this name pair have notable phonetic differences when spoken. Retacrit and Ferrlecit differ in terms of: Dose: weight-based vs. 125 mg once weekly Strength: 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL vs. 62.5 mg/mL
68.	Accuretic	54 (Ortho-71)	The prefixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sounds different. Accuretic has 4 syllables and Retacrit has 3 syllables,
69.	Cetacaine	54 (Ortho-71)	The suffixes of this name pair have sufficient orthographic differences. The third syllable of this name pair sounds different.

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira*" **Dosage form:** Injection **Strength(s):**2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adults 50 to 100 units/kg IV or SQ three times a week. **Pediatric:** 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adults: 150 to 300 units/kg three times a week. **Adults:** 40,000 to 60,000 units SQ weekly for 4 weeks. **Pediatric:** 600 to 900 units/kg IV weekly	**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**
70.	Beta Carotene	54 (Ortho-70)	The infixes and suffixes of this name pair have sufficient orthographic differences. The third of this name pair sounds different. Beta Carotene has 5 syllables and Retacrit has 3 syllables.

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

No.	Name	POCA Score (%)
1.	Tetracaine	52
2.	Acai Extract	52
3.	Cat hair extract	48
4.	Cerinta	52
5.	Neutracare mint	52
6.	Tea Tree Extract	50
7.	Americet	53
8.	Creatine	51
9.	Liver Extract	51
10.	Articaine	52
11.	Calcitare	44
12.	Clearly IT!	52
13.	Corn Extract	53
14.	Edarbi CLT	54

No.	Name	POCA Score (%)
15.	Edarbi CTD	54
16.	Okra extract	53
17.	Apricot Extract	52
18.	Arctice	49
19.	Elder Extract	50
20.	Gericet	52
21.	Licorice Extract	50
22.	Tartaric acid	50
23.	Tilia Extract	47
24.	Triacin	52
25.	Turmeric Extract	48
26.	Ureacin-10	53
27.	Ureacin-20	53

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.	Uritact	70 (ortho-77)	This name was identified in RxNorm. The brand name is discontinued per RedBook and there are no generic equivalents available.
2.	(b) (4)***	68 (ortho-78)	The proposed name was found unacceptable in OSE# (b) (4). Subsequently, the Applicant submitted the proposed name, Trulance*** on November 18, 2015 under IND 74883 and on February 23, 2016 under NDA 208745. The proposed name, Trulance*** was found acceptable in OSE # 2015-2032572 and 2016-2862855.
3.	Renitec	64 (ortho-70)	This is an international product marketed In Argentina, Australia, Austria, Belgium, Brazil and China.
4.	Tacrine	64 (ortho-80)	This name was identified in RxNorm. However this product has been withdrawn FR effective 8/19/13.There are no generic equivalents available.
5.	Rinatec	63	This an international product marketed in Ireland and the UK.
6.	Vetaket	62	This product is not a drug, it is a veterinary product.
7.	Betadren	61	This is an international product formerly marketed Italy, Germany, and Greece.
8.	Ceteareth 20	61 (ortho-74)	This product is not a drug it is a mixture of cetyl and stearyl alcohol, and ethylene oxide.

No.	Name	POCA Score (%)	Failure preventions
9.	Ceteareth 8	61(ortho-74)	This product is not a drug it is a mixture of cetyl and stearyl alcohol, and ethylene oxide.
10.	Ceteareth-10	61 (ortho-74)	This product is not a drug it is a mixture of cetyl and stearyl alcohol, and ethylene oxide.
11.	Ceteareth-12	61 (ortho-74)	This product is not a drug it is a mixture of cetyl and stearyl alcohol, and ethylene oxide.
12.	Ceteareth-15	61 (ortho-74)	This product is not a drug it is a mixture of cetyl and stearyl alcohol, and ethylene oxide.
13.	Ceteareth-2	61 (ortho-74)	This product is not a drug it is a mixture of cetyl and stearyl alcohol, and ethylene oxide.
14.	Ceteareth-22	61 (ortho-74)	This product is not a drug it is a mixture of cetyl and stearyl alcohol, and ethylene oxide.
15.	Ceteareth-25	61 (ortho-74)	This product is not a drug it is a mixture of cetyl and stearyl alcohol, and ethylene oxide.
16.	Ceteareth-30	61 (ortho-74)	This product is not a drug it is a mixture of cetyl and stearyl alcohol, and ethylene oxide.
17.	Ceteareth-33	61 (ortho-74)	This product is not a drug it is a mixture of cetyl and stearyl alcohol, and ethylene oxide.
18.	Ceteareth-6	61 (ortho-74)	This product is not a drug it is a mixture of cetyl and stearyl alcohol, and ethylene oxide.
19.	Estracyt	61 (Ortho-72)	This is an international product.
20.	(b) (4)***	60	The proposed name was found acceptable in OSE# (b) (4). However, the name was withdrawn by the Applicant on (b) (4). Subsequently, the Applicant submitted the name, (b) (4) which was approved in OSE# (b) (4). This name is evaluated in Appendix E.
21.	Reviparin	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
22.	Riociquat***	60	Riociquat is the established name for the product, Adempas which is approved under NDA 204819.
23.	Rynacrom	60 (Phonetic-70)	This is an international product marketed in Turkey, Ireland, Australia, Mexico, Singapore, and Thailand.
24.	Uritact Ds	60	This name was identified in RxNorm. The brand name is discontinued per RedBook and there are no generic equivalents available.
25.	Rapi-Ject	60	This product is not a drug, it is drug delivery tubing.
26.	Respiclick***	60	This is the modifier for ProAir (Albuterol Sulfate), Air Duo (Fluticasone Propionate and Salmeterol), and ArmonAir (Fluticasone Propionate).

No.	Name	POCA Score (%)	Failure preventions
27.	Renotec	59	This name was identified in Drugs at FDA. However, this product is listed as discontinued. It was withdrawn FR effective 3/13/09. There are no generic equivalents available.
28.	Ritodrine	59	This name was identified in RxNorm. However this product has been withdrawn FR effective 3/12/93. There are no generic equivalents available.
29.	Arachidate	59 (ortho-72)	This product is not a drug, it is a saturated fatty acid.
30.	(b) (4)***	59 (ortho-73)	The proposed name was found unacceptable in OSE# (b) (4). Subsequently, the Applicant submitted the proposed name, Symproic, which was approved in OSE# 2015-1115398.
31.	Metacresol	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
32.	Rectocort Hc	58	This name was identified in RxNorm database. The brand name is discontinued per Redbook and there are no generic equivalents available.
33.	Relaxin	58	This is an internal product marketed in Japan.
34.	Resmethrin	58	This is not a drug, it is an insecticide.
35.	Ritifed	58	This name was identified in RxNorm. The brand name is discontinued per RedBook and there are no generic equivalents available.
36.	Rivotril	58	This is an international product marketed in Japan, Turkey, Greece, Argentina, Australia, Austria. Beligium, and Brazil.
37.	Vetadryl	58	This product is a veterinary product.
38.	Artracin	58 (ortho-75)	This is an international product formerly marketed in the UK
39.	Ethacridine	58 (ortho-74)	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
40.	Tritec	58 (ortho-75)	Name identified in Drugs At FDA, however it was withdrawn FR effective 9/13/00. There are no generic equivalents available.
41.	Retin-A Forte	57 (ortho-71)	This is an internal product marketed in Mexico.
42.	Rapinovet	56	This product is an anesthetic for veterinary use.
43.	Resaid	56	This name was identified in Redbook. However, the brand name of this product is listed as discontinued. There are no generic equivalents available.
44.	Rimacid	56	This is an international product marketed in the UK.

No.	Name	POCA Score (%)	Failure preventions
45.	Rotersept	56	This is an international product formerly marketed in Belgium and the UK.
46.	Roxicet 5/500	56	The brand, Roxicet 5/500 is discontinued with no generic equivalents.
47.	Betadur Cr	56	This is an international product formerly marketed in the UK.
48.	Bretylate	56	This is an international product formerly marketed in the Israel and Singapore.
49.	Carrot Extract	56 (ortho-71)	This product is not a drug, it is an oil based extract from carrots.
50.	Certeareth-100	56 (ortho-72)	This product is not a drug it is a mixture of cetyl and stearyl alcohol, and ethylene oxide.
51.	Etretinate	56 (ortho-72)	This name was identified in RxNorm. However this product has been withdrawn FR effective 9/10/03. There are no generic equivalents available.
52.	(b) (4) ***	56 (ortho-72)	This is an alternate proprietary name submitted for (b) (4) The IND is still active with no name that has been found acceptable.
53.	Mite Extract	56 (ortho-71)	This product is not a drug, it is a pesticide.
54.	Pariet	56 (ortho-71)	This is an international product in various countries.
55.	Starch, Rice	56 (ortho-72)	This product is not a drug, it is a food.
56.	Totaretic	56 (ortho-71)	This is an international product formerly marketed in the UK.
57.	Rantec	55	This is an international product marketed in the UK.
58.	Rideril	55	This is an international product formerly marketed in the UK.
59.	Clarite	50 (ortho-73)	This is an international product marketed in Canada.
60.	Altacite	53 (ortho-72)	This is an international product marketed in the UK.
61.	Hectorite	53 (ortho-71)	This product is not a drug it is a white clay mineral.
62.	Encreta	62 (ortho-70)	Name identified in POCA database. Unable to find product characteristics in internal databases.
63.	Rheumatac Retard	54 (ortho-70)	This is an international product marketed in the UK.

No.	Name	POCA Score (%)	Failure preventions
64.	Terra cortril	54 (ortho-70)	Name identified in POCA, however it was withdrawn FR effective 4/27/09. There are no generic equivalents available.

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

No.	Name	POCA Score (%)
1.	Predicort-50	66
2.	Tricaprin	65
3.	Entaprin	64
4.	Triferic	64
5.	Adcetris	63
6.	Cresatin	63
7.	Tramacort	63
8.	Vectrin	63
9.	Dexacort	62
10.	Ecotrin	62
11.	Epicort	62
12.	Picrate	62
13.	Aristocort	61
14.	Catapres	61
15.	Kenacort	61
16.	Tartrate	61
17.	Zentrip	61
18.	Basic Red 51	60
19.	Cafetrate	60
20.	Cytadren	60
21.	Estrate	60
22.	Pramcort	60
23.	Predacorten	60
24.	Propacet	60
25.	Propacet 100	60
26.	Satric	60
27.	Tecentriq	60
28.	Tetracap	60
29.	Trecator	60

[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 (%)
30.	Triaprin	60
31.	Trivaris	60
32.	Fectrim	59
33.	Gestrin	59
34.	Isotrate	59
35.	Orenitram	59
36.	Orotic Acid	59
37.	Septrin	59
38.	Tricitrates	59
39.	Uticort	59
40.	Adrenaclick	58
41.	Bactrim	58
42.	Bethaprim	58
43.	Cenocort	58
44.	Clinacort	58
45.	Corifact	58
46.	Delta-Cortef	58
47.	Dermacort	58
48.	Dexatrim	58
49.	Dricort	58
50.	Elestrin	58
51.	Enaprilat	58
52.	Ergotrate	58
53.	(b) (4)***	58
54.	Frusetic	58
55.	Grisactin	58
56.	Grisactin 250	58
57.	Grisactin 500	58
58.	Jet-Alert	58
59.	Lactrase	58
60.	Ledercort	58
61.	(b) (4)***	58
62.	Medicort	58
63.	Mega-Trim	58
64.	Myrbetriq	58
65.	Nasacort	58
66.	Paracort	58
67.	Preferid	58
68.	Premarin	58
69.	Prevacid	58
70.	Stie-Cort	58
71.	Trasicor	58
72.	Tri-Nefrin	58

No.	Name	POCA Score (%)
73.	Vitrasert	58
74.	Westcort	58
75.	Xebcort	58
76.	Ardeparin	57
77.	Esoterica	57
78.	Fematrix 40	57
79.	Fematrix 80	57
80.	Laratrim	57
81.	Lidocort	57
82.	Triactin	57
83.	Trintex	57
84.	Tri-Tannate	57
85.	Uric Acid	57
86.	Veteribac	57
87.	(b) (4)***	57
88.	Acetic Acid	56
89.	Actedril	56
90.	Acticlate	56
91.	Altafrin	56
92.	Arestin	56
93.	Aristocort A	56
94.	Aristocort R	56
95.	Arixtra	56
96.	Articadent	56
97.	Briviact	56
98.	Caltrate	56
99.	Cartia Xt	56
100.	Certican	56
101.	Certoparin	56
102.	Citravet	56
103.	Cometriq	56
104.	Corticreme	56
105.	Creo-Terpin	56
106.	Drotaverin	56
107.	Duratestrin	56
108.	Eldecort	56
109.	Emagrin	56
110.	Eradacin	56
111.	Exaprin	56
112.	Femtrace	56
113.	Ferric Citrate	56
114.	Loestrin	56
115.	Loestrin 21 1.5/30	56

No.	Name	POCA Score (%)
116.	Loestrin 21 1/20	56
117.	Lyrica Cr	56
118.	(b) (4)***	56
119.	(b) (4)***	56
120.	Meticorten	56
121.	Nutracort	56
122.	Ormetoprim	56
123.	Otocort	56
124.	Pacitron	56
125.	Pedtrace-4	56
126.	Predaject-50	56
127.	Predicort Rp	56
128.	Prevacare R	56
129.	Primacor I.V.	56
130.	Proctocort	56
131.	Procto-Kit	56
132.	Sebacate	56
133.	Sudatrate	56
134.	Synacort	56
135.	Tagrisso	56
136.	(b) (4)***	56
137.	Tetra-Ide	56
138.	Theracran	56
139.	Topicort	56
140.	Tramacort-D	56
141.	Trideceth-10	56
142.	Trideceth-12	56
143.	Trideceth-5	56
144.	Trideceth-6	56
145.	Trideceth-8	56
146.	Trideceth-9	56
147.	Trifexis	56
148.	Tri-Kort	56
149.	Tri-Statin	56
150.	Tristearin	56
151.	Uristat	56
152.	Vetribute	56
153.	Virac Rex	56
154.	Viracept	56
155.	Xpect-At	56
156.	Zactran	56
157.	Zestril	56
158.	Cepastat	55

No.	Name	POCA Score (%)
159.	Crantex	55
160.	Depestrate	55
161.	Edetic Acid	55
162.	Esbriet	55
163.	Fetrin	55
164.	Penecort	55
165.	Prednicot	55
166.	Primestrin	55
167.	Promacet	55
168.	Tetracon	55
169.	Tetracyn	55
170.	Tridecane	55
171.	Ultragris-165	55
172.	Ultragris-330	55
173.	Westrim	55
174.	Zinecard	55

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
1.	N/A

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

NICOLE B GARRISON
03/17/2017

HINA S MEHTA
03/17/2017

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:	April 3, 2015
Application Type and Number:	BLA 125545
Product Name and Strength:	Retacrit ("Epoetin Hospira"*) Injection, 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Hospira
Panorama #:	2015-47422
DMEPA Primary Reviewer:	Neil Vora, PharmD, MBA
DMEPA Team Leader:	Yelena Maslov, PharmD

* Retacrit has been developed as a proposed biosimilar to the US-licensed Epogen®/Procrit® (epoetin alfa). Since the nonproprietary name for Retacrit has not yet been determined, "Epoetin Hospira" is used throughout this review as the nonproprietary name for this product.

Contents

1 INTRODUCTION

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

1.1 PRODUCT INFORMATION

The following product information is provided in the January 16, 2015 proprietary name submission.

- Intended Pronunciation: Ret-ə-krit
- Active Ingredient: "Epoetin Hospira"*
- Indication of Use:
    - Treatment of anemia due to Chronic Kidney Disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion
    - Treatment of anemia due to zidovudine administered at < 4200 mg/week in HIV-infected patients with endogenous serum erythropoietin levels of < 500 mUnits/mL
    - Treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy
    - Reduction of allogeneic RBC transfusions among patients with perioperative hemoglobin > 10 to < 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery
- Route of Administration: Intravenous or subcutaneous injection
- Dosage Form: Solution for injection
- Strength: 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL, 40,000 units/mL

* Retacrit has been developed as a proposed biosimilar to the US-licensed Epogen®/Procrit® (epoetin alfa). Since the nonproprietary name for Retacrit has not yet been determined, "Epoetin Hospira" is used throughout this review as the nonproprietary name for this product.

- Dose and Frequency:

Indication	Dose and Frequency
Anemia due to Chronic Kidney Disease	• Adult: 50 to 100 units/kg IV or SQ three times a week • Pediatric: 50 units/kg IV or SQ weekly
Anemia due to chemotherapy	• Adult: 150 to 300 units/kg three times a week • Adult: 40,000 to 60,000 units SQ weekly for 4 weeks • Pediatric: 600 to 900 units/kg IV weekly

- How Supplied: Single-dose vials
- Storage: Refrigerated at 2°C to 8°C (36°F to 46°F). Dot not freeze. Do not shake. Protect from light.
- Container and Closure Systems: Single-dose vial individually packed in a carton

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Hematology Products (DHP) 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[1].

2.2.2 Components of the Proposed Proprietary Name

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

[1]USAN stem search conducted on March 3, 2015.

2.2.4 FDA Name Simulation Studies

Eighty 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. Common misinterpretations included;

- "r" for "p"
- "i" for "e"
- "r" for "b"
- "a" for "i"
- "t" for "d"
- Insertion of the letter "s"
- Insertion of the letter "q"
- "r" for "u"

Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines at Initial Review

In response to the OSE, February 11, 2015 e-mail, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation and by (b) (4).

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	241
Low similarity name pair: combined match percentage score ≤49%	4

[2] POCA search conducted on March 2, 2015.

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

Our analysis of the two hundred and forty six names contained in Table 1 determined none of the names will pose a risk for confusion 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 Hematology Products (DHP) via e-mail on March 12, 2015. At that time we also requested additional information or concerns that could inform our review. DHP expressed their concern during the initial phase as well as during the midpoint with accepting the proposed name, Retacrit. DHP noted that the use of the same name as the EU-version would be problematic due to product differences between the EU and US products. This may lead to confusion that clinical (or any) information for EU-Retacrit is applicable to US-Retacrit. Additionally, they were also concerned that in the event of a shortage, if the EU-approved Retacrit would need to be imported, there would not be a way of distinguishing between the products if they have the same name.

DMEPA considered the concern articulated by DHP. However, we find it does not form a sufficient regulatory reason to deny the proposed Retacrit name. With respect to the clinical concern raised regarding mis-referencing of EU product information, we find that the concern is adequately managed in labeling as the prescribing information clearly references initial US approval date of the drug substance as part of the title line to indicate the product's US labeling. With respect to importation of EU-Retacrit to handle future shortages, any such risks that might be related to the shared Retacrit name and the possible importation of EU-Retacrit would be carefully considered and addressed as needed in concert with DHP and the Drug Shortages Staff at that time.

Given that we had not identified any misbranding or look-alike sound-alike safety concerns, and for the considerations described above relating to the EU-Retacrit product, we recommended to DHP and TBBT that we accept the use of the Retacrit name for Epoetin-Hospira. Both groups agreed on March 23, 2015 and March 24, 2015.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Sarah Harris, OSE project manager, at 240-402-4774.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your January 16, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

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 DNCE. OPDP or DNCE 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 DNCE 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. [3]

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

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

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

	product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form, etc.) may be limited when the strength or dose overlaps. We review such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the

name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

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

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

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

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

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

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 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 do 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?	**Y/N**	Do the names have different syllabic stresses?

	**FDA considers the length of names different if the names differ by two or more letters.*		
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 ≥50% 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: o 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. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o 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 ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Retacrit Study (Conducted on January 30, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Retacrit 4000 units three times weekly	Retacrit Inject 10,000 units subcutaneously, 3 times per week. #12
Outpatient Prescription: Retacrit inject 10,000 units subcutaneously three times per week Dispense # 12	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

252 People Received Study

80 People Responded

Study Name: Retacrit

Total	**27**	**27**	**26**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
BRETICRIT	0	1	0	1
PETACRET	1	0	0	1
PETACRIT	1	0	0	1
REDACRIT	0	1	0	1
REDICREST	0	1	0	1
REDICRISS	0	1	0	1
REDICRIT	0	14	0	14
REDOCRIT	0	1	0	1
RETACRET	2	0	0	2
RETACRIT	23	4	26	53
RETICRIT	0	2	0	2
RETIQUIT	0	1	0	1
RETRICRIT	0	1	0	1

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

No.	**Proposed name:** Retacrit **Established name:** "Epoetin Hospira" **Dosage form:** Injection **Strength(s):** 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL (vials) **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adult: 50 to 100 units/kg IV or SQ three times a week. Pediatric: 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adult: 150 to 300 units/kg three times a week. Adult: 40,000 to 60,000 units SQ weekly for 4 weeks. Pediatric: 600 to 900 units/kg IV weekly	**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.	Retitrate	74	The name identified is not a drug name. The suffix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sound different.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	retISERT	68
2.	Readi-Cat 2	66
3.	LetaIRIS	64

4.	Rotarix	64
5.	Zetacet	64
6.	Relarity	63
7.	retasqi	62
8.	Restart	62
9.	Ridiprin	62
10.	Rizaport	60
11.	Hematocrit	60
12.	RESTASIS	60
13.	ritALIN	60
14.	RotaTeq	59
15.	Cotacort	58
16.	RECLAST	58
17.	RESTORIL	58
18.	EDEcriN	57
19.	Reticular	57
20.	Relaxin	57
21.	Vistacot	57
22.	Rena-Vite	56
23.	ReadyPrep	56
24.	Res-Q-Dent	56
25.	Vanatrip	56
26.	Relagard	55
27.	retaVASE	55
28.	BetaTREX	54
29.	critIC-AID	54
30.	DUetacT	54
31.	LacriSERT	54
32.	Rectacort-HC	54
33.	RENACIDIN	54

34.	Rebitech	54
35.	Rexavite	54
36.	Ri-Tussin	54
37.	ROBAXIN	54
38.	ROBAXIN-750	54
39.	REPRALTA	53
40.	RYDAPT	53
41.	Rezamid	53
42.	RYTARY	53
43.	LAStacAFT	52
44.	Recalcitrant	52
45.	Reticulocyte	52
46.	MetaGLIP	52
47.	RAMIPRIL	52
48.	Rectacaine	52
49.	RELPAX	52
50.	Respa-BR	52
51.	Rhinaris	52
52.	ritALIN-SR	52
53.	ritifed	52
54.	Ron Acid	52
55.	ROXICET	52
56.	ROXICET 5/500	52
57.	Respi-TANN	51
58.	rizatriptan	51
59.	Trital SR	51
60.	Betasept	50
61.	MetaNDREN	50
62.	Rembrandt	50
63.	Repiderm	50

64.	Respivent	50
65.	retaine	50
66.	retaine PM	50
67.	retapamulin	50
68.	Reumacetin	50
69.	RHINOCORT	50
70.	Rid-A-Pain	50
71.	riociguat	50
72.	RisaQuad	50
73.	ritALIN LA	50
74.	ReQuip CR	50
75.	retaane	50

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Retacrit **Established name: "**Epoetin Hospira" **Dosage form:** Injection **Strength(s):** 2000 units/mL, 3000 units/mL, 4000 units/mL, 10,000 units/mL and 40,000 units/mL (vials) **Usual Dose:** **Anemia due to Chronic Kidney Disease:** Adult: 50 to 100 units/kg IV or SQ three times a week. Pediatric: 50 units/kg IV or SQ weekly **Anemia due to chemotherapy:** Adult: 150 to 300 units/kg three times a week. Adult: 40,000 to 60,000 units SQ weekly for 4 weeks. Pediatric: 600 to 900 units/kg IV weekly	**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.	Procrit	64	The prefix of this name pair has sufficient orthographic differences. The first syllables of this name pair sound different. Retacrit contains an extra syllable. Furthermore, these two products are identical and even if Procrit was administered instead of Retacrit, it would be acceptable since they are both dosed the same and used for the same patient population.
2.	ReFacto	60	The infix and suffix of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.

3.	(b) (4) ***	58	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
4.	REScriPTOR	58	The infix and suffix of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.
5.	Ridactate	58	The infix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
6.	ritUXAN	54	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
7.	Redutemp	53	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
8.	RibaTab	52	The suffix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sound different.
9.	RIBAVIRIN	52	The infix and suffix of this name pair have sufficient orthographic differences. The second, third and fourth syllables of this name sound different. Retacrit also has one less syllable.
10.	RIFADIN	52	The infix and suffix of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.

11.	Recothrom	50	The prefix, infix and suffix of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.
12.	RIFATER	50	The suffix of this name pair has sufficient orthographic differences. The first and third syllables of this name pair sound different.
13.	TRacriUM	50	The prefix, infix and suffix of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤49%)

No.	Name	POCA Score (%)
1.	Retin-A	49
2.	Relafen	46
3.	Antacid	42
4.	Revlimid	40

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.	CetacORT	66	Discontinued product with no generic equivalent available.
2.	Resicort	66	Veterinary product
3.	Uritact	64	Discontinued product with no generic equivalent available.

4.	Rectacreme	62	Discontinued product with no generic equivalent available.
5.	Rynacrom	62	International product, not marketed in the U.S.
6.	Betadren	60	International product, not marketed in the U.S.
7.	CetaPRED	60	Discontinued product with no generic equivalent available.
8.	retET	60	No information could be found in both internal and external databases
9.	ROBITET	59	Discontinued product with no generic equivalent available.
10.	Robitet 500	59	Discontinued product with no generic equivalent available.
11.	(b) (4) ***	58	Name withdrawn by sponsor, OSE# (b) (4)
12.	Respa-1st	58	Discontinued product with no generic equivalent available.
13.	Vetadryl	58	Veterinary product
14.	ritodrine	57	Discontinued product with no generic equivalent available.
15.	RabAvert	56	Veterinary product
16.	Rectacreame	56	Name found in RxNorm. No product characteristics available in common drug references.
17.	Renitec	56	International product, not marketed in the U.S.
18.	(b) (4) ***	56	Secondary name submitted by sponsor, OSE# (b) (4)

19.	resmethrin	56	Name found in RxNorm. No product characteristics available in common drug references.
20.	reviparin	56	Name found in RxNorm. No product characteristics available in common drug references.
21.	Ro-A-Vit	56	International product, not marketed in the U.S.
22.	Rotersept	56	International product, not marketed in the U.S.
23.	Betastat	54	Name found in RxNorm. No product characteristics available in common drug references.
24.	ramiprilat	54	Name found in RxNorm. No product characteristics available in common drug references.
25.	Rectacreme HC	54	Discontinued product with no generic equivalent available.
26.	Renaplus	54	Veterinary product
27.	RENOQUID	54	Discontinued product with no generic equivalent available.
28.	Respahist	54	Discontinued product with no generic equivalent available.
29.	reteplase	54	Name found in RxNorm. No product characteristics available in common drug references.
30.	RICE BRAN	54	Discontinued product with no generic equivalent available.

31.	Rinatec	54	International product, not marketed in the U.S.
32.	Rivotril	54	International product, not marketed in the U.S.
33.	tacrine	54	Name found in RxNorm. No product characteristics available in common drug references.
34.	Ketaset	53	Veterinary product
35.	(b) (4) ***	53	No information could be found in both internal and external databases
36.	Rimacid	53	International product, not marketed in the U.S.
37.	Uritact DS	53	Discontinued product with no generic equivalent available.
38.	ASELLacriN 10	52	No information could be found in both internal and external databases
39.	ASELLacriN 2	52	No information could be found in both internal and external databases
40.	Dixarit	52	International product, not marketed in the U.S.
41.	Ethacrynate	52	International product, not marketed in the U.S.
42.	metacresol	52	Name found in RxNorm. No product characteristics available in common drug references.
43.	Raciran	52	Name found in RxNorm. No product characteristics available in common drug references.
44.	Rapinovet	52	Veterinary product
45.	RE DualVit F	52	Discontinued product with

			no generic equivalent available.
46.	RenaKare	52	Veterinary product
47.	RENOTEC	52	No information could be found in both internal and external databases
48.	RENOVIST	52	Discontinued product with no generic equivalent available.
49.	Repan CF	52	Discontinued product with no generic equivalent available.
50.	Resaid	52	Discontinued product with no generic equivalent available.
51.	Respa C&C	52	Discontinued product with no generic equivalent available.
52.	(b) (4) ***	52	No information could be found in both internal and external databases
53.	RIBAV**A**RIN	52	No information could be found in both internal and external databases
54.	Rioci**q**uat	52	Established name was approved under Rioci**g**uat in OSE# 2013-471
55.	REGROTON	51	Discontinued product with no generic equivalent available.
56.	Britaject	50	International product, not marketed in the U.S.
57.	Redux	50	Discontinued product with no generic equivalent available.
58.	Respbid	50	Discontinued product with no generic equivalent available.

59.	Respiram	50	Name found in RxNorm. No product characteristics available in common drug references.
60.	REZIPAS	50	No information could be found in both internal and external databases
61.	Ricobid	50	International product, not marketed in the U.S.
62.	(b) (4) ***	50	No information could be found in both internal and external databases
63.	ROXIPRIN	50	Discontinued product with no generic equivalent available.

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

No.	Name	POCA Score (%)
1.	Predacort 50	65
2.	Predicort-50	60
3.	Levacet	58
4.	Propacet	58
64.	PROPACET 100	58
65.	(b) (4) ***	56
66.	TRIACORT	56
67.	CATAPRES	55
68.	Cetiri-D	55
69.	tricaprin	55
70.	CYTADREN	54
71.	Entaprin	54

72.	LTA II KIT	54
73.	Predacorten	54
74.	Preferid	54
75.	Procto-Kit	54
76.	Tramacort	54
77.	Brom-A-Cot	53
78.	Ledercort	53
79.	Methacort 40	53
80.	Methacort 80	53
81.	Promacot	53
82.	Acetocot	52
83.	ARISTOCORT	52
84.	DEXACORT	52
85.	Enaprilat	52
86.	Jet-Alert	52
87.	KENACORT	52
88.	Laboprin	52
89.	(b) (4) ***	52
90.	Lidocort	52
91.	Medicort	52
92.	PREMARIN	52
93.	Premarin	52
94.	(b) (4) ***	52
95.	PREVACID	52
96.	Prevacid	52
97.	PROCTOCORT	52
98.	Promacet	52
99.	sebacate	52
100.	tartrate	52
101.	TRIAPRIN	52

102.	Uristat	52
103.	Vectrin	52
104.	ADRENACLICK	51
105.	Bethaprim	51
106.	Entocort	51
107.	Legatrin PM	51
108.	(b) (4) ***	51
109.	Orastat	51
110.	ormetoprim	51
111.	TRIACET	51
112.	APAP Fruit	50
113.	Corifact	50
114.	cresatin	50
115.	Depandrate	50
116.	DICOPAC KIT	50
117.	drotaverin	50
118.	Emagrin	50
119.	Exaprin	50
120.	GRISACTIN	50
121.	Grisactin 250	50
122.	Grisactin 500	50
123.	LAC-HYDRIN	50
124.	Lactrase	50
125.	Laratrim	50
126.	LATANOPROST	50
127.	Lodocort	50
128.	(b) (4) ***	50
129.	Natafort	50
130.	ORENITRAM	50
131.	Orostat	50

132.	Orotic Acid	50
133.	OTOCORT	50
134.	Prednicot	50
135.	Primacor I.V.	50
136.	PROTOSTAT	50
137.	Thatzit	50
138.	Tri-Tex	50
139.	TRIVARIS	50
140.	Uric Acid	50
141.	UTICORT	50
142.	Vanacet	50
143.	VASOSTRICT	50
144.	Venastat	50
145.	VESPRIN	50
146.	VeteriBac	50
147.	VICOPRIN	50
148.	VITRASERT	50
149.	Zydaclin	50

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/s/

NEIL H VORA
04/03/2015

YELENA L MASLOV
04/03/2015