CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761054Orig1s000

PROPRIETARY NAME REVIEW(S)

MEMORANDUM

NONPROPRIETARY NAME SUFFIX

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 6, 2017
Requesting Office or Division:	Division of Pulmonary, Allergy, and Rheumatology Products (DPARP)
Application Type and Number:	BLA 761054
Product Name and Strength:	Renflexis (infliximab-abda) Injection 100 mg/vial
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Samsung Bioepis Co., LTD.
Submission Date:	October 18, 2016
OSE RCM #:	2016-2430
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, RPh
OMEPRM Deputy Director:	Lubna Merchant, MS, PharmD

1 PURPOSE OF MEMO

This memorandum summarizes our evaluation of the suffixes proposed by Samsung Bioepis for the nonproprietary name and communicates our recommendation for the nonproprietary name.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

FDA has determined that the use of a distinguishing suffix in the nonproprietary name for Samsung Bioepis' Renflexis product is necessary to distinguish this proposed product from Remicade (infliximab). As explained in FDA's draft Guidance for Industry, Nonproprietary Naming of Biological Products ("draft guidance"), FDA expects that a nonproprietary name for Renflexis that includes a distinguishing suffix will facilitate safe use and optimal pharmacovigilance. FDA advised Samsung Bioepis to provide proposed suffixes in accordance with the principles that are described in Section V of the draft guidance[a]. FDA has not finalized a policy on the nonproprietary naming of biological products. Accordingly, we reviewed Samsung Bioepis' proposed suffixes against the criteria described in the draft guidance.

On October 18, 2016, Samsung Bioepis submitted a list of suffixes, in their order of preference, to be used in the nonproprietary name of their product. We note that the applicant submitted three non-company based suffixes and three company-derived suffixes. We evaluated only the non-company based suffixes as that format is consistent with our current draft guidance, and conducted our review in the order of the preference listed by the Applicant. The Applicant also provided for our consideration findings from the evaluation they conducted based upon the factors described in Section V of our draft guidance on Nonproprietary Naming of Biological Products.

1. infliximab-abda

Samsung Bioepis' first proposed suffix, -abda, was determined to include some letter pairs that represent common medical abbreviations[b] and terms ('ab' as abbreviation for antibiotic and antibody). The sponsor did not identify this in their search, which looked only at the commonly used medical abbreviations and acronyms listed by the National Institutes of Health. We considered carefully whether the inclusion of these abbreviations and terms within the suffix could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or, more generally, based upon known causes of medication errors

We also considered whether "ab" could be confused with the AB code used to indicate that a drug product approved under the FD&C Act, generally a small molecule product, meets bioequivalency requirements for generic pharmaceutical products. Such codes may be included and displayed in electronic systems adjacent to drug names to guide pharmacies in substitution practices. Although such codes are not used for biologicals generally, and, specifically, are not, to our knowledge, used for products approved under the PHS Act, this distinction may not be widely known or understood by pharmacy staff. However, the 'da' couplet that follows ab in the proposed suffix should adequately serve to prevent misintrepration of 'ab' in electronic systems. Also, to the extent that such codes are displayed in electronic systems, they are not, to our knowledge, attached to the drug product's nonproprietary name by a hyphen. Therefore, although there is potential that some might observe that the 'ab' portion of

[a] FDA draft guidance for industry on Nonproprietary Naming of Biological Products (August 2015). When final, this guidance will represent FDA's current thinking on this topic. The guidances referenced in this document are available on the FDA Drugs guidance Web page at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

[b] Neil M Davis, *Medical Abbreviations: 30,000 Conveniences at the Expense of Communication and Safety*. Pennsylvania, 2009.

abda, given the overall context of use of the suffix, we find it unlikely that the suffix could be misconstrued as an FDA equivalency rating.

We also determined that –abda is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, and does not make promotional representations with respect to safety or efficacy of this product. The sponsor's evaluation identified a potential orthographic similarity between the USAN stem '-adol' and 'abda', but justified that the differences in upstrokes should preclude confusion. Our analysis finds that this justification is not supported, but there are other orthographic differences between the pair. Overall, we agree overall with the applicant's overall determination.

3 CONCLUSION

We find that Samsung Bioepis' proposed suffix "-abda" acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to infliximab-abda.

FDA's determination does not constitute or reflect a decision on a general naming policy for biological products, including biosimilars. FDA issued draft guidance on Nonproprietary Naming of Biological Products in August 2015, and the Agency is carefully considering the comments submitted to the public docket as we move forward in finalizing the draft guidance[a]. As a result, the nonproprietary name is subject to change to the extent that it is inconsistent with any general naming policy for biological products established by FDA. Were the name to change, FDA intends to work with Samsung Bioepis to minimize the impact this would have to its manufacture and distribution of this product, should it be licensed.

3.1 RECOMMENDATIONS FOR SAMSUNG BIOEPIS

We find the nonproprietary name, infliximab-abda, conditionally acceptable for your proposed product. Infliximab-abda will be the proper name designated in the license should your 351(k) BLA be approved. You should revise your proposed labels and labeling accordingly.

FDA's comments on the nonproprietary name for this product do not constitute or reflect a decision on a general naming policy for biosimilar products. FDA issued draft guidance on Nonproprietary Naming of Biological Products in August 2015, and the Agency is carefully considering the comments submitted to the public docket as we move forward in finalizing the draft guidance. As result, the nonproprietary name is subject to change to the extent that it is inconsistent with any general naming policy for biosimilar products established by FDA. Were the name to change, we would work with you to minimize the impact this would have to your manufacture and distribution of this product, should it be licensed.

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[a] FDA has received several citizen petitions directed to the nonproprietary naming of biosimilar products. The citizen petition submitted by Johnson & Johnson requests that FDA require biosimilar products to bear nonproprietary names that are similar to, but not the same as, those of their reference products or of other biosimilars (see Docket No. FDA-2014-P-0077). The citizen petitions submitted by the Generic Pharmaceutical Association and Novartis request that FDA require biosimilar products to be identified by the same nonproprietary name as their reference products (see Docket Nos. FDA-2013-P-1153 and FDA-2013-P-1398). Although FDA is designating a proper name that contains a distinguishing suffix for Renflexis, FDA is continuing to consider the issues raised by these citizen petitions, the comments submitted to the corresponding public dockets, and comments submitted to the dockets for the draft guidance for industry, "Nonproprietary Naming of Biological Products" (August 2015) and the proposed rule, "Designation of Official Names and Proper Names for Certain Biological Products" (80 FR 52224), with respect to establishing a general naming convention for biological products.

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

/s/

CARLOS M MENA-GRILLASCA
01/06/2017

LUBNA A MERCHANT
01/06/2017

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)

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Date of This Review:	June 2, 2016
Application Type and Number:	BLA 761054
Product Name and Strength:	Renflexis (SB2)* for Injection, 100 mg/vial
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Samsung Bioepis
Panorama #:	2016-3150625
DMEPA Primary Reviewer:	Matthew Barlow, RN, BSN
DMEPA Team Leader:	Mishale Mistry, PharmD, MPH
DMEPA Deputy Director:	Lubna Merchant, PharmD, MS

* Renflexis has been developed as a proposed biosimilar to US-licensed Remicade (infliximab). Since the proper names for Renflexis have not yet been determined, SB2 is used throughout this review as the nonproprietary name for this product.

Contents

1 INTRODUCTION

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

1.1 PRODUCT INFORMATION

The following product information is provided in the March 21, 2016 proprietary name submission.

- Intended Pronunciation: Ren-FLEK-sis
- Active Ingredient: SB2*
- Indication of Use: indicated for Crohn's Disease, Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Rheumatoid Arthritis in combination with Methotrexate, Ankylosing Spondylitis, Psoriatic Arthritis, and Plaque Psoriasis.
- Route of Administration: Intravenous Infusion
- Dosage Form: Lyophilized powder for Injection
- Strength: 100 mg/vial
- Dose and Frequency:
    - **Crohn's Disease**: 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg
    - **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0,2, and 6 weeks and then every 8 weeks
    - **Rheumatoid Arthritis** (in conjunction with methotrexate): 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks
    - **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.
- How Supplied: Each 100 mg vial is supplied in an individually packaged carton, and each single dose vial contains 100 mg of infliximab for final reconstitution volume of 10 mL.
- Storage: must be refrigerated at 2ºC to 8ºC (36ºF to 46ºF).

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* Renflexis has been developed as a proposed biosimilar to US-licensed Remicade (infliximab). Since the proper names for Renflexis have not yet been determined, SB2 is used throughout this review as the nonproprietary name for this product.

- Container and Closure Systems: N/A

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 Pulmonary, Allergy, and Rheumatology Products (DPARP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name*.

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Renflexis*** 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.

2.2.3 FDA Name Simulation Studies

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

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, April 13, 2016 e-mail, the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 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† organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation Study.

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*USAN stem search conducted on April 13, 2016.

† POCA search conducted on April 13, 2016.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	129
Low similarity name pair: combined match percentage score ≤49%	0

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

Our analysis of the 131names contained in Table 1 determined none of the names will 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 Pulmonary, Allergy, and Rheumatology Products (DPARP) via e-mail on May 26, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DPARP on June 2, 2016, they stated no additional concerns with the proposed proprietary name, Renflexis***.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Neil Vora, OSE project manager, at 240-402-4845.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your March 21, 2016 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.

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. *

* 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 does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥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: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

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

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤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.

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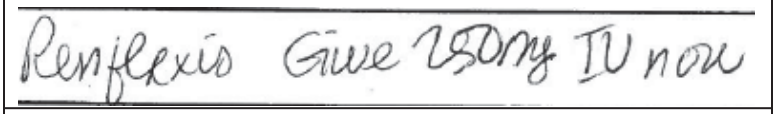
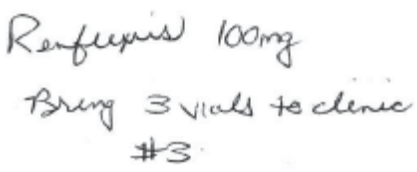
Appendix B: Prescription Simulation Samples and Results

Figure 1. Renflexis Study (Conducted on April 18, 2016)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Renflexis 100 mg Bring 3 vials to clinic Disp# 3 Vials

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Renflexis

Total	37	34	35	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTA
REDFLEXIS	0	1	0	1
REFLEXIS	0	1	1	2
REFLEXXUS	0	1	0	1
REFLUXUIS	1	0	0	1
REFUXIUS	1	0	0	1
REMFLEXIS	0	3	0	3
RENFESPIS	1	0	0	1
RENFEXRIS	1	0	0	1
RENFLAXIO	0	0	1	1
RENFLEXES	0	1	0	1
RENFLEXID	0	0	1	1
RENFLEXIO	0	0	9	9
RENFLEXIS	7	23	17	47
RENFLEXRIS	11	0	0	11

RENFLEXSIS	1	0	0	1
RENFLEXUS	2	3	0	5
RENFLIXIS	1	0	0	1
RENFLRXIO	0	0	1	1
RENFLRXIS	0	0	1	1
RENFREXRIS	1	0	0	1
RENFUPRIS	1	0	0	1
RENFUXIS	5	0	0	5
RENFUXRIS	4	0	0	4
RENIFLEXIO	0	0	1	1
RENIFLEXIS	0	0	2	2
RENIFLRXIS	0	0	1	1
REPHLEXIS	0	1	0	1

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

No.	**Proposed name: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose:** **Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0, 2, and 6 weeks, and then every 6 weeks.	**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.	Renflexis***	100%	This name is the subject of the review.
2.	(b) (4) ***	72%	(b) (4)

* Renflexis has been developed as a proposed biosimilar to US-licensed Remicade (infliximab). Since the proper names for Renflexis have not yet been determined, SB2 is used throughout this review as the nonproprietary name for this product.

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.	Rondex	56%
2.	Delflex	54%

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: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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.	Rhinoflex	65%	The prefixes and infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different. Strength: 500 mg acetaminophen/50 mg phenylotoloxamine citrate Dose: ½ to 1 tablet orally every 4 hours

* Renflexis has been developed as a proposed biosimilar to US-licensed Remicade (infliximab). Since the proper names for Renflexis have not yet been determined, SB2 is used throughout this review as the nonproprietary name for this product.

No.	**Proposed name: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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.	Relax-DS	62%	The lengths of these names differ by 2 letters. The infixes and suffixes of this name pair have sufficient orthographic differences. Renflexis has an additional syllable compared to the root name. The first and last syllables of this name pair sound different.
3.	Venclexta	62%	The infixes and suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
4.	Banflex	60%	The lengths of these names differ by 2 letters. The suffixes of this name pair have sufficient orthographic differences. The first and last syllables of this name pair sound different. This name contains one less syllable.

No.	**Proposed name: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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**
5.	ED Flex	60%	The lengths of these names differ by 2 letters. The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and last syllables of this name pair sound different.
6.	Relaxin	59%	The lengths of these names differ by 2 letters. The infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
7.	Be-flex plus	58%	The suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
8.	Combiflex ES	58%	The prefixes and infixes of this root name and proposed name have sufficient orthographic differences. The first and second syllables of this name pair sound different.

No.	**Proposed name: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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**
9.	Resectisol	57%	The infixes and suffixes of this name pair have sufficient orthographic differences. This name contains an additional syllable. The second/third/fourth syllables of this name pair sound different.
10.	Rapiflux	56%	The prefixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
11.	(b) (4)***	56%	(b) (4)

No.	**Proposed name: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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**
12.	Regulax SS	56%	The length of the root name and the proposed name differ by two letters. The prefixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
13.	Infliximab	56%	The suffixes of this name pair have sufficient orthographic differences. This name contains an additional syllable. The first/third/fourth syllables of this name pair sound different.
14.	Venelex	56%	The lengths of these names differ by 2 letters. 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: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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**
15.	Zanaflex	56%	The suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
16.	Granulex	55%	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
17.	Reclipsen	54%	The infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
18.	Refresh Plus	54%	The infixes and suffixes of this root name and the proposed name have sufficient orthographic differences. Renflexis has an additional syllable compared to the root name. The first and third syllables of this name pair sound different.

No.	**Proposed name: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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**
19.	Renovist	54%	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different.
20.	Replesta	54%	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
21.	Reprexain	54%	The prefixes and infixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
22.	Restasis	54%	The infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.

No.	**Proposed name: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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**
23.	Rulox Plus	54%	The infixes of this root name and the proposed name have sufficient orthographic differences. Renflexis has an additional syllable compared to the root name. The first syllables of this name pair sound different.
24.	Anaflex	54%	The lengths of these names differ by 2 letters. The prefixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
25.	Cephalexin	54%	The prefixes of this name pair have sufficient orthographic differences. This name contains an additional syllable. The first and second syllables of this name pair sound different.

No.	**Proposed name: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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**
26.	Paraflex	54%	The suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
27.	Vasoflex D1	54%	The suffixes of this root name and the proposed name have sufficient orthographic differences. The first and second syllables of this name pair sound different.
28.	Riboflavin	53%	The prefixes of this name pair have sufficient orthographic differences. This name contains an additional syllable. The first and second syllables of this name pair sound different.
29.	Ron-Acid Plus	53%	The infixes and suffixes of this root name and the proposed name have sufficient orthographic differences. The second syllables of this root name and the proposed name sound different.

No.	**Proposed name: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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**
30.	Dermaflex	53%	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
31.	Enablex	52%	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first/second/third syllables of this name pair sound different.
32.	Raplixa	52%	The infixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
33.	Readyflush	52%	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: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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.	Reclast	52%	The infixes and suffixes of this name pair have sufficient orthographic differences. This name contains one less syllable. The second/third syllables of this name pair sound different.
35.	Recofen Plus	52%	The infixes and suffixes of this root name and the proposed name have sufficient orthographic differences. The second and third syllables of this root name and the proposed name sound different.
36.	Replesta NX	52%	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
37.	(b) (4) ***	52%	(b) (4)

No.	**Proposed name: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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.	Reteplase	52%	The infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
39.	Revive Plus	52%	The length of the root name and the proposed name differ by 3 letters. The infixes of this root name and the proposed name have sufficient orthographic differences. The second syllables of this root name and the proposed name sound different.
40.	Rondec Drops	52%	The length of the root name and the proposed name differ by 3 letters. The infixes of this root name and the proposed name have sufficient orthographic differences. The second/third syllables of this name pair sound different.

No.	**Proposed name: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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**
41.	Eraxis	52%	The length of the names differs by 3 letters. The infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
42.	Everflex	52%	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
43.	Hemoplex F	52%	The infixes and suffixes of this root name and the proposed name have sufficient orthographic differences. The first and second syllables of this root name and the proposed name sound different.
44.	Inflectra	52%	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: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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**
45.	Jointflex Ice	52%	The infixes and suffixes of this root name and the proposed name have sufficient orthographic differences. The first syllables of this name pair sound different.
46.	Ranexa	51%	The lengths of the names differ by 3 letters. The infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
47.	Antiflex	51%	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
48.	Bromplex HD	51%	The infixes and suffixes of this root name and the proposed name have sufficient orthographic differences. This name contains one less syllable. The first syllables of this root name and the proposed name sound different.

No.	**Proposed name: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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**
49.	Euflexxa	51%	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
50.	Iodoflex	51%	The prefixes and suffixes of this name pair have sufficient orthographic differences, This name contains an additional syllable. The first, second, and third syllables of this name pair sound different.
51.	Keflex-C	51%	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first syllable of this name pair sound different.
52.	Rabdolax	50%	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.

No.	**Proposed name: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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**
53.	Remular-S	50%	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
54.	Renovist II	50%	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different.
55.	Revex	50%	The lengths of the names differ by 4 letters. The infixes and suffixes of this name pair have sufficient orthographic differences. This name contains one less syllable. The first and last syllables of this name pair sound different.
56.	Ri-Mox Plus	50%	The lengths of the names differ by 4 letters. The infixes of this root name and the proposed name have sufficient orthographic differences. The first and second syllables of this root name and the proposed name sound different.

No.	**Proposed name: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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**
57.	Rixubis	50%	The lengths of the names differ by 2 letters. The infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
58.	Robaxisal	50%	The infixes and suffixes of this name pair have sufficient orthographic differences. This name contains an additional syllable. The first and last syllables of this name pair sound different.
59.	Ronoxidil	50%	The infixes and suffixes of this name pair have sufficient orthographic differences. This name contains an additional syllable. The first, second, and last syllables of this name pair sound different.

No.	**Proposed name: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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**
60.	Roxilox	50%	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
61.	Ryna Liquid	50%	The lengths of the root name and proposed name differ by 5 letters. The prefixes and infixes of this root name and the proposed name have sufficient orthographic differences. The first and second syllables of this root name and the proposed name sound different.
62.	Beflex	50%	The lengths of the names differ by 3 letters. The suffixes of this name pair have sufficient orthographic differences. This name contains one less syllable. The first and last syllables of this name pair sound different.

No.	**Proposed name: Renflexis** **Established name: SB2*** **Dosage form: Injection** **Strength(s): 100 mg/vial** **Usual Dose: Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg **Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks and then every 8 weeks **Rheumatoid Arthritis (in conjunction with methotrexate):** 3 mg/kg at 0,2, and 6 weeks and then every 8 weeks, and some patients may benefit from increasing dose to 10 mg/kg or treating as often as every 4 weeks **Ankylosing Spondylitis:** 5 mg/kg at 0,2, and 6 weeks, and then every 6 weeks.	**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**
63.	Cidaflex	50%	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
64.	Jointflex	50%	The prefixes and suffixes of this name pair have sufficient orthographic differences. This name contains an additional syllable. The first syllables of this name pair sound different.
65.	Tobraflex	50%	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
66.	Xiaflex	50%	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.

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

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

No.	Name	POCA Score (%)	Failure preventions
1.	Trifexis	65%	Veterinary Product.
2.	Emflex	60%	International product marketed in the UK.
3.	Plenaxis	60%	Brand discontinued with no generic equivalent available. NDA 021320 withdrawn FR effective 07/19/2013.
4.	Synflex	60%	International product marketed in Italy, South Africa, Malaysia, Thailand, and Singapore.
5.	Uriflex-C	60%	International product marketed in the UK
6.	Renaplus	58%	Veterinary Product.
7.	Rheuflex	58%	International product marketed in the UK and Philippines.
8.	Rilexine	56%	Veterinary Product.
9.	Broflex	56%	International product marketed in India and the UK.
10.	Proflex	56%	International product marketed in the Philippines, South Africa, Ireland, and the UK.
11.	Laraflex	55%	International product marketed in the UK.
12.	Rendells	54%	International product marketed in the UK, Portugal, and New Zealand.

No.	Name	POCA Score (%)	Failure preventions
13.	Cephalexim	53%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
14.	Relaxyl	52%	International product marketed in India, Austria, and the UK.
15.	Relifex	52%	International product marketed in multiple countries.
16.	Renovue-Dip	52%	Brand discontinued with no generic equivalent available. NDA 17903 withdrawn FR effective 2/11/09.
17.	Benfluorex	52%	International product marketed in multiple countries.
18.	Rinfabate	51%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
19.	Convulex	51%	International product marketed in multiple countries.
20.	Indoflex	51%	International product marketed in South Africa and the UK.
21.	(b) (4) ***	50%	Proposed proprietary name found unacceptable by DMEPA (OSE# 2009-207). Product approved under new proprietary name, Zutripro.
22.	Ceftiflex	50%	Veterinary Product.

No.	Name	POCA Score (%)	Failure preventions
23.	Unna-flex	50%	Product is not a drug. It is different types of dressings and bandages.

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

No.	Name	POCA Score (%)
1.	GENTLAX S	59
2.	LENVIXI	58
3.	BRONKOLIXIR	55
4.	CRANTEX ER	55
5.	GENTLAX	55
6.	BRINTELLIX	54
7.	SENEXON S	54
8.	TRINTELLIX	54
9.	LEVOFLOXACIN	53
10.	CRANTEX	52
11.	CRANTEX HC	52
12.	ENPAXIQ	52
13.	ENROFLOX	52
14.	ENTEX PSE	52
15.	LITTLE NOSES	52
16.	TRINTEX	52
17.	VENTAVIS	52
18.	VERAFLOX	52
19.	BRONTEX	51
20.	DENTAL OXIDE	51
21.	DRONTAL PLUS	51
22.	ENTEX S	51
23.	ENTEX T	51

No.	Name	POCA Score (%)
24.	FLUXID	51
25.	PROFLOXACIN	51
26.	PRONTO PLUS	51
27.	BRITLOFEX	50
28.	CRANTEX LA	50
29.	DEMADEX I.V.	50
30.	EFLOXATE	50
31.	ENTEX ER	50
32.	FLOXIN	50
33.	GREPAFLOXACIN	50
34.	LOMEFLOXACIN	50
35.	LUCENTIS	50
36.	PROMOLAXIN	50
37.	SENNA LEAVES	50
38.	SENNALAX S	50

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

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06/02/2016

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