CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761066Orig1s000

PROPRIETARY NAME REVIEW(S)

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 18, 2019
Application Type and Number:	BLA 761066
Product Name and Strength:	Eticovo (etanercept-ykro) Injection 25 mg/0.5 mL and 50 mg/mL
Total Product Strength:	25 mg/0.5 mL and 50 mg/mL
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Samsung Bioepis (Samsung)
Panorama #:	2019-28628423
DMEPA Safety Evaluator:	Idalia E. Rychlik, PharmD.
DMEPA Team Leader:	Sarah K. Vee, PharmD.

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, (b) (4) on May 25, 2017. However, we found the name (b) (4) unacceptable due to phonetic similarities and shared product characteristics with the proprietary name, (b) (4) under BLA 761066 on August 18, 2017.[a] Subsequently, the Applicant submitted the proposed proprietary name, (b) (4) on November 8, 2017. However, we found the name (b) (4) unacceptable due to orthographic similarities and shared product characteristics with the established name (b) (4) under BLA 761066 on January 12, 2018.[b]

Thus, the Applicant submitted the name, (b) (4) for review on January 26, 2018; we found the proposed proprietary name, (b) (4) conditionally acceptable on March 20, 2018.[c] The application for BLA 761066 received a complete response (CR) on March 23, 2018.

On November 28, 2018, Samsung re-submitted the proposed proprietary name, (b) (4) for review. Samsung withdrew the proposed proprietary name (b) (4) on January 11, 2019. Samsung subsequently submitted the name, Eticovo, for review on January 22, 2019.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 22, 2019.

- Intended Pronunciation: E Ti Ko Vo
- Active Ingredient: etanercept-ykro
- Indication of Use:
    - Rheumatoid Arthritis (RA)
    - Polyarticular Juvenile Idiopathic Arthritis (JIA) in patients aged 2 years or older
    - Psoriatic Arthritis (PsA)
    - Ankylosing Spondylitis (AS)

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[a] Barlow M. Proprietary Name Review for (b) (4) for BLA 761066. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 AUG 18 Panorama No. 2017-15501519.

[b] McMillan, T. Proprietary Name Review for (b) (4) for BLA 761066. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 JAN 12 Panorama No. 2017-18383946.

[c] Mena-Grillasca, C. Proprietary Name Review for (b) (4) for BLA 761066. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 MAR 20 Panorama No. 2018-20605558.

- Plaque Psoriasis (PsO) in patients 4 years or older

- Route of Administration: Subcutaneous
- Dosage Form: Injection
- Strength: 25 mg/0.5 mL and 50 mg/mL
- Dose and Frequency: 50 mg once weekly or 50 mg twice weekly for 3 months followed by 50 mg weekly thereafter.
- How Supplied: single-dose pre-filled syringe
- Storage: Refrigerated at 36°F to 46°F (2°C to 8°C).
- Reference Listed Drug/Reference Product: Enbrel (NDA 103795)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Samsung did not provide a derivation or intended meaning for the proposed proprietary name, Eticovo, 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 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 24, 2019 e-mail, the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) did not forward any comments or concerns relating to Eticovo at the initial phase of the review.

[d] USAN stem search conducted on January 15, 2019.

2.2.4 FDA Name Simulation Studies

Ninety-two (92) practitioners participated in DMEPA's prescription studies for Eticovo. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[e] identified 74 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	66
Low similarity name pair: combined match percentage score ≤54%	5

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

Our analysis of the 72 names contained in Table 1 determined none of the names will pose a risk for confusion with Eticovo 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 Pulmonary, Allergy, and Rheumatology Products (DPARP) via e-mail on February 28, 2019. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) on March 1, 2019, they noted that the proposed proprietary name, Eticovo, sounds similar to Entyvio; however, the DPARP deferred to DMEPA for acceptability of the name pair.

[e] POCA search conducted on January 15, 2019 in version 4.3.

We evaluated the name pair Eticovo and Entyvio for the risk of confusion:

- Orthographically, the additional letter 'n' in between the letter string 'E-t', the infixes ('-ico-' *versus* downstroke letter 'y') provide sufficient differences.
- Phonetically, the first ("E-" *versus* "En-") and third syllable ("-co-" *versus* "-vi-") of this name pair provide sufficient differences.
- Eticovo will be available in two strengths, 25 mg/0.5 mL and 50 mg/mL, which will be specified on a prescription/medication order. The strengths of Eticovo do not overlap with the single strength of Entyvio (300 mg per vial).
- The dose/frequency of Eticovo is 50 mg administered subcutaneously once weekly or twice weekly, or weight-based (0.8 mg/kg) weekly dosing for pediatrics who weigh less than 63 kg (maximum dose of 50 mg per week). The dose/frequency of Eticovo does not overlap with that of Entyvio (300 mg infused intravenously over approximately 30 minutes at zero, two and six weeks, then every eight weeks thereafter).

Therefore, due to the considerations above, we find the name pair Eticovo and Entyvio acceptable.

3 CONCLUSION

The proposed proprietary name, Eticovo, is acceptable.

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

3.1 COMMENTS TO SAMSUNG BIOEPIS

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

If any of the proposed product characteristics as stated in your submission, received on January 22, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

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

[f] 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[g]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

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

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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

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

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

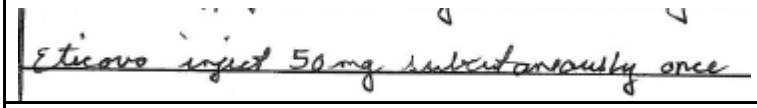
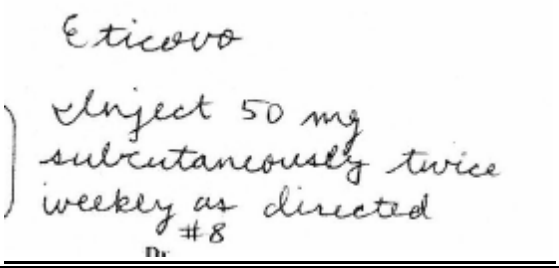
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Eticovo Study (Conducted on January 25, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Eticovo Inject 50 mg subcutaneously twice weekly as directed. #8
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate Report)

Total	53	19	20	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ECONO	0	1	0	1
ECTICOVO	1	0	0	1
EKCOHO	0	1	0	1
ETACOVO	0	2	0	2
ETAKOVO	0	3	0	3
ETERKOVO	0	1	0	1
ETIACOVO	0	1	0	1
ETICEVO	1	0	0	1
ETICOVA	0	0	1	1
ETICOVO	48	3	19	70
ETICUVO	2	0	0	2
ETIKOVO	0	2	0	2
ETOCOVO	1	4	0	5
ETOKOVO	0	1	0	1

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

No.	**Proposed name:** Eticovo **Established name:** etanercept-ykro **Dosage form:** Injection **Strength(s):** 25 mg/0.5 mL and 50 mg/mL **Usual Dose:** 50 mg once or twice weekly for 3 months followed by 50 mg once weekly thereafter.	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.	Eticovo	100	Subject of this review.

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 (%)
2.	Ertaczo	66
3.	Ticon	63
4.	Edsivo***	62
5.	Epzicom	62
6.	Oticot Hc	62
7.	Topicool	62
8.	Epitol	60
9.	Uticort	60
10.	Entyvio	59
11.	Evivo	59
12.	Acticort	56
13.	Acticort 100	56
14.	Chocovite	56
15.	Corticool	56
16.	Epanova	56
17.	Estivin	56
18.	Ethiodol	56
19.	Visicol	56

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:** Eticovo **Established name:** etanercept-ykro **Dosage form:** Injection **Strength(s):** 25 mg/0.5 mL and 50 mg/mL **Usual Dose:** 50 mg once or twice weekly for 3 months followed by 50 mg once weekly thereafter.	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.	Tibsovo	69	This name pair has sufficient orthographic and phonetic differences.
21.	Revcovi	64	This name pair has sufficient orthographic and phonetic differences.
22.	Acticon	62	This name pair has sufficient orthographic and phonetic differences.

23.	Edsivo***	62	Orthographically, the infixes ('-tico-' vs. '-dsi-') provide some differences. Phonetically, Eticovo has an additional syllable. The first syllables (E vs. Ed), onset of the second syllables (ti vs. si) and third syllables (co vs. vo) provide sufficient phonetic differences. There are further differences between the name pair's product characteristics. Namely, there is no [redacted] (b) (4)
24.	Descovy	62	This name pair has sufficient orthographic and phonetic differences.
25.	Entecavir	58	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Eticovo **Established name:** etanercept-ykro **Dosage form:** Injection **Strength(s):** 25 mg/0.5 mL and 50 mg/mL **Usual Dose:** 50 mg once or twice weekly for 3 months followed by 50 mg once weekly thereafter.	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.	Etopophos	58	This name pair has sufficient orthographic and phonetic differences.
27.	Citicoline	56	This name pair has sufficient orthographic and phonetic differences.
28.	Emete-Con	56	This name pair has sufficient orthographic and phonetic differences.
29.	Meclicot	56	This name pair has sufficient orthographic and phonetic differences.
30.	Meticorten	56	This name pair has sufficient orthographic and phonetic differences.
31.	Tricor	56	This name pair has sufficient orthographic and phonetic differences.
32.	Vimovo	56	This name pair has sufficient orthographic and phonetic differences.
33.	Edetol	55	This name pair has sufficient orthographic and phonetic differences.
34.	Oncovin	55	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
35.	Oretic	52

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
36.	Epicort	64	Root name of Epicort-MK and/or Epitort-GC, which are are international topical steriod products marketed in India.
37.	Diclovol	62	International drug product marketed in the United Kingdom.
38.	(b) (4)***	62	Proposed proprietary name denied in 2007 due to misbranding concerns (OSE consult 2007-1058) under IND (b) (4); IND was withdrawn on 9/8/2011.
39.	Etopofos	60	International drug product marketed in Sweden.
40.	Picot	57	International product marketed in France.
41.	Ecosave	56	This is not a drug product. It is a soap.
42.	Eco-Soft	56	Veterinary product.
43.	Episoft	56	This is not a drug. It is an emollient base.
44.	(b) (4)***	56	Proposed proprietary name was found acceptable under RCM (b) (4), under IND (b) (4). However, the Sponsor requested inactivation of IND (b) (4) on 1/18/2019.
45.	Otic Care	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
46.	Visicol 398/1102	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
47.	Neotic	52	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
48.	Vetiver Oil	50	This is not a drug. It is an essential oil.
49.	(b) (4)***	48	Proposed proprietary name denied on March 10, 2017 (OSE #2016-12053697); NDA 209963 approved on 12/14/2017 under Goprelto.
50.	Teoptic	48	This is an international drug product marketed in the Netherlands.

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

No.	Name	POCA Score (%)
51.	Mektovi	64
52.	(b) (4)***	61

[h] 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 (%)
53.	Pedi-Cort V	60
54.	Picato	60
55.	Demi-Cof	59
56.	(b) (4)***	59
57.	Acetocot	58
58.	Certiva	58
59.	(b) (4)***	58
60.	Viceton	58
61.	Victoza	58
62.	(b) (4)***	57
63.	(b) (4)***	56
64.	Rectiv	56
65.	(b) (4)***	56
66.	Tycolet	56
67.	Cetacort	55
68.	Isocom	55
69.	Ketocid	55
70.	Pediacof	55
71.	(b) (4)***	55
72.	(b) (4)***	55
73.	Triclos	55

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/s/

IDALIA E RYCHLIK
03/18/2019 02:24:48 PM

SARAH K VEE
03/18/2019 02:27:25 PM

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:	December 28, 2018
Responsible OND Division:	Division of Pulmonary, Allergy, and Rheumatology Products (DPARP)
Application Type and Number:	BLA 761066
Product Name and Strength:	(b) (4) (etanercept-ykro) Injection, 25 mg/0.5 mL and 50 mg/mL
Product Type:	Combination Product (Drug-Device)
Applicant/Sponsor Name:	Samsung Bioepis Co.,LTD (Samsung)
OSE RCM #:	2017-1029-2
DMEPA Primary Reviewer:	Carlos M. Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

1 PURPOSE OF MEMO

This memorandum is to reassess the FDA-generated suffix, -ykro, for BLA 761066, which was found conditionally acceptable on February 22, 2018[a], for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761066.

1.1 Regulatory History

FDA generated a four-letter suffix, -ykro, for BLA 761066 on February 22, 2018[b]. However, BLA 761066 received a Complete Response (CR) letter on March 23, 2018[c]. Thus, Samsung submitted a Class 2 Resubmission on October 25, 2018. In their submission, Samsung proposes the suffix -ykro for the nonproprietary name for BLA 761066.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

Etanercept-ykro

We reassessed the previously generated four-letter suffix, -ykro, using the principles described in the applicable guidance[d].

We determined that the FDA-generated suffix -ykro, 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, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMEPA'S ANALYSIS

These findings were shared with OPDP. In email correspondence dated December 21, 2018, OPDP did

not identify any concerns that would render this suffix unacceptable. DMEPA also communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) via e-mail on December 28, 2018.

4 CONCLUSION

We find the suffix -ykro acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to etanercept-ykro.

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[a] Mena-Grillasca, C. Nonproprietary Name Suffix Memorandum for etanercept-ykro (BLA 761066). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 FEB 22. RCM No.: 2017-1029-1.

[b] Mena-Grillasca, C. Nonproprietary Name Suffix Memorandum for etanercept-ykro (BLA 761066). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 FEB 22. RCM No.: 2017-1029-1.

[c] Chowdhury, B.A. Complete Response (BLA 761066). Silver Spring (MD): FDA, CDER, OND, DPARP (US); 2018 MAR 23.

[d] See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from:

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

4.1 Recommendation for Samsung Bioepis Co.,LTD

We find the nonproprietary name, etanercept-ykro, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, etanercept-ykro will be the proper name designated in the license and you should revise your proposed labels and labeling accordingly. However, please be advised that if your application receives a complete response, the acceptability of this suffix will be re-evaluated when you respond to the deficiencies. If we find the suffix unacceptable upon our re-evaluation, we would inform you of our finding.

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/s/

CARLOS M MENA-GRILLASCA
12/28/2018 08:37:57 PM

DANIELLE M HARRIS
01/02/2019 01:02:07 PM

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)

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Date of This Review:	February 22, 2018
Requesting Office or Division:	Division of Pulmonary, Allergy, and Rheumatology Products (DPARP)
Application Type and Number:	BLA 761066
Product Name and Strength:	SB4[a] (etanercept-ykro) Injection 25 mg/0.5 mL and 50 mg/mL
Product Type:	Single-ingredient combination product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Samsung Bioepis
OSE RCM #:	2017-1029-1
DMEPA Safety Evaluator:	Carlos M Mena-Grillasca, BSPharm
DMEPA Deputy Director (Acting):	Danielle Harris, PharmD, BCPS

[a] SB4 has been developed as a proposed biosimilar to US-licensed Enbrel (etanercept). Since the proprietary name for SB4 has not yet been determined, SB4 is used throughout this review in place of the proprietary name for this product.

1 PURPOSE OF MEMO

This memorandum summarizes our evaluation of the four-letter suffix for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761066.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

Samsung Bioepis submitted three suffixes for review on May 25, 2017. However, these suffixes were found unacceptable[a].

Samsung Bioepis was notified that their proposed suffixes were found unacceptable and of the Agency's intention to designate a proper name that includes a four-letter distinguishing suffix for its product in an advice letter[b].

2.1 *Etanercept-ykro*

FDA generated a four letter suffix, -ykro. This suffix was evaluated against the principles described in the applicable guidance[c].

We determined that the FDA-generated suffix "-ykro", is not too similar to any other product's 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 any misrepresentations with respect to safety or efficacy of this product.

These findings were shared OPDP. In email correspondence dated February 22, 2018, OPDP did not identify any issues that would render this suffix unacceptable.

3 CONCLUSION

We find the suffix "-ykro" acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to etanercept-ykro.

3.1 RECOMMENDATIONS FOR THE APPLICANT

We find the nonproprietary name, etanercept-ykro, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, etanercept-ykro will be the nonproprietary name designated in the license and you should revise your proposed labels and labeling accordingly. However, please be advised that if your application receives a complete response, the acceptability of the proposed suffix will be re-evaluated when you respond to the deficiencies. If we find the suffix unacceptable upon our re-evaluation, we would inform you of our finding.

---

[a] Mena-Grillasca, C. Nonproprietary Name Suffix Review for BLA 761066. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 NOV 07. RCM No. 2017-1029.

[b] Merchant, L. General Advice Letter for BLA 761066. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 NOV 15.

[c] See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

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/s/

CARLOS M MENA-GRILLASCA
02/22/2018

DANIELLE M HARRIS
02/26/2018

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)

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Date of This Review:	January 12, 2018
Application Type and Number:	BLA 761066
Product Name and Strength:	(b) (4) (SB4)[a] injection 25 mg/(b) (4) mL and 50 mg/(b) (4) mL
Product Type:	Drug-device Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Samsung Bioepis
Panorama #:	2017-18383946
DMEPA Safety Evaluator:	Teresa McMillan, PharmD
DMEPA Team Leader:	Sarah K. Vee, PharmD
DMEPA Acting Associate Director:	Mishale Mistry, PharmD, MPH
DMEPA Division Director:	Todd Bridges, R.Ph.

[a] (b) (4) has been developed as a proposed biosimilar to US-licensed Enbrel (etanercept). Since the proper names for (b) (4) have not yet been determined, SB4 is used throughout this review as the nonproprietary name for this product.

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/s/

TERESA S MCMILLAN
01/12/2018

SARAH K VEE
01/12/2018

MISHALE P MISTRY
01/16/2018

TODD D BRIDGES
01/16/2018

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)

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Date of This Review:	November 7, 2017
Requesting Office or Division:	Division of Pulmonary, Allergy, and Rheumatology Products (DPARP)
Application Type and Number:	BLA 761066
Product Name and Strength:	Etanercept-xxxx Injection 25 mg/0.5 mL and 50 mg/mL
Product Type:	Single Ingredient Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Samsung Bioepis
Submission Date:	May 25, 2017
OSE RCM #:	2017-1029
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BSPharm
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

On May 25, 2017, 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 suffixes. We conducted our review in the order of preference listed by the Applicant. We note that the Applicant submitted an evaluation of their proposed suffixes. We reviewed Samsung Bioepis's proposed suffixes against the criteria described in the guidance[a].

1. etanercept-(b) (4)

Samsung Bioepis's first proposed suffix, (b) (4), is comprised of two distinct letters (b) (4) The suffix is inconsistent with FDA's final guidance on this topic which recommends that the suffixes be composed of at least three unique letters.

2. etanercept-(b) (4)

Samsung Bioepis's second proposed suffix, (b) (4), is comprised of two distinct letters (b) (4) The suffix is inconsistent with FDA's final guidance on this topic which recommends that the suffixes be composed of at least three unique letters.

3. etanercept-(b) (4)

Samsung Bioepis's third proposed suffix, (b) (4), is comprised of the first and last letters (b) (4) We note that the use of letter (b) (4) as the first and last letter follows a similar pattern as seen with their approved biosimilar infliximab-(b) (4) While the currently proposed suffix does differ from –(b) (4) in the second and third letters, we find the repeated use of the letters (b) (4) in the first and last letter across Samsung Bioepis's products would create an implied meaning of "(b) (4)" for all products with such suffixes. The proposed suffix -(b) (4) is therefore not devoid of meaning and thus inconsistent with the criteria outlined in section VI of the guidance. Therefore, we find this suffix unacceptable for Samsung Bioepis's proposed etanercept product.

3 CONCLUSION

For the reasons described above, we find that Samsung Bioepis's proposed suffixes are unacceptable for the proposed nonproprietary name, etanercept. Therefore, the decision to deny the suffixes will be communicated to the Applicant via letter.

These findings were shared with the TBBS, ORP, OCC and OPDP. In email correspondence dated November 3, 2017, the workgroup concurred with DMEPA's assessment and conclusion.

3.1 COMMENTS FOR THE APPLICANT

1. We find your proposed nonproprietary name, etanercept-(b) (4) and etanercept(b) (4) unacceptable, as the proposed suffixes (b) (4) and (b) (4) are each comprised of only two distinct letters thus inconsistent with FDA's final guidance on this topic which recommends that the suffixes be composed of at least three unique letters.

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[a] Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

2. We find your proposed nonproprietary name, etanercept- (b) (4) unacceptable as the proposed suffix, - (b) (4), is comprised of the first and last letters (b) (4) We note that the use of letter (b) (4) as the first and last letter follows a similar pattern as seen with your approved biosimilar infliximab- (b) (4) While the currently proposed suffix does differ from – (b) (4) in the second and third letters, we find the repeated use of the letters (b) (4) as the first and last letter across Samsung Bioepis's products would create an implied meaning of (b) (4) for all products with such suffixes. The proposed suffix - (b) (4) is therefore not devoid of meaning and thus inconsistent with the criteria outlined in section VI of the guidance.

3. We note that you have not proposed any additional suffixes for our evaluation. Since your proposed suffixes were found unacceptable, please be informed that in the absence of other alternative proposals, we intend to designate the proper name with an FDA generated suffix should your 351(k) BLA be licensed this review cycle. Should you wish to avoid licensure of a proper name that includes an FDA-generated suffix, any alternatives should be communicated to FDA at your earliest convenience and no later than November 30, 2017.

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/s/

CARLOS M MENA-GRILLASCA
11/07/2017

LUBNA A MERCHANT
11/08/2017

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:	August 18, 2017
Application Type and Number:	BLA 761066
Product Name and Strength:	(b) (4) (SB4)* injection 25 mg/(b) (4) mL and 50 mg/(b) (4) mL
Product Type:	Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Samsung Bioepis
Panorama #:	2017-15501519
DMEPA Primary Reviewer:	Matthew Barlow, RN, BSN
DMEPA Team Leader:	Sarah K. Vee, PharmD
DMEPA Acting Associate Director:	Mishale Mistry, PharmD, MPH
DMEPA Division Director:	Todd Bridges, R.Ph.

* (b) (4) has been developed as a proposed biosimilar to US-licensed Enbrel (etanercept). Since the proper names for (b) (4) have not yet been determined, SB4 is used throughout this review as the nonproprietary name for this product.

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/s/

MATTHEW J BARLOW
08/18/2017

MISHALE P MISTRY on behalf of SARAH K VEE
08/18/2017

MISHALE P MISTRY
08/18/2017

TODD D BRIDGES
08/18/2017