CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761086Orig1s000

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:	March 1, 2019
Responsible OND Division:	Division of Pulmonary, Allergy, and Rheumatology Products (DPARP)
Application Type and Number:	IND 122136 BLA 761086
Product Name and Strength:	Avsola (infliximab-axxq) For Injection, 100 mg/vial
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Amgen Inc. (Amgen)
FDA Received Date:	May 31, 2018 (IND) December 14, 2018 (BLA)
OSE RCM #:	2018-1179 (IND) 2018-2748 (BLA)
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

1 PURPOSE OF MEMO

This memorandum summarizes our evaluation of the four-letter suffixes proposed by Amgen for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for IND 122136 and BLA 761086.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On May 31, 2018 and December 14, 2018, Amgen submitted a list of 10 suffixes to IND 122136 and BLA 761086, respectively, in their order of preference, to be used in the nonproprietary name of their product[a]. Table 1 presents a list of suffixes submitted by Amgen:

Table 1. Suffixes submitted by Amgen***	
1.	axxq
	(b) (4)

We reviewed Amgen's proposed suffixes in order of preference listed by Amgen, using the principles described in the applicable guidance.[b]

2.1 infliximab-axxq

Amgen's first proposed suffix, -axxq, is composed of 3 distinct letters (a, x, q). We note that the proposed suffix, -axxq, (b) (4) The proposed suffix -axxq is therefore not devoid of meaning and thus inconsistent with the principles outlined in section VI of the guidance. (b) (4) However, our evaluation considered all of the suffixes that are currently pending or approved by FDA, which includes the 5 proposed suffixes identified above. Given that proposed suffixes create a conflict that can be resolved by approving one of the conflicting suffixes, but not one of the others, and that this -axxq suffix is

[a] Cover Letter – Request for FDA Review of Suffixes for ABP 710 Proper Name (IND 122136). Thousand Oaks (CA): Amgen Inc.; 2018 May 31. Available from: \\cdsesub1\evsprod\ind122136\0036\m1\us\cover-letter.pdf

Cover Letter – Request for FDA Review of Suffixes for ABP 710 Proper Name (BLA 761086). Thousand Oaks (CA): Amgen Inc.; 2018 Dec 14. Available from: \\cdsesub1\evsprod\bla761086\0001\m1\us\rqt-for-proprietary-name.pdf

[b] 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

submitted under a BLA application versus an IND application, we have concluded that BLA 761086 should have the right to use the proposed suffix containing the shared letters.

Apart from the discussion above, we determined that the proposed suffix -axxq, 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. Per an email correspondence dated January 24, 2019, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA also communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) via e-mail on March 1, 2019.

4 CONCLUSION

We find Amgen's proposed suffix -axxq acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to infliximab-axxq. DMEPA will communicate our findings to the Applicant via letter.

4.1 Recommendations for Amgen Inc.

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

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CARLOS M MENA-GRILLASCA
03/01/2019 04:18:08 PM

DANIELLE M HARRIS
03/05/2019 01:19:25 PM

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:	February 21, 2019
Application Type and Number:	BLA 761086
Product Name and Strength:	Avsola (infliximab-xxxx)* For Injection 100 mg/vial
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Amgen
Panorama #:	2018-28016714
DMEPA Safety Evaluator:	Melina Fanari (Griffis), R.Ph.
DMEPA Team Leader:	Sarah K. Vee, PharmD

* Avsola has been developed as a proposed biosimilar to US-licensed Remicade (infliximab). Since the proper names for Avsola have not yet been determined, ABP 710 is used throughout this review as the nonproprietary name for this product.

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Amgen previously submitted the proposed proprietary name, Avsola*** on December 7, 2017. We found the name, Avsola*** acceptable under IND 122136 on June 4, 2018.[a] Thus, they summitted Avsola*** for review under the BLA on December 14, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 14, 2018.

- Intended Pronunciation: av-SOH-luh
- Active Ingredient: infliximab-xxxx*
- Indication of Use: Active moderate to severe rheumatoid arthritis (RA), Moderate to severe ulcerative colitis (UC), Moderate to severe pediatric UC, Moderate to severe adult Crohn's disease (CD), Moderate to severe pediatric CD, Ankylosing spondylitis, Psoriatic arthritis, Chronic severe plaque psoriasis
- Route of Administration: intravenous
- Dosage Form: lyophilized powder for injection
- Strength: 100 mg/vial
- Dose and Frequency: the usual dosage for this product is 3 to 5 mg/kg. The frequency of administration is at 0, 2 and 6 weeks then every 8 weeks for RA, UC, CD, psoriatic arthritis and psoriasis and at 0, 2 and 6 weeks then every 6 weeks for ankylosing spondylitis; thus, the dosing intervals are one week, 6 weeks and 8 weeks, depending upon the treated indication. The maximum daily dose is 10 mg/kg.
- How Supplied: this product will be available in 20 mL vials.
- Storage: product should be refrigerated at 2°C to 8°C.
- Reference Listed Drug/Reference Product: Remicade (BLA 103772)

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[a]Barlow, M. Proprietary Name Review for Avsola (IND 122136). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 Jun 4. Panorama No. 2017-19547920.

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

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Avsola 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 Avsola.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Amgen did not provide a derivation or intended meaning for the proposed proprietary name, Avsola, 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 10, 2019 e-mail, the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) did not forward any comments or concerns relating to Avsola at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One hundred practitioners participated in DMEPA's prescription studies for Avsola. 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 identified 84 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that

[b] USAN stem search conducted on January 23, 2019.

none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified five names not previously analyzed. 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%	3
Low similarity name pair: combined match percentage score ≤54%	1

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

Our analysis of the five names contained in Table 1 determined none of the names will pose a risk for confusion with Avsola 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 8, 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 February 11, 2019, they stated no additional concerns with the proposed proprietary name, Avsola.

3 CONCLUSION

The proposed proprietary name, Avsola, 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 AMGEN

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

If any of the proposed product characteristics as stated in your submission, received on December 14, 2018, 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. [c]

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[c] 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[d]. 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).

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

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

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

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

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

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Avsola Study (Conducted on January 11, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Avsola give 350 mg intravenously now	Avsola Bring to clinic #2 vials
Outpatient Prescription: Avsola Bring to clinic #2 vials	

FDA Prescription Simulation Responses (Aggregate Report)

304 People Received Study
100 People Responded

Study Name: Avsola

Total	58	16	26	100

INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
ABSOLA	0	1	0	1
ABSOLAR	0	1	0	1
ABSOULA	0	1	0	1
ANSOLA	1	0	0	1
ARSOLA	14	0	0	14
ARSOLO	1	0	0	1
AUSOLA	2	0	0	2
AVSOLA	37	9	25	71
AVSOLO	2	0	1	3
HAVESOLA	0	1	0	1
HAVSOLA	0	2	0	2
ORSOLO	1	0	0	1
PAPSOLA	0	1	0	1

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

No.	**Proposed name:** Avsola **Established name:** infliximab-xxxx **Dosage form:** for injection **Strength(s):** 100 mg/vial **Usual Dose:** the usual dosage for this product is 3 to 5 mg/kg. The frequency of administration is at 0, 2 and 6 weeks then every 8 weeks for RA, UC, CD, psoriatic arthritis and psoriasis and at 0, 2 and 6 weeks then every 6 weeks for ankylosing spondylitis	**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.	Avsola	100	This name is the subject of this review.

Appendix D: N/A

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:** Avsola **Established name:** infliximab-xxxx **Dosage form:** for injection **Strength(s):** 100 mg/vial **Usual Dose:** the usual dosage for this product is 3 to 5 mg/kg. The frequency of administration is at 0, 2 and 6 weeks then every 8 weeks for RA, UC, CD, psoriatic arthritis and psoriasis and at 0, 2 and 6 weeks then every 6 weeks for ankylosing spondylitis	**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.	Ibsrela***	56	Ibsrela has an additional upstroke letter 'b' in the prefix of the name which provides some orthographic differences.

No.	**Proposed name:** Avsola **Established name:** infliximab-xxxx **Dosage form:** for injection **Strength(s):** 100 mg/vial **Usual Dose:** the usual dosage for this product is 3 to 5 mg/kg. The frequency of administration is at 0, 2 and 6 weeks then every 8 weeks for RA, UC, CD, psoriatic arthritis and psoriasis and at 0, 2 and 6 weeks then every 6 weeks for ankylosing spondylitis	**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**
			The second syllable ('rel' vs 'so') of the names provide some phonetic differences. The following differences in product characteristics may also help to mitigate the risk of errors: • Frequency of Administration: Ibsrela is taken orally twice daily vs. Avsola is administered via intravenous infusion at 0, 2, 6, and 8-week intervals. Therefore, there is no overlap in frequency of administration. Therefore, due to the above-mentioned factors we find this name pair acceptable.
3.	(b) (4) ***	54	This name pair has sufficient orthographic and phonetic differences.

Appendix F: 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
4.	Eescula	60	Name identified in RxNorm database. Unable to find product in commonly used drug databases
5.	Avoca	55	Foreign product

Appendix H: N/A

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MELINA N FANARI
02/21/2019 02:02:16 PM

SARAH K VEE
02/21/2019 02:05:53 PM