CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761358Orig1s000

PROPRIETARY NAME REVIEW(S)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

Memorandum

From:

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Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

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Through:

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Gerald Dal Pan, MD, MHS
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Subject: Evaluation of the nonproprietary name for BLA 761358

Celltrion Inc. (Celltrion) is the license holder for Inflectra (infliximab-dyyb) for injection, 100 mg, for intravenous use, approved in Biologics License Application BLA 125544 on April 5, 2016, under section 351(k) of the Public Health Service (PHS) Act. Inflectra is approved as a biosimilar to the

corresponding reference product Remicade (infliximab) for injection, 100 mg, for intravenous use (BLA 103772). Inflectra (infliximab-dyyb) is a tumor necrosis factor (TNF) blocker and is approved for the treatment of Crohn's Disease, Pediatric Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, Rheumatoid Arthritis, and Plaque Psoriasis. Inflectra is supplied as a lyophilized powder in 100 mg single-dose vials for reconstitution and dilution.

On December 22, 2022, Celltrion submitted a new BLA 761358 pursuant to section 351(a) of the PHS Act for a new infliximab subcutaneous formulation for maintenance dosing. The product that Celltrion proposes in BLA 761358 differs from Celltrion's Inflectra in key aspects such as strength, dosage form, and route of administration. Specifically, the new formulation in BLA 761358 contains the same drug substance (DS) as Inflectra, formulated in a liquid formulation in 120 mg/mL pre-filled syringe and pre-filled pen presentations intended for the subcutaneous administration of infliximab-xxxx for the maintenance dosing for the Ulcerative Colitis and Crohn's Disesase indications only. See Appendix 1 – Product Characteristics Comparison Table for more information.

FDA issued a final guidance entitled Nonproprietary Naming of Biological Products on January 13, 2017, which generally describes FDA's current thinking on the need for biological products licensed under the PHS Act to bear a nonproprietary name containing a four-letter distinguishing suffix.[a] The Naming Guidance did not specifically address situations like this where an applicant has an approved biosimilar for a reference product and is proposing a new 351(a) BLA for a product that has the same DS as its approved biosimilar, but which proposes a strength, dosage form, and/or route of administration, or condition of use, for which there is not a corresponding reference product.

OSE in consultation with FDA's Biological Product Naming Working Group considered the following elements in the determination for the need of a nonproprietary name suffix for BLA 761358:

1. The Naming Guidance does not address the scenario where an applicant with an approved 351(k) biosimilar license is proposing a new 351(a) BLA for a strength, dosage form, and/or route of administration, or condition of use, for which there is not a corresponding reference product.
2. The DS in the approved formulation (BLA 125544) and the proposed formulation (BLA 761358) are essentially unchanged with respect to product quality attributes (identity, purity, etc.). The main differences between the products are the strength, dosage form, dose, route of administration, frequency of administration, and formulation.

[a] Available at https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf (hereafter "Naming Guidance").

3. From an analytical perspective, the drug substance of Inflectra (BLA 125544) and Zymfentra (BLA 761358) are deemed comparable based on DS release data (except for the pH and protein concentration), extended characterizations, and stability profiles obtained from stability indicating quality attributes. Therefore, although the formulations are not identical, Office of Biological Products (OBP) did not identify any significant difference in critical quality attributes that impact the safety and effectiveness profiles of these two biological products. In addition, OBP confirmed there are no major differences in DS manufacture; (b) (4)
4. Considering that BLA 125544 and BLA 761358 share the same DS and formulation similarities, no significant differences in immunogenicity profiles is expected. In fact, based on the Division of Gastroenterology's (DG) current review of the available information to date, DG cannot conclude that there is any clinically significant immunogenicity difference between Inflectra and Zymfentra.
5. We note that other product characteristics are the same or similar: indications (plaque psoriasis, psoriatic arthritis, Crohn's disease, ulcerative colitis, pediatric Crohn's disease, and pediatric ulcerative colitis vs. Crohn's disease and ulcerative colitis), frequency of administration (weeks 0, 2, 6 and every 4, 6 or 8 weeks thereafter vs. every 2 weeks). See Appendix 1.
6. Celltrion is proposing to have a separate U.S. prescribing information (USPI) for BLA 761358 that would include the proposed product and proposed indications. Additionally, Celltrion is proposing to have a different proprietary name for the proposed formulation, Zymfentra, which was found conditionally acceptable by DMEPA 1[b]. The naming convention of using a different proprietary name for the same product that has different formulation has been found acceptable by the Agency.

As noted in the Naming Guidance, distinguishing nonproprietary names will facilitate pharmacovigilance when other means to track a specific dispensed product are not readily accessible or available; facilitate accurate identification of these biological products by health care practitioners and patients; and help prevent inadvertent substitution that may lead to medication errors. As the guidance explains, a distinguishing suffix supports the tracking of product-specific events over time, our ability to track adverse events to a specific manufacturer (and as appropriate, to a lot or manufacturing site for a particular biological product), and our ability to detect safety signals throughout the life cycle of a product so that the Agency and the manufacturer can act

[b] Abraham, S. Proprietary Name Review for Zymfentra (BLA 761358). Silver Spring (MD); FDA, CDER, OSE, DMEPA 1 (US); 20 Jul 2023, Nexus PNR ID 2023-1044725128.

swiftly and in a targeted manner to identify and address a problem. As noted above, the DS proposed in BLA 761358, infliximab-xxxx, is essentially the same as the DS in BLA 125544 with respect to product quality attributes. Also, as noted above, Celltrion is the license holder for BLA 125544 and the applicant for BLA 761358. Thus, from a manufacturer-specific pharmacovigilance perspective, there is no need to designate a new suffix.

Given the above considerations, OSE and the Biological Product Naming Working Group concurred that a different nonproprietary name for BLA 761358 would not be designated in this particular case.

This memo documents the Agency's justification and agreement with respect to the considerations for the proper name for this BLA 761358.

The following will be communicated to Celltrion in an advice letter.

Comments for Celltrion for BLA 761358:

We have determined that infliximab-dyyb will be the proper name designated in the license should your 351(a) BLA be approved during this review cycle. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review.

Appendix A

Product Name	Zymfentra (BLA 761358)	Inflectra (BLA 125544)[c]
Initial Approval Date	N/A	April 5, 2016
Active Ingredient	infliximab-xxxx	infliximab-dyyb
Indication	ZYMFENTRA is indicated in adults for a) *maintenance treatment* of moderately to severely active Ulcerative Colitis following (b) (4) treatment with intravenous infliximab products (b) (4) b) *maintenance treatment* of moderately to severely active Crohn's disease following (b) (4) treatment with intravenous infliximab products (b) (4)	*Crohn's Disease:* reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease. *Pediatric Crohn's Disease* reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy. *Ulcerative Colitis* reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

[c] Inflectra. Dailymed. Accessed on June 27, 2023: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=37eaca10-d812-48bc-8b8e-b836bfa9968f

Product Name	Zymfentra (BLA 761358)	Inflectra (BLA 125544)[c]
		Pediatric Ulcerative Colitis reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy. *Rheumatoid Arthritis in combination with methotrexate:* reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active disease. *Ankylosing Spondylitis* reducing signs and symptoms in adult patients with active disease. *Psoriatic Arthritis* reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in adult patients. *Plaque Psoriasis* treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.
Route of Administration	subcutaneous	intravenous
Dosage Form	injection	for injection
Strength	120 mg/mL	100 mg/vial

Product Name	Zymfentra (BLA 761358)	Inflectra (BLA 125544)[c]
Dose and Frequency	(b) (4)	*Crohn's Disease* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg every 8 weeks if they later lose their response. *Pediatric Crohn's Disease (≥ 6 years old)* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. *Ulcerative Colitis* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. *Pediatric Ulcerative Colitis (≥ 6 years old)* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. *Rheumatoid Arthritis* In conjunction with methotrexate, 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some patients may benefit from increasing the dose up to 10 mg/kg every 8 weeks or treating as often as every 4 weeks. *Ankylosing Spondylitis* 5 mg/kg at 0, 2 and 6 weeks, then every 6 weeks. *Psoriatic Arthritis and Plaque Psoriasis* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.
	Ulcerative Colitis / Crohn's Disease: Administer 120 mg subcutaneously every 2 weeks	
	(b) (4)	
How Supplied	Each carton contains 1, 2, 4, or 6 prefilled syringe, pre-filled syringe with automatic needle guard, or pre-filled pen	One single-dose vial (lyophilized powder for reconstitution and dilution) individually packaged in a carton.

Product Name	Zymfentra (BLA 761358)	Inflectra (BLA 125544)[c]
Storage	Store in refrigerator (b) (4) at 2° C to 8° C (36° F to 46° F). DO NOT FREEZE. Keep the product in its outer carton until time of administration in order to protect from light. (b) (4) (b) (4)	Store unopened INFLECTRA® vials in a refrigerator at 2° C to 8° C (36° F to 46° F). If needed, unopened INFLECTRA vials may be stored at room temperature up to a maximum of 30° C (86° F) for a single period up to 6 months but not exceeding the original expiration date. The new expiration date must be written in the space provided on the carton. Once removed from the refrigerator, INFLECTRA cannot be returned to the refrigerator.

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
10/18/2023 05:04:41 PM

MISHALE P MISTRY
10/19/2023 08:42:15 AM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	July 20, 2023
Application Type and Number:	BLA 761358
Product Name and Strength:	Zymfentra (infliximab-xxxx[a]) injection, 120 mg/mL
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Celltrion, Inc (Celltrion)
PNR ID #:	2023-1044725128
DMEPA 1 Safety Evaluator:	Sherly Abraham, R.Ph.
DMEPA 1 Team Leader:	Idalia E. Rychlik, Pharm.D.
DMEPA 1 Division Director (Acting):	Irene Z. Chan, Pharm.D.

[a] The proposed nonproprietary name has not yet been conditionally accepted. We therefore refer to the proposed product as "infliximab-xxxx" throughout this review in place of the nonproprietary name for this product.

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The applicant previously submitted the proposed proprietary name, [redacted] (b) (4) for the intravenous formulation of CT-P13 on May 20, 2014 under IND 118135 and September 26, 2014 under BLA 125544. We found the name, [redacted] (b) (4) conditionally acceptable in OSE Review Panorama #2014-17373 and Panorama #2014-36963, dated October 28, 2014.[b]

On November 27, 2014, Celltrion submitted another proprietary name, Inflectra, for our review under BLA 125544. On February 10, 2015, Celltrion withdrew their conditionally acceptable proprietary name [redacted] (b) (4) and we initiated the review of the alternate name, Inflectra.[c] On February 23, 2015, we found the proposed proprietary name Inflectra conditionally acceptable in OSE Panorama review #2014-44603.[d] BLA 125544 was approved on April, 5, 2016 as a biosimilar to US-licensed Remicade (infliximab) under the proprietary name, Inflectra.

Celltrion submitted the proposed proprietary name, [redacted] (b) (4) for BLA 761358 on May 4, 2023. We found the name [redacted] (b) (4) unacceptable (OSE PNR ID# 2022-1044724903 dated March 22, 2023) due to OPDP's objection that [redacted] (b) (4) "misleadingly [redacted] (b) (4) [redacted]"[e]

Thus, Celltrion submitted the proposed proprietary name, Zymfentra, for our review on May 4, 2023.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on May 4, 2023, and amendment received on May 25, 2023.

- Intended Pronunciation: zim fen' trah
- Nonproprietary Name: infliximab-xxxx[a]
- Indication of Use: ZYMFENTRA is indicated in adults for

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[b]Mcmillan, T. Proprietary Name Review for [redacted] (b) (4) (IND 118135 and BLA 125544). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2014 OCT 28 Panorma #s. 2014-17373 and 2014-36963.

[c]Acknowledge Proprietary Name Withdrawal Letter. February 17, 2015. https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af8037a5ca

[d]Mcmillan, T. Proprietary Name Review for Inflectra (BLA 125544). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 FEB 23 Panorama # 2014-44603.

[e]Abraham, S. Proprietary Name Review for [redacted] (b) (4) BLA 761358). Silver Spring (MD): FDA, CDER, OSE, DMEPA1 (US); 2023 MAR 22 PNR ID#2022-1044724903)

a)*maintenance treatment* of moderately to severely active ulcerative colitis following [redacted] treatment with intravenous infliximab products [redacted]

b)*maintenance treatment* of moderately to severely active Crohn's disease following [redacted] treatment with intravenous infliximab products [redacted].

- Route of Administration: subcutaneous
- Dosage Form: injection
- Strength: 120 mg/mL
- Dose and Frequency:

[redacted]

Ulcerative Colitis and Crohn's Disease: Administer 120 mg subcutaneously every 2 weeks [redacted]

- How Supplied: Each carton contains 1, 2, 4, or 6 prefilled syringe, pre-filled syringe with automatic needle guard, or pre-filled pen
- Storage: Store in refrigerator [redacted] at 2°C to 8°C (36°F to 46°F). DO NOT FREEZE. Keep the product in its outer carton until time of administration in order to protect from light. [redacted]

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Zymfentra would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Zymfentra. The Division of Gastroenterology (DG) concurred with the findings of OPDP's assessment for Zymfentra.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Celltrion did not provide a derivation or intended meaning for the proposed proprietary name, Zymfentra, in their submission. This proprietary name is comprised of a single word. We note that Zymfentra includes the letter string '-tr-,' a medical abbreviation for 'time-release' and '-tra', a medical abbreviation for 'tramadol'. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the location of the abbreviation, '-tr-,' and '-tra' in the suffix of the name is unlikely to be separated from the rest of the name in a manner that would lead to confusion in this case. Thus, in this case, we do not object to the inclusion of the letter strings '-tr-' and '-tra' in the suffix of the proposed proprietary name.

2.2.3 Comments from Other Review Disciplines at Initial Review

On May 26, 2023, the Division of Gastroenterology (DG) did not forward any comments or concerns relating to Zymfentra at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-one (n=81) practitioners participated in DMEPA's prescription studies for Zymfentra. 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 prescription simulation studies.

2.2.5. Discussion of Dual Proprietary Names

Celltrion intends to market a subcutaneous injection (pre-filled syringe, pre-filled syringe with automatic needle guard, and a pre-filled pen) under the proposed dual proprietary name, Zymfentra, for maintenance treatment of moderately to severely active ulcerative colitis and moderately to severely active Crohn's disease following (b) (4) treatment with intravenous infliximab products (b) (4) Celltrion currently markets intravenous infliximab-dyyb (BLA 125544) under the approved proprietary name, Inflectra, for moderately to severely active Crohn's Disease and Ulcerative Colitis for adults and pediatric patients 6 years of age and older.

See Table 1 below, for a comparison of product characteristics between the proposed proprietary name Zymfentra, and the currently marketed intravenous injection, Inflectra.

Table 1: Comparison of product characteristics between Zymfentra and Inflectra

[f] USAN stem search conducted on June 23, 2023.

Product Name	Zymfentra (BLA 761358)	Inflectra (BLA 125544)[g]
Pronunciation	zim fen' trah	In flec tra
Initial Approval Date	N/A	April 5, 2016
Active Ingredient	infliximab-xxxx[a]	infliximab-dyyb
Indication	ZYMFENTRA is indicated in adults for a)*maintenance treatment* of moderately to severely active Ulcerative Colitis following (b) (4) treatment with intravenous infliximab products (b) (4) b)*maintenance treatment* of moderately to severely active Crohn's disease following (b) (4) treatment with intravenous infliximab products (b) (4)	*Crohn's Disease:* reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease. *Pediatric Crohn's Disease* reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy. *Ulcerative Colitis* reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. *Pediatric Ulcerative Colitis* reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active disease who have had an inadequate response to conventional therapy.

[g] Inflectra. Dailymed. Accessed on June 27, 2023: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=37eaca10-d812-48bc-8b8e-b836bfa9968f

Product Name	Zymfentra (BLA 761358)	Inflectra (BLA 125544)[g]
		Rheumatoid Arthritis in combination with methotrexate: reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active disease. *Ankylosing Spondylitis* reducing signs and symptoms in adult patients with active disease. *Psoriatic Arthritis* reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in adult patients. *Plaque Psoriasis* treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.
Route of Administration	subcutaneous	intravenous
Dosage Form	injection	for injection
Strength	120 mg/mL	100 mg
Dose and Frequency	(b) (4) Ulcerative Colitis / Crohn's Disease: Administer 120 mg subcutaneously every 2 weeks (b) (4) (b) (4)	*Crohn's Disease* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg every 8 weeks if they later lose their response. *Pediatric Crohn's Disease (≥ 6 years old)* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. *Ulcerative Colitis* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. *Pediatric Ulcerative Colitis (≥ 6 years old)* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. *Rheumatoid Arthritis* In conjunction with methotrexate, 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some patients may benefit from increasing the dose up to 10 mg/kg every 8 weeks or treating as often as every 4 weeks.

Product Name	Zymfentra (BLA 761358)	Inflectra (BLA 125544)[g]
	(b) (4)	*Ankylosing Spondylitis* 5 mg/kg at 0, 2 and 6 weeks, then every 6 weeks. *Psoriatic Arthritis and Plaque Psoriasis* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.
How Supplied	Each carton contains 1, 2, 4, or 6 prefilled syringe, pre-filled syringe with automatic needle guard, or pre-filled pen	One single-dose vial (lyophilized powder for reconstitution and dilution) individually packaged in a carton.
Storage	Store in refrigerator (b) (4) at 2°C to 8°C (36°F to 46°F). DO NOT FREEZE. Keep the product in its outer carton until time of administration in order to protect from light. (b) (4) (b) (4)	Store unopened INFLECTRA® vials in a refrigerator at 2°C to 8°C (36°F to 46°F). If needed, unopened INFLECTRA vials may be stored at room temperature up to a maximum of 30°C (86°F) for a single period up to 6 months but not exceeding the original expiration date. The new expiration date must be written in the space provided on the carton. Once removed from the refrigerator, INFLECTRA cannot be returned to the refrigerator.

We have evaluated the risks associated with the naming strategy of using a dual proprietary name and note that post-marketing experience with other drug products have shown concomitant therapy to be a common type of error when an active ingredient is marketed under two or more names.

We consulted the DG clinical team to determine if they had any concerns regarding the sponsor's proposal to use a separate proprietary name for this product or regarding the risk of adverse events

that may occur in patients that receive duplicate therapy. Per their March 8, 2023 response to our email, DG clinical team stated that they have no clinical concerns regarding the Sponsor's dual proprietary name approach (b) (4) Moreover, the PI states that (b) (4) ".

Additionally, we reviewed the Sponsor's rationale for a dual proprietary name submitted on May 25, 2023 and agree with their rationale; thus we do not object to the use of a dual proprietary name in this case.[h]

2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[i] identified 87 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.

2.2.7 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%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	83
Low similarity name pair: combined match percentage score ≤54%	2

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

Our analysis of the 87 names contained in Table 1 determined none of the names will pose a risk for confusion with Zymfentra as described in Appendices C through H.

2.2.9 Communication of DMEPA's Determination

On July 20, 2023, DMEPA 1 communicated our determination to the Division of Gastroenterology (DG).

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[h]Amendment to request for Proprietary Name Review for BLA 761358. May 25, 2023. \\CDSESUB1\EVSPROD\bla761358\0031\m1\us\proprietary-name.pdf

[i] POCA search conducted on June 23, 2023 in version 5.2.

3 CONCLUSION

The proposed proprietary name, Zymfentra, is conditionally acceptable.

If you have further questions or need clarifications, please contact Alvis Dunson, OSE project manager, at 301-796-6400.

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. [j]

***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)).

[j] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors Last accessed 10/05/2020.

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 names7F[k]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
- Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

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

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

Four 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, verbal pronunciation of the drug name or during computerized provider order entry. 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 vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated,

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

each consisting of a combination of marketed and unapproved drug products, including the proposed name.

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.

   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?	**Y/N**	Do the names have different syllabic stresses?

	**FDA considers the length of names different if the names differ by two or more letters.*		
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

.Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥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

<table>
<tr><td></td><td colspan="2">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</td></tr>
<tr><td>Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><td></td><td>Orthographic Checklist (Y/N to each question)
• Do the names begin with different first letters?
Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.
• Are the lengths of the names dissimilar* when scripted?
*FDA considers the length of names different if the names differ by two or more letters.
• Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?
• Is there different number or placement of cross-stroke or dotted letters present in the names?
• Do the infixes of the name appear dissimilar when scripted?
• Do the suffixes of the names appear dissimilar when scripted?</td><td>Phonetic Checklist (Y/N to each question)
• Do the names have different number of syllables?
• Do the names have different syllabic stresses?
• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
• Across a range of dialects, are the names consistently pronounced differently?</td></tr>
</table>

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.

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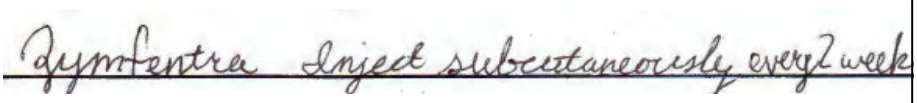
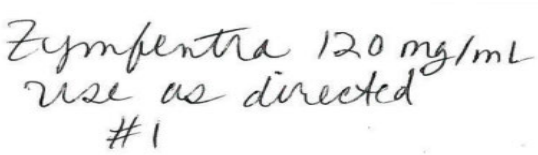
Appendix B: **Prescription Simulation Samples and Results**

Figure 1. Zymfentra Study (Conducted on May 26, 2023)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Zymfentra 120 mg/mL Use as directed #1
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Zymfentra	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Zymfentra

People Received Study: 256

People Responded: 81

Total	**23**	**20**	**19**	**19**	**81**
INTERPRETATION	**INPATIENT**	**OUTPATIENT**	**VOICE**	**CPOE**	**TOTAL**
QYMFENTRA	1	0	0	0	1
ZEMPHENTRA	0	0	1	0	1
ZIMFENTRA	0	0	6	0	6
ZIMVENTRA	0	0	8	0	8
ZINFENTRA	0	0	1	0	1
ZYMFENTRA	20	20	1	19	60

ZYMFENTRA INJECTION	1	0	0	0	1
ZYMFENTREE	1	0	0	0	1
ZYMVENTRA	0	0	1	0	1
ZYNVENTRA	0	0	1	0	1

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

No.	**Proposed name:** Zymfentra **Established name:** infliximab-xxxx[a] **Dosage form:** injection **Strength(s):** 120 mg/mL **Usual Dose[l]:** 120 mg (b) (4) every 2 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.	Zymfentra	100	Name subject of review.
2.	Semintra	70	Veterinary product.

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-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:** Zymfentra **Established name:** infliximab-xxxx[a] **Dosage form:** injection **Strength(s):** 120 mg/mL **Usual Dose[l]:** 120 mg (b) (4) mg every 2 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.	(b) (4)***	68	This name pair has sufficient orthographic and phonetic differences.
2.	Hizentra	65	This name pair has sufficient orthographic and phonetic differences.
3.	(b) (4)***	64	This name pair has sufficient orthographic and phonetic differences.

(b) (4)

Ulcerative Colitis and Crohn's Disease: Administer 120 mg subcutaneously every 2 weeks (b) (4)

(b) (4)

No.	**Proposed name:** Zymfentra **Established name:** infliximab-xxxx[a] **Dosage form:** injection **Strength(s):** 120 mg/mL **Usual Dose[l]:** 120 mg (b) (4) mg every 2 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**
4.	Selzentry	64	This name pair has sufficient orthographic and phonetic differences.
5.	Menactra	64	This name pair has sufficient orthographic and phonetic differences.
6.	Zynlonta	63	Phonetically, the second syllables ('fen' vs. 'lon') provide phonetic differentiation. Furthermore, the following product characteristics can help to mitigate the likelihood of medication errors: Zynlonta is an oncology drug, dosed based on body weight (0.15 mg/kg or 0.075 mg/kg) whereas Zymfentra is a fixed dose of (b) (4) 120 mg (b) (4) Therefore, the dose for Zynlonta or Zymfentra would need to be specified on the prescription order. There is no overlap in prescribed dose between the two products. Zymfentra is a subcutaneous injection available in a prefilled syringe, prefilled syringe with needle guard, and prefilled pen and administered by patients and/or caregivers via subcutaneous injection every 2 weeks. Zynlonta is a lyophilized powder available in a single-dose vial that needs to be reconstituted and further

No.	**Proposed name:** Zymfentra **Established name:** infliximab-xxxx[a] **Dosage form:** injection **Strength(s):** 120 mg/mL **Usual Dose[l]:** 120 mg (b) (4) every 2 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**
			diluted by a healthcare provider and infused every 3 weeks in clinic. A prescription for Zymfentra would need to specify which syringe/pen presentation is to be dispensed. Furthermore, because injectable oncology drugs administered by healthcare professionals typically undergo independent double checks by two pharmacists in the usual clinical setting, the likelihood of both pharmacists overlooking the differences in dose, route of administration, frequency of administration, and indication is minimized. When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
7.	Fentora	63	This name pair has sufficient orthographic and phonetic differences.
8.	Inflectra	62	This name pair has sufficient orthographic and phonetic differences.
9.	(b) (4) ***	62	This name pair has sufficient orthographic and phonetic differences.
10.	Fylnetra	62	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Zymfentra **Established name:** infliximab-xxxx[a] **Dosage form:** injection **Strength(s):** 120 mg/mL **Usual Dose[l]:** 120 mg (b) (4) every 2 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**
11.	Zyban SR	60	This name pair has sufficient orthographic and phonetic differences.
12.	Procentra	60	This name pair has sufficient orthographic and phonetic differences.
13.	Onzetra	60	This name pair has sufficient orthographic and phonetic differences.
14.	Kcentra	60	This name pair has sufficient orthographic and phonetic differences.
15.	(b) (4) ***	60	This name pair has sufficient orthographic and phonetic differences.
16.	Sufenta	58	This name pair has sufficient orthographic and phonetic differences.
17.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.
18.	Tymtran	58	This name pair has sufficient orthographic and phonetic differences.
19.	Fentamox	57	This name pair has sufficient orthographic and phonetic differences.
20.	Phenavent LA	56	This name pair has sufficient orthographic and phonetic differences.
21.	Tums Ultra	56	This name pair has sufficient orthographic and phonetic differences.
22.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Zymfentra **Established name:** infliximab-xxxx[a] **Dosage form:** injection **Strength(s):** 120 mg/mL **Usual Dose[l]:** 120 mg (b) (4) every 2 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.	Zenchent	56	This name pair has sufficient orthographic and phonetic differences.
24.	Humavent LA	56	This name pair has sufficient orthographic and phonetic differences.
25.	Systane Ultra	56	This name pair has sufficient orthographic and phonetic differences.
26.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
27.	(b) (4) ***	55	This name pair has sufficient orthographic and phonetic differences.
28.	Bromfenac	55	This name pair has sufficient orthographic and phonetic differences.
29.	Zentrip	55	This name pair has sufficient orthographic and phonetic differences.
30.	Econtra	55	This name pair has sufficient orthographic and phonetic differences.
31.	Remifentanil	55	This name pair has sufficient orthographic and phonetic differences.
32.	Fentanyl-87	55	This name pair has sufficient orthographic and phonetic differences.
33.	Fentanyl-75	55	This name pair has sufficient orthographic and phonetic differences.
34.	Fentanyl-62	55	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Zymfentra **Established name:** infliximab-xxxx[a] **Dosage form:** injection **Strength(s):** 120 mg/mL **Usual Dose[l]:** 120 mg (b) (4) every 2 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**
35.	Fentanyl-50	55	This name pair has sufficient orthographic and phonetic differences.
36.	Fentanyl-37	55	This name pair has sufficient orthographic and phonetic differences.
37.	Fentanyl-25	55	This name pair has sufficient orthographic and phonetic differences.
38.	Fentanyl-12	55	This name pair has sufficient orthographic and phonetic differences.
39.	Fentanyl-100	55	This name pair has sufficient orthographic and phonetic differences.
40.	Fentanyl	55	This name pair has sufficient orthographic and phonetic differences.
41.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
42.	TelCentris	56	This name pair has sufficient orthographic and phonetic differences.
43.	(b) (4) ***	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 (%)
1.	Metra	54
2.	Zetran	53

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

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4)***	68	Proposed proprietary name for IND 120874 found unacceptable, due to a conflict with a marketed product, by DMEPA (OSE Panorama# 2019-34271035 dated 02/28/2020. Subsequently, the proposed proprietary name Tavneos*** was found conditionally acceptable for NDA #214487.
2.	Femintrol	63	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
3.	(b) (4)***	63	Proposed proprietary name for IND 127387 found conditionally acceptable by DMEPA (OSE# 2020-40824629) on December 16, 2020. On September 21, 2021 Amicus submitted a proprietary name withdrawal for (b) (4)*** under IND 127387. Proposed proprietary name Opfolda***was found conditionally acceptable by DMEPA (2021-1044724098) under NDA 215211 and application is still pending.
4.	Dimaphen Sr	62	Name identified in RxNorm database. Per Redbook, drug product is deactivated with no generic equivalents available.
5.	Zymine XR	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
6.	(b) (4)***	60	Proposed proprietary name for IND (b) (4) found unacceptable, due to a conflict with a marketed product, by DMEPA (OSE RCM# (b) (4)). IND (b) (4) is pending and no new names have been submitted.
7.	(b) (4)***	60	Proposed proprietary name for CBER IND 15324 found to be unacceptable on August 1, 2018 (initial denial) and February 15, 2019 (reconsideration denial). An alternate proprietary name, Zynteglo*** was found acceptable on November 28, 2018.
8.	Venbid TR	58	Name identified in RxNorm database. Per Redbook, drug product is deactivated with no generic equivalents available.
9.	(b) (4)***	58	Proposed proprietary name for IND 127471 found unacceptable, due to a conflict with a marketed product, by DMEPA (OSE Panorama# 2021-1044724061 dated 01/11/2022). IND 127471 is pending and a new name (Cobenfy***) has been submitted.

No.	Name	POCA Score (%)	Failure preventions
10.	Zymine DXR	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
11.	Gentaspray	58	Name identified in RxNorm database. Per Redbook, drug product is deactivated with no generic equivalents available.
12.	Bromfed SR	57	Name identified in RxNorm database. Per Redbook, drug product is deactivated with no generic equivalents available.
13.	Zimeta	56	Veterinary product.
14.	Zimecterin	56	Veterinary product
15.	Ventmax SR	56	Name identified in RxNorm database. Per Redbook, drug product is deactivated with no generic equivalents available.
16.	(b) (4)***	56	Proposed proprietary name was conditionally accepted under IND (b) (4) (OSE Panorama# (b) (4)) dated (b) (4). IND (b) (4) was withdrawn on (b) (4).
17.	Bifenthrin	56	Name identified in RxNorm database. Per Redbook, drug product is deactivated with no generic equivalents available.
18.	Lumefantrine	56	Name identified in RxNorm database. Per Redbook, drug product is deactivated with no generic equivalents available.
19.	Gentran 70	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
20.	Gentran 40	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
21.	Pentran	56	International drug product marketed in United Kingdom.
22.	Femtrace	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

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

[m] 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 (%)
1.	Rymed-TR	63
2.	Symmetry	60
3.	Fybranta	60
4.	Fasenra	60
5.	Myfembree	59
6.	Symmetrel	58
7.	Stendra	58
8.	(b) (4)***	56
9.	Symtan A	56
10.	Selfemra	56
11.	Nitenpyram	56
12.	Metandren	56
13.	Gen-Lanta	56
14.	Dymenate	56
15.	(b) (4)***	56
16.	Gamifant	55
17.	(b) (4)***	55
18.	Bynfezia	55

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/

SHERLY ABRAHAM
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IDALIA E RYCHLIK
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IRENE Z CHAN
07/20/2023 02:25:08 PM

PROPRIETARY NAME REVIEW
Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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 22, 2023
Application Type and Number:	BLA 761358
Product Name and Strength:	(b) (4) (infliximab-xxxx[a]) injection, 120 mg/mL
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Celltrion, Inc (Celltrion)
PNR ID #:	2022-1044724903
DMEPA 1 Safety Evaluator:	Sherly Abraham, R.Ph.
DMEPA 1 Team Leader:	Idalia E. Rychlik, Pharm.D.
DMEPA 1 Division Director:	Mishale Mistry, Pharm.D., MPH

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[a] The proposed nonproprietary name has not yet been conditionally accepted. We therefore refer to the proposed product as "infliximab-xxxx" throughout this review in place of the nonproprietary name for this product.

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/s/

SHERLY ABRAHAM
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